

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

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the Fiscal Year ended December 31, 2003

or

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

For the transition period from _____ to _____

Commission File No. 0-29100

eResearchTechnology, Inc.

(Exact name of issuer as specified in its charter)

Delaware
(State of incorporation)

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

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

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

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

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

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

The aggregate market value of the registrant's Common Stock, \$.01 par value, held by non-affiliates, computed by reference to the closing price of the Common Stock as reported by Nasdaq on June 30, 2003 was \$430,389,598.

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

DOCUMENTS INCORPORATED BY REFERENCE

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

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

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

Our solutions improve the accuracy, timeliness and efficiency of trial set-up, data collection and interpretation and new drug, biologic and device application submission. We offer Cardiac Safety services, which are utilized by clinical trial sponsors and CROs during their conduct of clinical trials, including comprehensive Thorough Phase I ECG studies. Services may be provided through the Digital ECG Franchise program, which offers a unique approach designed to address the growing capacity demands for eRT's ECG services through partnerships with sponsors that desire dedicated resources within eRT to address specific levels of cardiac safety monitoring transactions. Additionally, we offer the licensing and, at the client's option, hosting of our proprietary Clinical Data Management software products and the provision of maintenance and consulting services in support of our proprietary Clinical Data Management software products.

We conduct our operations through offices in the United States and the United Kingdom (UK). Our international net revenues represented approximately 21%, 24% and 22% of total net revenues for the years ended December 31, 2001, 2002 and 2003, respectively. See Note 12 to the Consolidated Financial Statements appearing herein for information pertaining to our international operations.

Product and Service Offerings

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 physician electrocardiographer interpretation of ECGs performed on research subjects in connection with our clients' clinical trials. The ECG provides an electronic map of the heart's rhythm and structure, and typically is performed in most clinical trials. This service permits assessment of the safety of therapies by documenting the occurrence of cardiac electrical change.

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EXPeRT is designed specifically to address the emerging global regulatory guidance and technical standards for digital ECG processing to include digital collection, waveform measurements and annotations, review and output to the regulatory standard file format. EXPeRT also provides for paper-based ECG processing as well as for paper ECGs to be scanned into a digital format and then to be annotated and submitted to the physician electrocardiographer for interpretation. EXPeRT includes the ability for ECGs to be viewed as side-by-side ECG images for comparison, supplemented by the ability to review prior patient ECG tracings. The Cardiac Safety data can be effectively distributed through the Digital ECG Community technology, which provides timely access to safety and related trial information in an easy to use format.

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

These services, which we provide on a centralized basis, are required as part of many new drug studies. Digital or analog Holter recordings are also delivered to us for processing, interpretation and distribution of cardiac safety data. We also provide cardiac safety equipment to clients to perform the ECGs and Holter recordings and provide electronic ECG collection and web-based data reporting services.

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

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

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

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

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

FDA XML ECG Service. FDA XML (Extensible Markup Language) ECG service provides our clients with electronic versions of each ECG processed by EXPeRT. The ECGs processed by EXPeRT are rendered in a format compliant with the FDA's emerging XML standard for digital ECGs.

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

eResearch Network[]
(eResNet[])

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

eStudy Conduct[]

A clinical trial management technology to set up clinical trials, establish standards, track study activities, plan resources, distribute supplies, manage the financial aspects of a trial and electronically view clinical trial data.

eData Management (eDM[])

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

eSafety Net[]

An adverse event management system. This application facilitates compliance by sponsors, CROs and investigators with regulatory reporting requirements regarding adverse events and with the sponsor's or CRO's own internal requirements for safety data analysis. Sponsors or CROs can utilize this application to match their own processes and forms.

eData Entry[] (eDE[])

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

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eResearch
Community(eResCom)

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

Project Assurance/
Implementation Assurance

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

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

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

Technology

Our eResNet, eDE, eResCom and EXPeRT applications were developed with web architectures. We developed these applications using industry-standard development tools including XML, HTML, Java and Oracle Developer, all of which provide rapid access to the underlying Oracle database. Our philosophy of using industry-

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standard tools allows us to focus our attention on the features and functions delivered through the client interface and the application layer in order to meet our clients' strategic business requirements. Our clients also use those tools to benefit from the underlying data stored in the clinical database.

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

The capacity of our EXPeRT processing platforms was significantly expanded in 2003 by optimizing our software application and increasing the number and processing speeds of our server infrastructure. These enhancements to our capacity continue to provide us the capability for handling the continued and significant growth in the volume of ECGs being processed.

Research and Development

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

As of December 31, 2003, we had 30 employees engaged in research and development, together with 11 consultants. Our research and development efforts are focused on improving and enhancing our existing products and services as well as developing new products and services. We are also partnering with other companies to broaden our product offerings.

We developed an internal application service provider capability in support of our Digital ECG Community service offering. Additionally, we have a relationship with International Business Machines Corporation (IBM) to deliver the eResNet, EDC and eResCom as a hosted offering. Research and development expenses were \$4.9 million for 2001, \$4.3 million for 2002 and \$4.6 million for 2003.

Our Clients

We serve pharmaceutical, biotechnology and medical device companies as well as CROs. We have master service agreements, which establish the overall contractual relationship between us and our clients, with 100 clients and Digital ECG Franchise agreements with three clients. We provide our solutions to 28 of the 50 largest pharmaceutical companies globally, as well as 54 clients with software modules installed worldwide. In 2003, one client, Novartis AG, accounted for 10% or more of our consolidated net revenues.

Sales and Marketing

We market and sell products and services primarily through our global direct sales, sales support and professional services organization. As of December 31, 2003, our Business Development Team consisted of approximately 40 sales, marketing and consulting professionals worldwide, which included a direct sales force of 22 sales professionals located in Philadelphia, Pennsylvania, Bridgewater, New Jersey and Peterborough, United Kingdom.

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

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

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few weeks to as long as nine months depending upon the scope of the products and services being discussed and the scope of the clinical trial.

Partnerships

Recent regulatory guidance requires [thorough] cardiac safety monitoring in specially designed Phase I trials. Increasingly, we expect work in this Thorough Phase I ECG Study area will be performed by organizations valued for their capability, capacity, science, process and compliance. We have formalized agreements with Clinical Pharmacology Units (CPUs) that understand the need to provide cardiac safety assessments to their clients consistent with the recent guidance. CPUs provide a range of services including the conduct of clinical studies to comprehensively explore safety, tolerability, pharmacokinetics and pharmacodynamics of novel compounds. We have developed relationships with various CPUs in which we provided our Cardiac Safety services to the clients of these CPUs. Our alliances enable us and the CPUs to deliver fully integrated Clinical Pharmacology solutions to drug developers. We also have working relationships with other CPUs that are not part of a formal eRT Clinical Pharmacology partnership.

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

Competition

The market for our products and services is extremely fragmented, with hundreds of companies providing niche solutions to satisfy small parts of the clinical research process. We believe we are the only provider of technology-based solutions in the clinical research industry that offers end-to-end research solutions that enable electronic processing while also addressing manual, paper-based processes used in clinical research. With the launch of EXPeRT in August 2002, we were the first company to utilize technology to address the digital regulatory initiative in providing ECG services.

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

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

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

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

Government Regulation

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

Because our products and services assist the sponsor or CRO in conducting the trial and preparing the new drug, biologics, or device application, we must comply with these requirements. We also must comply with similar regulatory requirements in foreign countries. These foreign regulations vary somewhat from country to country, but generally establish requirements similar to those of the FDA.

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

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

In November 2001, the FDA held a public meeting at which it proposed requiring sponsors of new drugs to submit ECG raw data in digital format and annotated. Annotated data refers to the defining of measurement points and events that are used in the analysis of such data. A more recent meeting held in January 2003, which was supported by a preliminary concept paper issued in November 2002, further discussed the trial design, ECG acquisition, analysis and reporting for digital ECGs. In February 2002, the International Conference on Harmonization (ICH) released (at Step 3) S7B: Safety Pharmacology Studies for Assessing the Potential for Delayed Ventricular Repolarization (QT Interval Prolongation) by Human Pharmaceuticals. The objective of this guideline is to recommend the design and timing of studies in the clinical development process and provide general recommendations on available non-clinical methodologies to assess the potential risk of QT interval prolongation of a pharmaceutical product. At Step 3, the guideline is under regulatory consideration by the three regions (US, EU and Japan). The next ICH meeting is scheduled for June 2004. There is currently no defined timeline for completion of Step 4 (adoption of a tripartite harmonized text) and Step 5 (implementation by regulatory regions). The results of the non-clinical studies outlined in these guidelines contribute to the design and evaluation of clinical trials to determine the potential risk of QT prolongation in humans. As a result, the evaluation methodology and trial designs supported by eRT will be driven by the outcomes of these non-clinical studies.

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

Potential Liability and Insurance

We attempt to manage our risk of liability for personal injury or death to patients from administration of products under study through contractual indemnification provisions with clients and through insurance maintained by our clients and us. Contractual indemnification generally does not protect us against certain of our own actions, such as negligence. The terms and scope of such indemnification vary from client to client and from trial to trial. Although most of our clients are large, well-capitalized companies, the financial viability of these indemnification provisions cannot be assured. Therefore, we bear the risk that the indemnifying party may not

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have the financial ability to fulfill its indemnification obligations to us. We maintain errors and omissions liability insurance in the amount of \$6 million per claim and professional liability insurance in the amount of \$1 million per claim. Our operating results could be materially and adversely affected if we were required to pay damages or incur defense costs in connection with a claim that is beyond the scope of an indemnity provision or beyond the scope or level of insurance coverage maintained by us or the client or where the indemnifying party does not fulfill its indemnification obligations to us.

Intellectual Property

Our services have been enhanced by significant investment in information technology. Our information services group is committed to achieving operating efficiencies through technical advances. We have developed certain computer software and technically derived procedures that we seek to protect through a combination of contract law, trademarks and trade secrets. We have sought patent protection in the United States, Canada and the European Union for certain aspects of our method and systems for processing ECGs through the EXPeRT system, although there is no assurance such protection will be granted. Although we do not believe that our intellectual property rights are as important to our results of operations as are such factors as technical expertise, knowledge, ability and experience of our professionals, we believe that our technical capabilities provide significant benefits to our clients.

Employees

At December 31, 2003, we had a total of 284 employees, with 227 employees (223 full-time, 4 part-time) at our locations in the United States and 57 full-time employees at our location in the United Kingdom. We had 183 employees performing services directly for our clients, 30 employees in research and development, 40 employees in sales and marketing and 31 employees involved in general and administrative activities.

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

Website

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

ITEM 2. PROPERTIES

Our corporate headquarters are located at 30 South 17th Street, Philadelphia, Pennsylvania, where we lease approximately 39,000 square feet, of which approximately 840 square feet is subleased to a third party. Our lease expires in August 2008. We also lease approximately 31,000 square feet of office space in Bridgewater, New Jersey, which expires in January 2011. We also lease approximately 9,000 square feet of office space in Peterborough, United Kingdom, which expires in September 2009.

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

ITEM 3. LEGAL PROCEEDINGS

In April 2003, we were named as a defendant in an action brought in the Superior Court for Middlesex County, Commonwealth of Massachusetts (Barbara L. Budge et al. v. Robert Kleiman, M.D., et al. (Civ. Act. No. MICV 2003-01728)). The complaint alleges that our company and Dr. Kleiman, who performed services during the relevant period as an independent contractor for us, were negligent in treatment of one of the plaintiffs, resulting in various injuries for which plaintiffs seek unspecified damages. One of the plaintiffs was a subject in a clinical trial for which we were providing certain services to the trial's sponsor. Pursuant to the agreement under

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which the services were performed, our company and our agents are entitled to indemnification from the sponsor for claims such as those asserted by the plaintiff. The sponsor has agreed to reimburse our company for the cost of our defense and to indemnify our company and Dr. Kleiman in this matter, subject to a reservation of rights in the event the facts establish that either our company or Dr. Kleiman is not entitled to indemnification in accordance with the terms of the agreement. Dr. Kleiman has been dismissed as a defendant and discovery has commenced. We believe we have meritorious defenses and we intend to defend this matter vigorously.

In December 2003, we were named as a defendant in an action brought in Common Pleas Court for Philadelphia County, Commonwealth of Pennsylvania (Colburn et al. v. eResearchTechnology, Inc. (No. 002521 Dec. Term 2003)). The complaint is based on a warrant that entitled the plaintiffs' alleged predecessor-in-interest to purchase \$1.0 million worth of shares in our former wholly-owned subsidiary (the "Former Subsidiary") at an exercise price to be established upon the occurrence of the Former Subsidiary's initial public offering of its common stock. The initial public offering never took place. The plaintiffs allege that the subsequent merger of the Former Subsidiary with and into our company, as a result of which the separate legal existence of the Former Subsidiary ceased and our company was the surviving corporation, constituted a de facto initial public offering. The complaint alleges breach of contract, unjust enrichment and promissory estoppel. The plaintiffs also seek declaratory relief entitling them to exercise a warrant for 383,142 shares of our common stock at an exercise price of \$2.61 per share. Although the case is in the early stages of litigation and formal discovery has not commenced, we believe we have meritorious defenses and intend to defend this matter vigorously.

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

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

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

SPECIAL ITEM. EXECUTIVE OFFICERS OF REGISTRANT

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

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

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

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Dr. Morganroth has served as our Chairman since 1999, our Chief Scientist since March 2001 and a member of our Board of Directors since 1997. He served as our Chief Executive Officer from 1993 to March 2001. In addition, Dr. Morganroth has consulted for us since 1976. Dr. Morganroth is a globally recognized cardiologist and clinical researcher. Dr. Morganroth served for over ten years as a Medical Review Officer/Expert for the U.S. Food and Drug Administration.

Mr. Brown has been our Senior Vice President, Outsourcing Partnerships since July 2002. From January 2000 to June 2002, Mr. Brown was our Senior Vice President, Cardiac Safety. From December 1997 to December 1999, Mr. Brown served as our Vice President, Business Development. Mr. Brown has been employed with us for over 20 years.

Mr. Devine has been our Senior Vice President and Chief Development Officer since April 2003. From August 2002 to April 2003, Mr. Devine was our Vice President of Research and Development. Prior to joining us, Mr. Devine was employed by eHUB, Inc., an electronic commerce company, from January 2000 to July 2002. From January 1997 to January 2000, Mr. Devine worked for Lockheed Martin, most recently as Director of Systems Integration, after spending approximately 16 years at IBM.

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

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

Mr. Johnson has been our Senior Vice President and Chief Financial Officer since February 2000. He also served as our Secretary from February 2000 to April 2002. Mr. Johnson has 30 years of previous experience in public accounting and financial management positions. From March 1999 to November 1999, Mr. Johnson served as Chief Operating Officer and Chief Financial Officer of HealthAxis.com. From February 1988 to March 1999, Mr. Johnson was employed by N2K Inc., an online music entertainment company, most recently as Senior Vice President, Chief Financial Officer and director. Mr. Johnson is a certified public accountant.

Dr. Litwin is a cardiologist and has been our Senior Vice President and Chief Medical Officer since July 2000. Dr. Litwin was previously employed by Executive Health Group, a leading international provider of physical examinations for corporate executives, from May 1993 to July 2000, most recently as Executive Vice President and Chief Operating Officer. Dr. Litwin also served as a consultant for Schlumberger, Ltd. from March 1996 to July 2000 and for the American and National League of Professional Baseball Clubs from April 1995 to March 1999.

Ms. Pagliaccetti has been our Senior Vice President and General Counsel since January 2004. She previously served as our Vice President and General Counsel since August 2001. She has also served as our Secretary since April 2002. From March 2000 to August 2001, Ms. Pagliaccetti served as our Corporate Controller and Associate General Counsel. Prior to joining us, Ms. Pagliaccetti served as Corporate Controller for CDNOW, Inc. and its predecessor companies from December 1993 to March 2000. Ms. Pagliaccetti is licensed to practice law in Pennsylvania and is also a certified public accountant. She is a member of the American and Pennsylvania Bar Associations and the American Institute of Certified Public Accountants.

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

[Back to Contents](#)**PART II****ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES**

Our common stock has been traded on the Nasdaq National Market System since February 4, 1997, currently under the symbol "ERES." Below is the range of high and low sales prices for the common stock for the following quarters as quoted on the Nasdaq National Market System. On July 16, 2002, we effected a 3-for-2 split of our common stock. On May 29, 2003, the Company effected a 2-for-1 split of its common stock and on November 26, 2003, the Company effected a 3-for-2 split of its common stock. Market prices in the following table have been restated to reflect these splits of the Company's common stock as if the stock splits had occurred as of December 31, 2001.

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

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

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

[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 Report.

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

	Year Ended December 31,				
	1999	2000	2001	2002	2003
Net revenues:					
Licenses	\$ 4,381	\$ 5,189	\$ 1,372	\$ 2,119	\$ 5,738
Services	21,694	22,878	26,625	39,407	61,104
CRO operations	16,710	□	□	□	□
Total net revenues	42,785	28,067	27,997	41,526	66,842
Costs of revenues:					
Cost of licenses	319	721	576	896	658
Cost of services	12,578	13,296	12,388	17,117	24,083
Cost of CRO operations	12,512	□	□	□	□
Total costs of revenues	25,409	14,017	12,964	18,013	24,741
Gross margin	17,376	14,050	15,033	23,513	42,101
Operating expenses:					
Selling and marketing	5,124	4,754	5,427	6,719	7,763
General and administrative	6,565	6,593	5,188	5,695	6,804
Research and development	2,472	4,840	4,865	4,256	4,564
Write-off of registration costs	□	782	□	□	□
Total operating expenses	14,161	16,969	15,480	16,670	19,131
Operating income (loss)	3,215	(2,919)	(447)	6,843	22,970
Other income, net	735	1,770	941	868	310
Investment impairment charge	□	□	(5,686)	□	□
Gain on sale of domestic CRO operation	4,850	2,114	1,422	35	□
Income (loss) before income taxes and minority interest	8,800	965	(3,770)	7,746	23,280
Income tax provision (benefit)	3,520	322	(112)	1,596	8,817
Minority interest dividend(1)	□	523	116	□	□
Net income (loss)	\$ 5,280	\$ 120	\$ (3,774)	\$ 6,150	\$ 14,463
Basic net income (loss) per share	\$ 0.17	\$ 0.00	\$ (0.12)	\$ 0.20	\$ 0.44
Diluted net income (loss) per share	\$ 0.16	\$ 0.00	\$ (0.12)	\$ 0.18	\$ 0.40

Consolidated Balance Sheet Data (in thousands)

	December 31,				
	1999	2000	2001	2002	2003

Cash, cash equivalents and short-term investments	\$ 21,065	\$ 27,657	\$ 18,430	\$ 26,750	\$ 51,922
Working capital	25,266	30,689	20,689	24,693	45,777
Total assets	45,212	53,964	41,000	53,392	91,978
Total stockholders' equity	35,377	34,170	32,792	40,580	69,259

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

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

Cautionary Statement for Forward-Looking Information

The following discussion and analysis should be read in conjunction with our financial statements and the related notes to the financial statements appearing elsewhere in this Annual Report. The following includes a number of forward-looking statements that reflect our current views with respect to future events and financial performance. We use words such as anticipate, believe, expect, intend and similar expressions to identify forward-looking statements. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this Annual Report. These forward-looking statements are subject to risks and uncertainties such as competitive factors, technology development, market demand and our ability to obtain new contracts and accurately estimate net revenues due to 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 provide technology and services that enable the pharmaceutical, biotechnology and medical device industries to collect, interpret and distribute cardiac safety and clinical data more efficiently. We are a market leader in providing centralized electrocardiographic services (Cardiac Safety services or EXPeRT eECG services) and a leading provider of technology and services that streamline the clinical trials process by enabling our clients to evolve from traditional, paper-based methods to electronic processing that leverages the power of the Internet using our Clinical Data Management products and services.

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

Our solutions improve the accuracy, timeliness and efficiency of trial set-up, data collection and interpretation and new drug, biologic and device application submission. We offer Cardiac Safety services, which are utilized by clinical trial sponsors and CROs during their conduct of clinical trials, including comprehensive Thorough Phase I ECG studies and 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/or 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.

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 between the deliverable elements might impact the timing of revenue recognition, but would not change the total revenue recognized on the contract.

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Cost of licenses consists primarily of applications service provider (ASP) fees for those clients that choose hosting, the cost of producing compact disks and related documentation and royalties paid to third parties in connection with their contributions to our product development. Cost of services includes the cost of Cardiac Safety services and the cost of technology consulting, training and maintenance services. Cost of Cardiac Safety services consists primarily of direct costs related to our centralized Cardiac Safety services and includes wages, cardiac safety equipment rent and related supplies, depreciation, shipping expenses 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. 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 United Kingdom (UK). Our international net revenues represented approximately 21%, 24% and 22% of total net revenues for the years ended December 31, 2001, 2002 and 2003, respectively.

Results of Operations

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

	Year Ended December 31,		
	2001	2002	2003
Net revenues:			
Licenses	4.9%	5.1%	8.6%
Services	95.1	94.9	91.4
Total net revenues	100.0	100.0	100.0
Costs of revenues:			
Cost of licenses	2.1	2.2	1.0
Cost of services	44.2	41.2	36.0
Total costs of revenues	46.3	43.4	37.0
Gross margin	53.7	56.6	63.0
Operating expenses:			
Selling and marketing	19.4	16.2	11.6
General and administrative	18.5	13.7	10.2
Research and development	17.4	10.2	6.8
Total operating expenses	55.3	40.1	28.6
Operating income (loss)	(1.6)	16.5	34.4
Other income, net	3.3	2.1	0.4
Investment impairment charge	(20.3)	□	□
Gain on sale of domestic CRO operation	5.1	0.1	□
Income (loss) before income taxes and minority interest	(13.5)	18.7	34.8
Income tax provision (benefit)	(0.4)	3.9	13.2
Minority interest dividend	0.4	□	□

Net income (loss)	(13.5)%	14.8%	21.6%
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[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,		Increase (Decrease)	
	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	\$ 33,062	\$ 53,299	\$ 20,237	61.2%
Costs of revenues	14,236	20,100	5,864	41.2%
Gross margin	\$ 18,826	\$ 33,199	\$ 14,373	76.3%
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	\$ 39,407	\$ 61,104	\$ 21,697	55.1%
Costs of revenues	17,117	24,083	6,966	40.7%
Gross margin	\$ 22,290	\$ 37,021	\$ 14,731	66.1%
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%
Total operating expenses	16,670	19,131	2,461	14.8%
Operating income	6,843	22,970	16,127	235.7%
Other income, net	868	310	(558)	(64.3%)
Gain on sale of domestic CRO operation	35	□	(35)	(100.0%)

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Income before income taxes	7,746	23,280	15,534	200.5%
Income tax provision	1,596	8,817	7,221	452.4%
Net income	\$ 6,150	\$ 14,463	\$ 8,313	135.2%

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

	Year Ended December 31,		Increase (Decrease)
	2002	2003	
Cost of licenses	42.3%	11.5%	(30.8%)
Cost of services:			
Cardiac Safety	43.1%	37.7%	(5.4%)
Technology consulting and training	65.8%	76.2%	10.4%
Software maintenance	32.5%	27.1%	(5.4%)
Total cost of services	43.4%	39.4%	(4.0%)
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 and revenue from the rental of cardiac safety equipment, which our clients use to perform cardiac safety procedures. Additionally, the average revenue per transaction has 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 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, rental and depreciation costs associated with cardiac safety rental equipment, and increased 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 have accelerated the amortization of certain internal use software costs due to an upgrade replacement that is 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 is \$76,000 commencing in the fourth quarter of 2003 and will continue through March 2005. Amortization expense related to internal use software costs was \$1,434,000 for the year ended December 31, 2003 and \$420,000 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.

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

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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 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 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 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 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 \$419,000 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.

At December 31, 2003, the carrying value for AmericasDoctor.com, Inc. was \$509,000. We periodically assess the fair value of AmericasDoctor.com, Inc. and whether or not any decline in fair value below the current cost basis is deemed to be other than temporary. If declines in the fair value of AmericasDoctor.com are judged to be other than temporary, the cost basis of this investment would be written down to fair value, and the amount of the write-down would be included in our results.

Our effective tax rate was 37.9% and 20.6% for the years ended December 31, 2003 and 2002, 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 \$587,000. 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. We expect this trend to continue in 2004. 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 39.7% in 2004. The 2002 tax rate was primarily impacted by the reversal of \$1,074,000 of valuation allowances related to certain state net operating loss carryforwards.

[Back to Contents](#)**Year Ended December 31, 2002 Compared to the Year Ended December 31, 2001**

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

	Year Ended December 31,		Increase	
	2001	2002	(Decrease)	
Licenses				
Net revenues	\$ 1,372	\$ 2,119	\$ 747	54.4%
Costs of revenues	576	896	320	55.6%
Gross margin	\$ 796	\$ 1,223	\$ 427	53.6%
Services:				
Cardiac Safety				
Net revenues	\$ 19,617	\$ 33,062	\$ 13,445	68.5%
Costs of revenues	8,596	14,236	5,640	65.6%
Gross margin	\$ 11,021	\$ 18,826	\$ 7,805	70.8%
Technology consulting and training				
Net revenues	\$ 3,104	\$ 2,464	\$ (640)	(20.6%)
Costs of revenues	2,346	1,621	(725)	(30.9%)
Gross margin	\$ 758	\$ 843	\$ 85	11.2%
Software maintenance				
Net revenues	\$ 3,904	\$ 3,881	\$ (23)	(0.6%)
Costs of revenues	1,446	1,260	(186)	(12.9%)
Gross margin	\$ 2,458	\$ 2,621	\$ 163	6.6%
Total services				
Net revenues	\$ 26,625	\$ 39,407	\$ 12,782	48.0%
Costs of revenues	12,388	17,117	4,729	38.2%
Gross margin	\$ 14,237	\$ 22,290	\$ 8,053	56.6%
Total				
Net revenues	\$ 27,997	\$ 41,526	\$ 13,529	48.3%
Costs of revenues	12,964	18,013	5,049	38.9%
Gross margin	15,033	23,513	8,480	56.4%
Operating expenses:				
Selling and marketing				
	5,427	6,719	1,292	23.8%
General and administrative				
	5,188	5,695	507	9.8%
Research and development				
	4,865	4,256	(609)	(12.5%)
Total operating expenses	15,480	16,670	1,190	7.7%
Operating income (loss)	(447)	6,843	7,290	1630.9%
Other income, net	941	868	(73)	(7.8%)
Investment impairment charge	(5,686)	□	5,686	100.0%

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Gain on sale of domestic CRO operation	1,422	35	(1,387)	(97.5%)
	<u> </u>	<u> </u>	<u> </u>	
Income (loss) before income taxes and minority interest	(3,770)	7,746	11,516	305.5%
Income tax provision (benefit)	(112)	1,596	1,708	1525.0%
Minority interest dividend	116	□	(116)	(100.0%)
	<u> </u>	<u> </u>	<u> </u>	
Net income (loss)	\$ (3,774)	\$ 6,150	\$ 9,924	263.0%
	<u> </u>	<u> </u>	<u> </u>	

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

	Year Ended December 31,		Increase (Decrease)
	2001	2002	
Cost of licenses	42.0%	42.3%	0.3%
Cost of services:			
Cardiac Safety	43.8%	43.1%	(0.7%)
Technology consulting and training	75.6%	65.8%	(9.8%)
Software maintenance	37.0%	32.5%	(4.5%)
Total cost of services	46.5%	43.4%	(3.1%)
Total costs of revenues	46.3%	43.4%	(2.9%)
Operating expenses:			
Selling and marketing	19.4%	16.2%	(3.2%)
General and administrative	18.5%	13.7%	(4.8%)
Research and development	17.4%	10.2%	(7.2%)

The increase in license revenues was primarily due to an increase in software licensed on a monthly and annual basis with new clients during the year ended December 31, 2002.

The increase in Cardiac Safety service revenues was primarily due to increased sales volume with both new and existing clients, including an increase in revenue from the rental of cardiac safety equipment, which our clients use to perform cardiac safety procedures.

The decrease in technology consulting and training service revenues was primarily due to reductions in consulting activity for our existing clients, partially offset by increases in implementation fees from new licenses.

Software maintenance service revenues did not increase proportionately with license revenues due to a low level of new license sales that included maintenance as a separate component of revenue. Annual licenses do not contain a separate maintenance component.

The increase in the cost of licenses, both in absolute terms and as a percentage of license revenues, was primarily due to an increase in ASP hosting fees associated with expanding hosting capabilities to support additional ASP accounts. Additionally, the increase was due to termination fees associated with a change in ASP hosting providers in 2002.

The increase in the cost of Cardiac Safety services was primarily due to an increase in rental and depreciation costs associated with cardiac safety rental equipment, and increased labor, 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. The decrease in the cost of Cardiac Safety services as a percentage of Cardiac Safety service revenues was primarily due to the increase in Cardiac Safety service revenues without a comparable increase in costs, many of which are fixed in nature.

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 consulting and labor costs during the year ended December 31, 2002. The decrease in the cost of technology consulting and training services was also due to a decrease in variable costs associated with the decrease in technology consulting and training service revenues.

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 depreciation, travel and other costs during the year ended December 31, 2002.

The increase in selling and marketing expenses was due primarily to increased commissionable revenue and labor and advertising costs during the year ended December 31, 2002. Additionally, we held our users conference

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in the second quarter of 2002. We did not hold a users conference in 2001. The decrease in selling and marketing expenses as a percentage of total net revenues was primarily due to the increase in total net revenues with a less than proportional increase in selling and marketing expenses.

The increase in general and administrative expenses was due primarily to an increase in labor expense, public relations, insurance, professional fees and facilities expense during the year ended December 31, 2002. This increase was partially offset by a reduction in expenses as a result of the elimination of the amortization of goodwill. We did not record any goodwill amortization expense for the year ended December 31, 2002 due to the January 1, 2002 adoption of SFAS No. 142. Under SFAS No. 142, we are no longer required to amortize goodwill and other intangible assets with indefinite lives, but such assets will be subject to testing for impairment at least annually. We recorded \$316,000 of goodwill amortization expense for the year ended December 31, 2001. The decrease in general and administrative expenses as a percentage of total net revenues was primarily due to the increase in total net revenues with a less than proportional increase in general and administrative expenses, many of which are fixed in nature, along with the elimination of goodwill amortization.

The decrease in research and development expenses, both in absolute terms and as a percentage of total net revenues, was primarily due to a reduction in labor, travel and other related costs during the year ended December 31, 2002. This reduction was partially due to the capitalization of costs associated with the development of internal use software. The decrease in research and development expenses as a percentage of total net revenues was also due to the increase in total net revenues without a corresponding increase in research and development expenses.

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. During the year ended December 31, 2002, we recorded a net realized gain of \$419,000 from the sale of our remaining shares of DAC (formerly known as Medical Advisory Systems, Inc.), and \$47,000 of interest income that was earned on the escrow accounts related to the sale of the domestic clinical research operations to SCP Communications, Inc. The primary reason for the decrease in other income, net, was lower interest rates offset by the gain on DAC and an increase in interest expense related to capital lease obligations during the year ended December 31, 2002.

We recorded an investment impairment charge of \$5.7 million in the year ended December 31, 2001. This charge was primarily the result of continued negative market conditions affecting the carrying value of our investments in DAC, AmericasDoctor.com, Inc., and INNX, Inc. At December 31, 2002, the carrying value for AmericasDoctor.com, Inc. was \$509,000. We periodically assess the fair value of AmericasDoctor.com, Inc. and whether or not any decline in fair value below the current cost basis is deemed to be other than temporary. If declines in the fair value of AmericasDoctor.com are judged to be other than temporary, the cost basis of this investment would be written down to fair value, and the amount of the write-down would be included in our results.

In December 1999, we sold our domestic CRO operations to SCP Communications, Inc. During the year ended December 31, 2002, we recorded \$35,000 of additional gain on the sale compared to \$1.4 million recorded in the year ended December 31, 2001. During the first quarter of 2002, we finalized the accounting for the disposition related to certain earn-outs. The escrow account that was established in connection with the transaction has been closed effective as of the last income distribution we received during the first quarter of 2002.

In the first quarter of 2001, we accrued \$116,000 of dividends on preferred stock. This preferred stock was redeemed during the second quarter of 2001.

Our effective tax rate was 20.6% and 3.0% for the years ended December 31, 2002 and 2001, respectively. The 2002 tax rate was primarily impacted by the reversal of valuation allowances related to certain state net operating loss carryforwards. The 2001 tax rate was primarily impacted by the investment impairment charge recognized in 2001, for which no tax benefit was recorded, due to the uncertainty of the realization of any tax benefit associated with these long-term capital losses in future periods. The tax impact related to the investment impairment charge was partially offset by \$807,000 of tax credits recorded in 2001.

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Liquidity and Capital Resources

For the year ended December 31, 2003, our operations provided cash of \$30.6 million compared to \$10.9 million during the year ended December 31, 2002. The change was primarily the result of improved operating income, increased deferred revenue, depreciation and amortization and stock option income tax benefits recognized during the year ended December 31, 2003 compared to the year ended December 31, 2002. This change was partially offset by an increase in both accounts receivable and income taxes payable.

For the year ended December 31, 2003, our investing activities used cash of \$13.1 million compared to \$5.9 million during the year ended December 31, 2002. The change was primarily the result of the net purchases of short-term investments, which totaled \$4.3 million for the year ended December 31, 2003, compared to \$2.2 million for the year ended December 31, 2002. Also, there were \$2.4 million of proceeds from the sales of marketable securities during the year ended December 31, 2002 and none during the year ended December 31, 2003.

During the year ended December 31, 2003, we capitalized \$8.9 million of property and equipment compared to \$6.2 million capitalized in 2002. 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 Cardiac Safety activity and contributed significantly to the increase in revenues in 2003. Included in property and equipment is internal use software associated with the development of a data and communications management services software product used in connection with our centralized core cardiac safety electrocardiographic services. We capitalize our internal use software costs in accordance with Statement of Position 98-1, "Accounting for the Costs of Computer Software Developed or Obtained for Internal Use." We began amortization of \$4.0 million of internal use software costs in August of 2002, which resulted in an additional amortization charge to the cost of Cardiac Safety services of approximately \$84,000 per month. Additional internal use software costs of \$1.1 million were capitalized throughout the remainder of 2002 and through the first quarter of 2003, which resulted in additional amortization charges of approximately \$22,000 per month beginning in the second quarter of 2003. We started a new internal use software project in the second quarter of 2003 for which we expect to capitalize costs through the first quarter of 2004. As of December 31, 2003, related costs of \$799,000 were capitalized and we expect to begin amortizing these costs in the first quarter of 2004. Also, we began capitalizing costs associated with an upgrade to the data and communications management services software product used in connection with our centralized core cardiac safety electrocardiographic services beginning in the fourth quarter of 2003 and continuing through approximately the first quarter of 2005. As of December 31, 2003, related costs of \$444,000 were capitalized and we expect to begin amortizing these costs during 2005. As this upgrade will replace many parts of the existing data and communications management services software product, we accelerated the amortization of \$3.6 million of certain related costs to fully amortize the associated costs by the end of the first quarter of 2005, which resulted in an increase in amortization expense of approximately \$76,000 per month beginning in the fourth quarter of 2003.

In December 1999, we sold our domestic clinical research operation to SCP Communications, Inc. The Asset Purchase Agreement related to this sale called for two escrow accounts (collectively hereinafter referred to as the "Escrow Account") from which we would be entitled to additional proceeds upon the occurrence of certain events. In 2001, we received \$3.0 million from the Escrow Account of which \$1.6 million was recorded as additional gain on sale in the fourth quarter of 2000 and \$1.4 million was recorded as additional gain on sale in 2001. During the year ended December 31, 2002, we recorded \$35,000 of additional gain on the sale. During the first quarter of 2002, we finalized the accounting for the disposition related to certain earn-outs. The Escrow Account has been closed effective as of the last income distribution received during the first quarter of 2002.

For the year ended December 31, 2003, our financing activities provided cash of \$3.1 million compared to \$826,000 during the year ended December 31, 2002. The change was primarily the result of net proceeds received from the exercise of stock options during the year ended December 31, 2003. During the year ended December 31, 2003, we received \$3.7 million in cash from the exercise of stock options versus \$1.3 million in 2002.

We have a line of credit arrangement with Wachovia Bank, National Association totaling \$3.0 million. At December 31, 2003, we had no outstanding borrowings under the line.

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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, 2003:

Contractual Obligations	Payments due by period				
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Capital lease obligations	\$ 775,000	\$ 644,000	\$ 131,000	\$ 0	\$ 0
Operating leases	15,857,000	3,950,000	6,553,000	3,397,000	1,957,000
Total	\$ 16,632,000	\$ 4,594,000	\$ 6,684,000	\$ 3,397,000	\$ 1,957,000

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 January 2003, the Financial Accounting Standards Board (FASB) issued FASB Interpretation No. 46 (FIN 46), [Consolidation of Variable Interest Entities](#). The requirements for variable interest entities after January 31, 2003 were adopted on February 1, 2003. Our current results of operations and financial position have not been affected. 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. We do not expect that the adoption of this statement will have any impact on our consolidated financial statements.

In May 2003, the Emerging Issues Task Force (EITF) reached a consensus on EITF Issue No. 00-21, [Revenue Arrangements with Multiple Deliverables](#), (EITF 00-21). EITF 00-21 addresses certain aspects of the accounting by a vendor for arrangements under which it will perform multiple revenue-generating activities. It also addresses when and how an arrangement involving multiple deliverables should be divided into separate units of accounting. The guidance in EITF 00-21 is effective for revenue arrangements entered into in fiscal periods beginning after June 15, 2003. The adoption of EITF Issue No. 00-21 did not have any impact on our financial statements.

SFAS No. 150, [Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity](#), was issued in May 2003. This Statement establishes standards for the classification and measurement of certain financial instruments with characteristics of both liabilities and equity. The Statement also includes required disclosures for financial instruments within its scope. For our Company, the Statement was effective for instruments entered into or modified after May 31, 2003 and otherwise will be effective as of January 1, 2004, except for mandatorily redeemable financial instruments. For certain mandatorily redeemable financial instruments, the Statement will be effective for our Company on January 1, 2005. The effective date has been deferred indefinitely for certain other types of mandatorily redeemable financial instruments. We currently do not have any financial instruments that are within the scope of this Statement.

In April 2002, SFAS No. 145, [Rescission of FASB Statements No. 4, 44 and 64, Amendment of FASB Statement No. 13, and Technical Corrections](#), was issued. SFAS No. 145 amends existing guidance on reporting gains and losses on the extinguishment of debt to prohibit the classification of the gain or loss as extraordinary, as the use of such extinguishments have become part of the risk management strategy of many companies. SFAS No. 145 also amends SFAS No. 13, [Accounting for Leases](#), to require sale-leaseback accounting for certain lease modifications that have economic effects similar to sale-leaseback transactions. The provisions of SFAS No. 145 related to the rescission of SFAS No. 4, [Reporting Gains and Losses from Extinguishment of Debt](#),

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were applied in fiscal years beginning after May 15, 2002. The provisions of SFAS No. 145 related to Statement 13 were effective for transactions occurring after May 15, 2002. The adoption of Statement 145 had no effect on our financial statements.

In June 2002, SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities," was issued. SFAS No. 146 addresses financial accounting and reporting for costs associated with exit or disposal activities and nullifies EITF Issue No. 94-3, "Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity." The provisions of SFAS No. 146 were effective for exit or disposal activities initiated after December 31, 2002, with early application encouraged. The adoption of SFAS No. 146 did not have any impact on our financial statements.

In November 2002, FASB Interpretation No. 45, "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others," was issued. This Interpretation enhances the disclosures to be made by a guarantor in its interim and annual financial statements about its obligations under guarantees it has issued. The Interpretation also clarifies that a guarantor is required to recognize, at inception of a guarantee, a liability for the fair value of the obligation undertaken. The initial recognition and measurement provisions of the Interpretation were applicable to guarantees issued or modified after December 31, 2002 and the disclosure requirements were effective for financial statements of interim or annual periods ending after December 15, 2002. The adoption of FASB Interpretation No. 45 did not have any impact on our financial statements.

In December 2002, SFAS No. 148 was issued. SFAS No. 148 amends SFAS No. 123 to provide alternative methods of transition for a voluntary change to the fair value method of accounting for stock-based employee compensation. In addition, SFAS No. 148 amends the disclosure requirements of SFAS No. 123 to require prominent disclosures in both annual and interim financial statements. Disclosures required by this standard are included in the notes to these financial statements.

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 two sources: license fees and services. 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.

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 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.

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

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whether the fee is fixed or determinable is based upon the payment terms of the transaction. If a significant portion of a fee is due after our normal payment terms or upon implementation or client acceptance, the fee is accounted for as not being fixed or determinable. In these cases, revenue is recognized as the fees become due or after implementation or client acceptance has occurred.

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

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

Investments in Non-Marketable Securities

We account for our investments in non-marketable securities under the cost method in accordance with APB Opinion No. 18, "The Equity Method of Accounting for Investments in Common Stock," as we do not have "significant influence" over our investees as defined in APB Opinion No. 18. If a decline in the fair value of a non-marketable security occurs, management is required to assess whether such a decline is other than temporary and, if so determined, the cost basis of the investment would be written down to fair value and an investment impairment charge would be recognized in our consolidated statements of operations. Our non-marketable investments consist of investments in privately held entities for which fair values are not readily determinable. Given the nature of these investments, management's assessments of fair value are judgmental and based upon available financial and other data. Testing for impairment of investments requires significant management judgment including the identification of potentially impaired investments, the determination of their fair value and the assessment of whether any decline in value is other than temporary. Revisions of impairment judgments are made when new information becomes known, and any resulting impairment charges are made at that time. Management's review for impairment includes, but is not limited to, reviewing the investee's cash position, earnings and revenue outlook, liquidity and management/ownership. See Note 1 in the Notes to Consolidated Financial Statements for more information.

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, 2003, we had a valuation allowance of \$2.3 million primarily related to the realization of certain deferred tax assets. See Note 6 in the Notes to Consolidated Financial Statements for more information.

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.

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See our audited Consolidated Financial Statements and Notes thereto, which begin on page F-1 of this Annual Report on 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 Report. However, these risk factors are not exhaustive, as new risks emerge from time to time, and it is not possible for management to predict all such risk factors or to assess the impact of all such risk factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Accordingly, forward-looking statements should not be relied upon as a prediction of actual results.

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 market 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 vast 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.

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.

If we lose existing 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. In 2003, one client accounted for more than 10% of net revenues.

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. The 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. In addition, 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.

Extensive governmental regulation of the clinical trial process could require costly modifications to our products or could adversely affect prospective clients' willingness to use our products and services.

We may incur increased expenses or suffer a reduction in revenues if our products and services do not comply with applicable government regulations. 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

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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. Annotated data refers to the defining of measurement points and events that are used in the analysis of such data. A more recent meeting held in January 2003, which was supported by a preliminary concept paper issued in November 2002, further discussed the trial design, ECG acquisition, analysis and reporting for digital ECGs. In February 2002, the International Conference on Harmonization released (at Step 3) S7B: Safety Pharmacology Studies for Assessing the Potential for Delayed Ventricular Repolarization (QT Interval Prolongation) by Human Pharmaceuticals. The objective of this guideline is to recommend the design and timing of studies in the clinical development process and provide general recommendations on available non-clinical methodologies to assess the potential risk of QT interval prolongation of a pharmaceutical product. At Step 3, the guideline is under regulatory consideration by the three regions (US, EU and Japan). The next ICH meeting is scheduled for June 2004. There is currently no defined timeline for completion of Step 4 (adoption of a tripartite harmonized text) and Step 5 (implementation by regulatory regions). The results of the non-clinical studies outlined in these guidelines contribute to the design and evaluation of clinical trials to determine the potential risk of QT prolongation in humans. As a result, the evaluation methodology and trial designs supported by eRT will be driven by the outcomes of these non-clinical studies.

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.

If general economic conditions worsen, potential clients may be unwilling to make large capital software purchases, 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 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 market analysts and investors, which would likely cause the market price of our common stock to decline.

Our clients may not adopt our eResNet annual license solution, which could prevent us from generating recurring revenues. If we are unable to generate the recurring revenues that securities analysts expect, our stock price will likely fall.

A key element of our business strategy is the establishment of eResNets, which are electronic research networks that integrate a combination of our products and services. We sell monthly and annual licenses for these products. If we are not successful in establishing eResNets and collecting monthly license fees, we will not generate the volume of recurring revenues in the future that we are expecting and our stock price will likely fall. The eResNet annual license model is still in its early stages and is subject to uncertain market acceptance. Our clients may not adopt the concept of eResNets and may, instead, continue to use our products or services on an individual or a modular basis.

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.

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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 market 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 market 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 are generally lengthy and variable
- 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.

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.

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

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

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

We have relationships with providers of clinical pharmacology services, hardware and software systems, telecommunications, web-hosting and development, systems integration and website content that support our sales and marketing efforts by satisfying other needs of our existing clients that our solutions do not address and by providing us access to their clients as potential sources of new business. We do not generally have long-term contracts with our strategic partners, so they may cease doing business with us on relatively short notice.

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

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If our products and services do not achieve widespread acceptance by our clients, our revenues and market share will likely decline. Our competitors include internal research departments of pharmaceutical, biotechnology and medical device companies, 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.

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.

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.

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

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

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

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

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

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 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. Despite our efforts to protect our proprietary rights, unauthorized parties may copy or otherwise obtain and use our products and technology. 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.

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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.

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 subsidiaries' earnings in our income even if the subsidiaries do not distribute money to us. As a result, less cash would be available to us in the United States.

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

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ITEM QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

7A.

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, 2003 would have decreased by less than \$400,000. This estimate assumes that the decrease occurred on the first day of 2003 and reduced the yield of each investment by 100 basis points. The impact on our future interest income of future changes in investment yields will depend largely on the gross amount of our cash, cash equivalents 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, 2003 by less than \$650,000.

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 CONTROLS AND PROCEDURES

9A.

We carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our controls and procedures pursuant to Rule 13a-15 under the Securities Exchange Act of 1934, as amended, as of the end of the period covered by this report. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective to ensure that information required to be disclosed by our Company (including our consolidated subsidiaries) in our periodic filings with the Securities and Exchange Commission is recorded, processed, summarized and reported, within the time periods specified in the Commission's rules and forms. There has been no change in our internal control over financial reporting during the fourth quarter of fiscal 2003 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

[Back to Contents](#)**PART III****ITEM DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT****10.**

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 20, 2004, 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 Report.

ITEM EXECUTIVE COMPENSATION**11.**

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

ITEM SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

"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, 2003 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	4,305,861	\$ 4.27	1,567,500
Equity compensation plans not approved by security holders	□	□	□
Total	4,305,861	\$ 4.27	1,567,500

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

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

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

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

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PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K

(a) The following documents are filed as part of this Report:

1. The financial statements of eResearchTechnology, Inc. (the [Company]) filed as a part of this Report 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 Report is listed in the attached Index to Consolidated Financial Statements and Financial Statement Schedule at [F-1]
3. Exhibits.
 - 3.1 Amended and Restated Certificate of Incorporation, as amended.(10)
 - 3.2 Bylaws.(1)
 - 3.3 Amendment to Bylaws.(3)
 - 3.4 Certificate of Merger between the Company and eRT Operating Company.(8)
 - 4.1 Form of Stock Certificate.(8)
 - 10.1 Registration Rights Agreement dated August 27, 1999.(2)
 - 10.2 Amendment to Management Consulting Agreement between Dr. Joel Morganroth and the Company effective January 1, 2003.(9)*
 - 10.3 2003 Stock Option Plan.(11)*
 - 10.7 1996 Stock Option Plan, as amended.(8)*
 - 10.23 Sublease Agreement between the Company and Raytheon Engineers & Constructors, Inc.(3)
 - 10.25 Amendment to the Sublease Agreement between the Company and 17th Ludlow Property, L.L.C.(12)
 - 10.30 Promissory Note to Wachovia Bank, National Association.(12)
 - 10.31 Loan Agreement with Wachovia Bank, National Association.(12)
 - 10.34 Management Employment Agreement effective January 1, 2000 between Joseph A. Esposito and the Company.(4)*
 - 10.35 Management Employment Agreement effective January 27, 2000 between Bruce Johnson and the Company.(4)*
 - 10.36 Management Employment Agreement effective January 1, 2000 between Vincent Renz and the Company.(4)*
 - 10.37 Amendment to Management Employment Agreement effective January 2, 2002 between Bruce Johnson and the Company.(8)*

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- 10.38 Management Employment Agreement effective January 1, 2004 between Joseph Esposito and the Company.*
- 10.40 Amendment to Management Consulting Agreement effective January 1, 2004 between Dr. Joel Morganroth and the Company.*
- 10.48 Management Employment Agreement effective as of January 1, 2000 between Robert Brown and the Company, as amended.(5)*
- 10.51 Management Employment Agreement effective as of July 5, 2000 between Jeffrey Litwin, M.D. and the Company, as amended.(5)*
- 10.52 Lease Agreement dated August 18, 2000 between Advance/GLD 2 L.L.C. and the Company.(6)
- 10.56 Management Employment Agreement effective May 21, 2001 between Dr. Joel Morganroth and the Company.(7)*
- 10.57 Management Consulting Agreement effective May 21, 2001 between Dr. Joel Morganroth and the Company.(7)*
- 10.58 Management Employment Agreement effective as of October 16, 2000 between Scott Grisanti and the Company.(8)*
- 10.59 Attornment Agreement between 17th Ludlow Property, L.L.C. and the Company.(8)
- 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 8-K on September 9, 1999.
- (3) Incorporated by reference to the exhibit with the same number, filed in connection with the Company's Form 10-K on March 31, 1999.
- (4) Incorporated by reference to the exhibit with the same number, filed in connection with the Company's Form 10-Q on May 15, 2000.

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- (5) Incorporated by reference to the exhibit with the same number, filed in connection with the Company's Form 10-Q on August 14, 2000.
- (6) Incorporated by reference to the exhibit with the same number, filed in connection with the Company's Form 10-Q on November 13, 2000.
- (7) Incorporated by reference to the exhibit with the same number, filed in connection with the Company's Form 10-Q on August 10, 2001.
- (8) Incorporated by reference to the exhibit with the same number, filed in connection with the Company's Form 10-K on March 12, 2002.
- (9) Incorporated by reference to the exhibit with the same number, filed in connection with the Company's Form 10-K on March 14, 2003.
- (10) Incorporated by reference to the exhibit with the same number, filed in connection with the Company's Form 10-Q on May 9, 2003.
- (11) Incorporated by reference to the exhibit with the same number, filed in connection with the Company's Form 10-Q on August 7, 2003.
- (12) Incorporated by reference to the exhibit with the same number, filed in connection with the Company's Form 10-Q on November 7, 2003.

(b) Reports on Form 8-K.

On October 22, 2003, the Company filed a report on Form 8-K relating to financial information for eResearchTechnology, Inc. for the quarter and nine months ended September 30, 2003 and forward-looking statements relating to 2003 and 2004 as presented in a press release of October 22, 2003.

[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 15th day of March, 2004.

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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>Joseph A. Esposito</u>	President and Chief Executive Officer, Director	March 15, 2004
Joseph A. Esposito	(Principal executive officer)	
<u>Joel Morganroth</u>	Chairman of the Board of Directors and Chief Scientist	March 15, 2004
Joel Morganroth, M.D.		
<u>Bruce Johnson</u>	Senior Vice President and Chief Financial Officer	March 15, 2004
Bruce Johnson	(Principal financial and accounting officer)	
<u>Sheldon M. Bonovitz</u>	Director	March 15, 2004
Sheldon M. Bonovitz		
<u>David D. Gathman</u>	Director	March 15, 2004
David D. Gathman		
<u>Arthur H. Hayes, Jr.</u>	Director	March 15, 2004
Arthur H. Hayes, Jr., M.D.		
<u>Stephen S. Phillips</u>	Director	March 15, 2004
Stephen S. Phillips		

John M. Ryan

Director

March 15, 2004

John M. Ryan

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Report of Independent Auditors

The Board of Directors and Stockholders
eResearchTechnology, Inc.:

We have audited the 2002 and 2003 consolidated financial statements of eResearchTechnology, Inc. and subsidiaries as listed in the accompanying index. In connection with our audits of the 2002 and 2003 consolidated financial statements, we also have audited the 2002 and 2003 financial statement schedule as listed in the accompanying index. 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. The 2001 consolidated financial statements and financial statement schedule of eResearchTechnology, Inc. and subsidiaries as listed in the accompanying index were audited by other auditors who have ceased operations. Those auditors expressed an unqualified opinion on those consolidated financial statements and financial statement schedule, before the revisions described in Note 1 to the consolidated financial statements, in their report dated February 5, 2002.

We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audits 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 2002 and 2003 consolidated financial statements referred to above present fairly, in all material respects, the financial position of eResearchTechnology, Inc. and subsidiaries as of December 31, 2002 and 2003, and the results of their operations and their cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the related 2002 and 2003 financial statement schedules, 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.

As discussed above, the 2001 consolidated financial statements of eResearchTechnology, Inc. and subsidiaries as listed in the accompanying index were audited by other auditors who have ceased operations. As described in Note 1, these consolidated financial statements have been revised to include the transitional disclosures required by Statement of Financial Accounting Standards No. 142, Goodwill and Other Intangible Assets, which was adopted by the Company as of January 1, 2002. In our opinion, the disclosures for 2001 in Note 1 are appropriate. In addition, as described in Note 1, all share and per share data have been restated to reflect a 2-for-1 stock split and two 3-for-2 stock splits. We audited the adjustments that were applied to restate the share and per share data reflected in the 2001 consolidated financial statements. In our opinion, such adjustments are appropriate and have been properly applied. However, we were not engaged to audit, review, or apply any procedures to the 2001 consolidated financial statements of eResearchTechnology, Inc. and subsidiaries other than with respect to such disclosures and adjustments and, accordingly, we do not express an opinion or any other form of assurance on the 2001 consolidated financial statements taken as a whole.

/s/ KPMG LLP

Philadelphia, Pennsylvania
January 29, 2004

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The following report is a copy of a previously issued Arthur Andersen LLP (["Andersen"]) report, and the report has not been reissued by Andersen. The prior-period financial statements have been revised and restated. The Andersen report refers to the consolidated balance sheets as of December 31, 2000 and 2001 and the consolidated statements of operations, stockholders' equity and cash flows for the years ended December 31, 1999 and 2000, which are no longer included in the accompanying financial statements.

To eResearchTechnology, Inc.:

We have audited the accompanying consolidated balance sheets of eResearchTechnology, Inc. and subsidiaries as of December 31, 2000 and 2001, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2001. These financial statements and the schedule referred to below are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the 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 financial statements referred to above present fairly, in all material respects, the financial position of eResearchTechnology, Inc. and subsidiaries, as of December 31, 2000 and 2001, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2001, in conformity with accounting principles generally accepted in the United States.

Our audits were made for the purpose of forming an opinion on the basic financial statements taken as a whole. The schedule listed in the index of financial statements and schedule is presented for purposes of complying with the Securities and Exchange Commission's rules and is not part of the basic financial statements. This schedule has been subjected to the auditing procedures applied in the audit of the basic financial statements and, in our opinion, fairly states in all material respects the financial data required to be set forth therein in relation to the basic financial statements taken as a whole.

/s/ Arthur Andersen
LLP

Philadelphia, PA
February 5, 2002

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eResearchTechnology, Inc. and Subsidiaries
Consolidated Balance Sheets

	December 31,	
	2002	2003
Assets		
Current Assets:		
Cash and cash equivalents	\$ 17,443,000	\$ 38,364,000
Short-term investments	9,307,000	13,558,000
Accounts receivable, net	6,954,000	13,947,000
Prepaid expenses and other	2,542,000	2,219,000
Deferred income taxes	485,000	277,000
	36,731,000	68,365,000
Total current assets		
Property and equipment, net	12,587,000	16,416,000
Goodwill	1,212,000	1,212,000
Investments in non-marketable securities	509,000	509,000
Other assets	21,000	168,000
Deferred income taxes	2,332,000	5,308,000
	\$ 53,392,000	\$ 91,978,000
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	\$ 2,000,000	\$ 3,513,000
Accrued expenses	3,705,000	4,446,000
Income taxes payable	960,000	1,584,000
Current portion of capital lease obligations	599,000	644,000
Deferred revenues	4,774,000	12,401,000
	12,038,000	22,588,000
Total current liabilities		
Capital lease obligations, excluding current portion	774,000	131,000
Commitments and contingencies (Note 9)		
Stockholders' Equity:		
Preferred stock \$10.00 par value, 500,000 shares authorized, none issued and outstanding		
Common stock \$.01 par value, 50,000,000 shares authorized, 34,386,573 and 36,490,609 shares issued and outstanding, respectively	344,000	365,000
Additional paid-in capital	40,692,000	54,420,000
Accumulated other comprehensive income	410,000	1,038,000
Retained earnings	2,363,000	16,826,000
Treasury stock, 2,686,500 and 2,708,346 shares at cost	(3,229,000)	(3,390,000)
	40,580,000	69,259,000
Total stockholders' equity		
	\$ 53,392,000	\$ 91,978,000

The accompanying notes are an integral part of these statements.

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eResearchTechnology, Inc. and Subsidiaries
Consolidated Statements of Operations

	Year Ended December 31,		
	2001	2002	2003
Net revenues:			
Licenses	\$ 1,372,000	\$ 2,119,000	\$ 5,738,000
Services	26,625,000	39,407,000	61,104,000
Total net revenues	27,997,000	41,526,000	66,842,000
Costs of revenues:			
Cost of licenses	576,000	896,000	658,000
Cost of services	12,388,000	17,117,000	24,083,000
Total costs of revenues	12,964,000	18,013,000	24,741,000
Gross margin	15,033,000	23,513,000	42,101,000
Operating expenses:			
Selling and marketing	5,427,000	6,719,000	7,763,000
General and administrative	5,188,000	5,695,000	6,804,000
Research and development	4,865,000	4,256,000	4,564,000
Total operating expenses	15,480,000	16,670,000	19,131,000
Operating income (loss)	(447,000)	6,843,000	22,970,000
Other income, net	941,000	868,000	310,000
Investment impairment charge	(5,686,000)	□	□
Gain on sale of domestic CRO operation	1,422,000	35,000	□
Income (loss) before income taxes	(3,770,000)	7,746,000	23,280,000
Income tax provision (benefit)	(112,000)	1,596,000	8,817,000
Minority interest dividend	116,000	□	□
Net income (loss)	\$ (3,774,000)	\$ 6,150,000	\$ 14,463,000
Basic net income (loss) per share	\$ (0.12)	\$ 0.20	\$ 0.44
Diluted net income (loss) per share	\$ (0.12)	\$ 0.18	\$ 0.40
Shares used to calculate basic net income (loss) per share	31,254,000	31,443,000	32,974,000
Shares used to calculate diluted net income (loss) per share	31,254,000	33,873,000	36,022,000

The accompanying notes are an integral part of these statements.

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eResearchTechnology, Inc. and Subsidiaries
Consolidated Statements of Stockholders' Equity

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Retained Earnings (Accumulated Deficit)	Treasury Stock	Total
	Shares	Amount					
Balance, December 31, 2000	33,618,093	\$ 336,000	\$ 38,600,000	\$ (2,042,000)	\$ (13,000)	\$ (2,711,000)	\$ 34,170,000
Comprehensive income (loss)							
Net loss	□	□	□	□	(3,774,000)	□	(3,774,000)
Reclassification adjustment for investment impairment losses on marketable securities	□	□	□	2,042,000	□	□	2,042,000
Unrealized gain on marketable securities	□	□	□	665,000	□	□	665,000
Total comprehensive loss	□	□	□	2,707,000	(3,774,000)	□	(1,067,000)
Purchase of treasury stock	□	□	□	□	□	(518,000)	(518,000)
Tax benefit from exercise of non-qualified stock options	□	□	10,000	□	□	□	10,000
Issuance of common stock options to non-employee	□	□	29,000	□	□	□	29,000
Exercise of stock options	90,000	1,000	167,000	□	□	□	168,000
Balance, December 31, 2001	33,708,093	337,000	38,806,000	665,000	(3,787,000)	(3,229,000)	32,792,000
Comprehensive income (loss)							
Net income	□	□	□	□	6,150,000	□	6,150,000
Currency translation adjustment	□	□	□	410,000	□	□	410,000
Reclassification adjustment for unrealized gain on marketable securities	□	□	□	(665,000)	□	□	(665,000)
Total comprehensive income (loss)	□	□	□	(255,000)	6,150,000	□	5,895,000
Tax benefit from exercise of non-qualified stock options	□	□	686,000	□	□	□	686,000
Issuance of common stock options to non-employee	□	□	42,000	□	□	□	42,000
Cancellation of fractional shares related to stock splits	(95)	□	□	□	□	□	□

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Exercise of stock options	678,575	7,000	1,158,000	□	□	□	1,165,000
Balance, December 31, 2002	34,386,573	344,000	40,692,000	410,000	2,363,000	(3,229,000)	40,580,000
Comprehensive income							
Net income	□	□	□	□	14,463,000	□	14,463,000
Currency translation adjustment	□	□	□	628,000	□	□	628,000
Total comprehensive income	□	□	□	628,000	14,463,000	□	15,091,000
Tax benefit from exercise of non-qualified stock options	□	□	9,903,000	□	□	□	9,903,000
Cancellation of fractional shares related to stock splits	(2,416)	□	(46,000)	□	□	□	(46,000)
Exercise of stock options	2,106,452	21,000	3,871,000	□	□	(161,000)	3,731,000
Balance, December 31, 2003	36,490,609	\$ 365,000	\$ 54,420,000	\$ 1,038,000	\$ 16,826,000	\$ (3,390,000)	\$ 69,259,000

The accompanying notes are an integral part of these statements.

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eResearchTechnology, Inc. and Subsidiaries
Consolidated Statements of Cash Flows

	Year Ended December 31,		
	2001	2002	2003
Operating activities:			
Net income (loss)	\$ (3,774,000)	\$ 6,150,000	\$ 14,463,000
Adjustments to reconcile net income (loss) to net cash provided by operating activities:			
Gain on sale of domestic CRO operation	(1,422,000)	(35,000)	□
Gain on sale of marketable securities	□	(419,000)	□
Depreciation and amortization	1,775,000	3,104,000	5,306,000
Issuance of stock options to non-employees	29,000	42,000	□
Stock option income tax benefits	□	686,000	9,895,000
Investment impairment charge	5,686,000	□	□
Changes in operating assets and liabilities:			
Accounts receivable	911,000	(932,000)	(6,731,000)
Prepaid expenses and other	1,287,000	(1,325,000)	155,000
Accounts payable	(362,000)	599,000	1,484,000
Accrued expenses	(810,000)	1,289,000	720,000
Income taxes	(310,000)	441,000	(2,258,000)
Deferred revenues	(22,000)	1,263,000	7,533,000
Net cash provided by operating activities	2,988,000	10,863,000	30,567,000
Investing activities:			
Purchases of property and equipment	(4,633,000)	(6,191,000)	(8,887,000)
Purchases of short-term investments	(8,213,000)	(4,057,000)	(12,435,000)
Proceeds from sales of short-term investments	6,894,000	1,816,000	8,184,000
Net proceeds from sale of domestic CRO operation	3,039,000	35,000	□
Proceeds from sales of marketable securities	□	2,449,000	□
Net cash used in investing activities	(2,913,000)	(5,948,000)	(13,138,000)
Financing activities:			
Purchase of convertible preferred stock in subsidiary	(9,500,000)	□	□
Repayment of capital lease obligations	(12,000)	(459,000)	(601,000)
Minority interest dividend paid	(639,000)	□	□
Proceeds from exercise of stock options	48,000	1,285,000	3,685,000
Repurchase of common stock for treasury	(518,000)	□	□
Net cash provided by (used in) financing activities	(10,621,000)	826,000	3,084,000
Effect of exchange rate changes on cash	□	338,000	408,000
Net increase (decrease) in cash and cash equivalents	(10,546,000)	6,079,000	20,921,000
Cash and cash equivalents, beginning of period	21,910,000	11,364,000	17,443,000
Cash and cash equivalents, end of period	\$ 11,364,000	\$ 17,443,000	\$ 38,364,000

The accompanying notes are an integral part of these statements.

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eResearchTechnology, Inc. and Subsidiaries Notes To Consolidated Financial Statements

1. Background and Summary of Significant Accounting Policies:

Background

eResearchTechnology, Inc. (the "Company"), a Delaware corporation, is a provider of technology and services that enables the pharmaceutical, biotechnology and medical device industries to collect, interpret and distribute cardiac safety and clinical data more efficiently. The Company is a market leader in providing centralized electrocardiographic services (Cardiac Safety services or EXPeRT eECG services) and a leading provider of technology and services that streamline the clinical trials process by enabling its clients to evolve from traditional, paper-based methods to electronic processing using our Clinical Data Management products and services.

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

The Company's solutions improve the accuracy, timeliness and efficiency of trial set-up, data collection and interpretation and new drug, biologic and device application submission. The Company offers Cardiac Safety services, which are utilized by clinical trial sponsors and CROs during their conduct of clinical trials, including comprehensive Thorough Phase I ECG studies. Services may be provided through the Digital ECG Franchise program, which offers a unique approach designed to address the growing capacity demands for the Company's ECG services through partnerships with sponsors that desire dedicated resources within the Company to address specific levels of cardiac safety monitoring transactions. Additionally, the Company offers the licensing and/or hosting of its proprietary Clinical Data Management software products and the provision of maintenance and consulting services in support of its proprietary Clinical Data Management software products.

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company and its 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

The Company's license revenues consist of license fees for perpetual license sales and monthly and annual license sales. The Company's services revenues consist of Cardiac Safety services, technology consulting and training services and software maintenance services.

The Company recognizes software revenues in accordance with Statement of Position 97-2, "Software Revenue Recognition," as amended by Statement of Position 98-9. Accordingly, the Company recognizes

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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. The Company recognizes 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 the Company provides 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. The Company recognizes revenues from software maintenance contracts on a straight-line basis over the term of the maintenance contract, which is typically twelve months. The Company provides consulting and training services on a time and materials basis and recognizes revenues as it performs 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 based on the fair value of the undelivered elements, which is specific to us. Fair values for undelivered elements are based primarily upon stated renewal rates for future products or services.

The Company has recorded reimbursements received for out-of-pocket expenses incurred as revenue in the accompanying consolidated financial statements for the years ended December 31, 2002 and 2003 in accordance with Emerging Issues Task Force (EITF) Issue No. 01-14, "Income Statement Characterization of Reimbursements Received for "Out-of-Pocket Expenses". The Company has deemed reclassification for the year ended December 31, 2001 to be immaterial to the consolidated financial statements.

Cash and Cash Equivalents

The Company considers 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, municipal securities and bonds of government sponsored agencies.

Short-Term Investments

At December 31, 2003, 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. The Company has classified all of its short-term investments at December 31, 2003 as available-for-sale. At December 31, 2002 and 2003, unrealized gains and losses were immaterial. Realized gains and losses during 2001, 2002 and 2003 were immaterial. For the purpose of determining realized gains and losses, the costs of the securities sold is based upon specific identification.

Marketable Securities

In March 2001, in accordance with SFAS No. 115, management determined the decline in the fair value of the common stock of Digital Angel Corporation (DAC), a publicly traded company, to be other than temporary, and as a result wrote down the cost basis to \$2,029,000, which was the market value of the DAC common stock held on March 31, 2001. In connection with this write-down, an investment impairment charge of \$3,746,000 was recorded during the quarter ended March 31, 2001. During the year ended December 31, 2002, the Company sold all of its investment in DAC at prices per share of between \$2.30 and \$6.88 and recorded a realized gain of \$419,000.

Investments in Non-Marketable Securities

In July 1998, the Company paid \$1,000,000 for a minority equity position in AmericasDoctor.com, Inc. This investment is accounted for under the cost method. In 1999, in connection with the merger of AmericasDoctor.com, Inc. with Affiliated Research Centers, Inc. (Affiliated Research), the Company invested an additional \$1,500,000 in AmericasDoctor.com, Inc. During 2000, the carrying value of the Company's

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investment was reduced by \$200,000 as the result of proceeds received to buy out the Company's exclusive right to patient data under the original investment agreement. In 2001, in accordance with Accounting Principles Board (APB) Opinion No. 18, "The Equity Method of Accounting for Investments in Common Stock," management determined that a decrease in the value of the investment occurred which was deemed to be other than temporary, and as a result wrote down the cost basis of the investment to \$509,000. In connection with this write-down, an investment impairment charge of \$1,790,000 was recorded during 2001.

The Company will continue to assess the fair value of this investment and whether or not any decline in fair value below the current cost basis is deemed to be other than temporary. If a decline in the fair value of this investment is judged to be other than temporary, the cost basis of this investment would be written down to fair value, and the amount of the write-down would be included in the Company's results. Given the current performance and general market conditions for technology related companies, additional write-downs of this investment may occur in the future.

In 2000, the Company made an investment in INNX, Inc. (INNX) of \$150,000 for 2,706 shares of Series A preferred stock. In December 2001, in accordance with APB Opinion No. 18, management determined that a decrease in the value of the investment occurred that was deemed to be other than temporary, and as a result wrote off the entire cost basis of the investment. In connection with this write-off, an investment impairment charge of \$150,000 was recorded during the quarter ended December 31, 2001.

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," the Company capitalizes 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, 2001, 2002 and 2003, \$2,356,000, \$2,361,000 and \$1,610,000, respectively, of these costs have been capitalized. As of December 31, 2003, \$1,243,000 of capitalized costs have not yet been placed in service and are therefore not being amortized. The Company accelerated the amortization of certain internal use software costs due to an upgrade replacement that is scheduled to take place in 2005. The majority of these costs were to be amortized through August 2006. Amortization of capitalized software development costs was \$0, \$420,000 and \$1,434,000 for the years ended December 31, 2001, 2002 and 2003, 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 \$1,459,000, \$2,264,000 and \$3,876,000 for the years ended December 31, 2001, 2002 and 2003, respectively.

Goodwill

Effective January 1, 2002, the Company 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 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, the Company ceased the amortization of goodwill effective January 1, 2002. Prior to the adoption of SFAS No. 142, the Company amortized goodwill over eight years. Amortization expense was \$316,000 for the year ended December 31, 2001.

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The following table provides reconciliations of reported and adjusted net income (loss) and basic and diluted net income (loss) per share as if SFAS No. 142 had been adopted as of January 1, 2001:

	Year Ended December 31,		
	2001	2002	2003
Reported net income (loss)	\$ (3,774,000)	\$ 6,150,000	\$ 14,463,000
Add back goodwill amortization, net of tax	209,000	□	□
Adjusted net income (loss)	\$ (3,565,000)	\$ 6,150,000	\$ 14,463,000
Income (loss) per share □ basic:			
Reported net income (loss)	\$ (0.12)	\$ 0.20	\$ 0.44
Add back goodwill amortization, net of tax	0.01	□	□
Adjusted net income (loss)	\$ (0.11)	\$ 0.20	\$ 0.44
Income (loss) per share □ diluted:			
Reported net income (loss)	\$ (0.12)	\$ 0.18	\$ 0.40
Add back goodwill amortization, net of tax	0.01	□	□
Adjusted net income (loss)	\$ (0.11)	\$ 0.18	\$ 0.40

In accordance with the provisions of SFAS No. 142, the Company was required to perform a transitional goodwill impairment test by June 30, 2002. In addition, SFAS No. 142 requires that the Company 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 and 2003.

When it is determined that the carrying value of goodwill may not be recoverable based upon the existence of one or more indicators of impairment, 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

The Company continually evaluates whether events and circumstances have occurred that indicate the remaining estimated useful life of long-lived assets may warrant revision or that the remaining balance of long-lived assets may not be recoverable. If factors indicate that long-lived assets should be evaluated for possible impairment, the Company would use an estimate of the related undiscounted cash flows in measuring whether long-lived assets should be written down to their fair value, in accordance with SFAS No. 144, □Accounting for the Impairment or Disposal of Long-Lived Assets.□ Management believes that there has been no impairment of long-lived assets as of December 31, 2003.

Accrued Expenses

Included in accrued expenses at December 31, 2002 and 2003 was accrued compensation of \$1,890,000 and \$2,725,000, 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 development costs have not been significant after the establishment of technological feasibility, all such costs have been charged to expense as incurred.

Advertising Costs

The Company expenses advertising costs as incurred. Advertising expense for the years ended December 31, 2001, 2002 and 2003 was \$916,000, \$1,195,000 and \$947,000, respectively.

[Back to Index](#)**Stock-Based Compensation**

The Company applies APB Opinion No. 25, "Accounting for Stock Issued to Employees," and related interpretations for stock options and other stock-based awards while disclosing pro forma net income (loss) and net income (loss) per share as if the fair value method had been applied in accordance with SFAS No. 123, "Accounting for Stock-Based Compensation," as amended by SFAS No. 148, "Accounting for Stock-Based Compensation - Transition and Disclosure."

No stock-based employee compensation cost is reflected in net income (loss), as all options granted had an exercise price at least equal to the market value of the underlying common stock on the date of the grant. Had compensation cost for the Company's stock option plans been determined based upon the fair value of the options at the date of grant, as prescribed under SFAS No. 123, the Company's net income (loss) and basic and diluted net income (loss) per share would have been adjusted to the following pro forma amounts:

	Year Ended December 31,		
	2001	2002	2003
Net income (loss), as reported	\$ (3,774,000)	\$ 6,150,000	\$ 14,463,000
Deduct: Net stock-based employee compensation expense determined under fair value based method, net of related tax effects	(2,271,000)	(1,203,000)	(1,985,000)
Pro forma net income (loss)	\$ (6,045,000)	\$ 4,947,000	\$ 12,478,000
Earnings per share:			
Basic - as reported	\$ (0.12)	\$ 0.20	\$ 0.44
Basic - pro forma	\$ (0.19)	\$ 0.16	\$ 0.38
Diluted - as reported	\$ (0.12)	\$ 0.18	\$ 0.40
Diluted - pro forma	\$ (0.19)	\$ 0.15	\$ 0.35

The weighted average fair value per share of the Company's options granted during 2001, 2002 and 2003 was estimated as \$0.88, \$2.24, and \$4.56, 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:

	2001	2002	2003
Risk-free interest rate	4.65%	3.19%	2.05%
Expected dividend yield	0.00%	0.00%	0.00%
Expected life	3 years	3 years	3 years
Expected volatility	93.68%	76.90%	69.21%

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, the Company realized a net gain of \$419,000 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.

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Supplemental Cash Flow Information

The Company paid \$887,000, \$1,052,000 and \$1,139,000 for income taxes in the years ended December 31, 2001, 2002 and 2003, respectively.

During the years ended December 31, 2001, 2002 and 2003, the Company acquired \$507,000, \$1,336,000 and \$0, respectively, of property and equipment through the execution of capital leases.

Concentration of Credit Risk and Significant Clients

Financial instruments that potentially subject the Company 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, 2001, one client accounted for 11.1% of net revenues, and 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. The loss of any such client could have a material adverse effect on the Company's operations. The Company maintains 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 the Company's 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, 2002, the Company recorded accumulated foreign currency translation income of \$410,000. For the year ended December 31, 2003, the Company recorded foreign currency translation income of \$628,000, which increased the accumulated balance to \$1,038,000.

Stock Split

On July 16, 2002, the Company effected a 3-for-2 split of its common stock. On May 29, 2003, the Company effected a 2-for-1 split of its common stock and on November 26, 2003, the Company effected a 3-for-2 split of its common stock. All share and per share data have been restated to reflect these splits of the Company's common stock as if the stock splits had occurred as of December 31, 2000.

Net Income (Loss) per Common Share

Basic net income (loss) per share is computed by dividing net income (loss) by the weighted average number of shares of common stock outstanding during the year. Diluted net income (loss) per share is computed by dividing net income (loss) 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, computed using the treasury stock method.

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The table below sets forth the reconciliation of the numerators and denominators of the basic and diluted net income per share computations.

Year Ended December 31,	Net Income (Loss)	Shares	Per Share Amount
2001			
Basic net loss	\$ (3,774,000)	31,254,000	\$ (0.12)
Effect of dilutive shares			
Diluted net loss	\$ (3,774,000)	31,254,000	\$ (0.12)
2002			
Basic net income	\$ 6,150,000	31,443,000	\$ 0.20
Effect of dilutive shares		2,430,000	(0.02)
Diluted net income	\$ 6,150,000	33,873,000	\$ 0.18
2003			
Basic net income	\$ 14,463,000	32,974,000	\$ 0.44
Effect of dilutive shares		3,048,000	(0.04)
Diluted net income	\$ 14,463,000	36,022,000	\$ 0.40

In computing diluted net income (loss) per share, 3,745,275, 517,800 and 21,000 options to purchase shares of common stock were excluded from the computations for the years ended December 31, 2001, 2002 and 2003, respectively. The options were excluded from the 2001 computation because their effect would be anti-dilutive. The options were excluded from the 2002 and 2003 computations because the exercise prices of such options were greater than the average market price of the Company's common stock during the respective periods.

Comprehensive Income (Loss)

SFAS No. 130, "Reporting Comprehensive Income," requires companies to classify items of other comprehensive income (loss) by their nature in the financial statements and display the accumulated balance of other comprehensive income (loss) separately from retained earnings and additional paid-in-capital in the stockholders' equity section of the balance sheet. The Company's comprehensive income (loss) includes net income (loss) and unrealized gains and losses from foreign currency translation and marketable securities. For the year ended December 31, 2002, the Company recorded accumulated foreign currency translation income of \$410,000. For the year ended December 31, 2003, the Company recorded a foreign currency translation adjustment of \$628,000, which increased the accumulated balance to \$1,038,000. The foreign currency translation adjustment was immaterial for the year ended December 31, 2001. For the year ended December 31, 2001, the Company recorded an impairment loss and adjusted the mark to market on its investment in marketable securities to an unrealized gain of \$665,000. During the year ended December 31, 2002, the Company sold all of its investment in marketable securities and eliminated the unrealized gain of \$665,000. The Company recognized a gain of \$419,000 on the sale of its investment in marketable securities during 2002.

Recent Pronouncements

In January 2003, the Financial Accounting Standards Board (FASB) issued FASB Interpretation No. 46 (FIN 46), "Consolidation of Variable Interest Entities." The requirements for variable interest entities after January 31, 2003 were adopted on February 1, 2003. The Company's current results of operations and financial position have not been affected. 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. The Company currently does not have any variable interest entities as defined in FIN 46R. The adoption of this statement is not expected to have any impact on the Company's consolidated financial statements.

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In May 2003, the Emerging Issues Task Force (EITF) reached a consensus on EITF Issue No. 00-21, "Revenue Arrangements with Multiple Deliverables," (EITF 00-21). EITF 00-21 addresses certain aspects of the accounting by a vendor for arrangements under which it will perform multiple revenue-generating activities. It also addresses when and how an arrangement involving multiple deliverables should be divided into separate units of accounting. The guidance in EITF 00-21 is effective for revenue arrangements entered into in fiscal periods beginning after June 15, 2003. The adoption of EITF Issue No. 00-21 did not have any impact on the Company's financial statements.

SFAS No. 150, "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity," was issued in May 2003. This Statement establishes standards for the classification and measurement of certain financial instruments with characteristics of both liabilities and equity. The Statement also includes required disclosures for financial instruments within its scope. For the Company, the Statement was effective for instruments entered into or modified after May 31, 2003 and otherwise will be effective as of January 1, 2004, except for mandatorily redeemable financial instruments. For certain mandatorily redeemable financial instruments, the Statement will be effective for the Company on January 1, 2005. The effective date has been deferred indefinitely for certain other types of mandatorily redeemable financial instruments. The Company currently does not have any financial instruments that are within the scope of this Statement.

In April 2002, SFAS No. 145, "Rescission of FASB Statements No. 4, 44 and 64, Amendment of FASB Statement No. 13, and Technical Corrections," was issued. SFAS No. 145 amends existing guidance on reporting gains and losses on the extinguishment of debt to prohibit the classification of the gain or loss as extraordinary, as the use of such extinguishments have become part of the risk management strategy of many companies. SFAS No. 145 also amends SFAS No. 13, "Accounting for Leases," to require sale-leaseback accounting for certain lease modifications that have economic effects similar to sale-leaseback transactions. The provisions of SFAS No. 145 related to the rescission of SFAS No. 4, "Reporting Gains and Losses from Extinguishment of Debt," were applied in fiscal years beginning after May 15, 2002. The provisions of SFAS No. 145 related to Statement 13 were effective for transactions occurring after May 15, 2002. The adoption of Statement 145 had no effect on the Company's financial statements.

In June 2002, SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities," was issued. SFAS No. 146 addresses financial accounting and reporting for costs associated with exit or disposal activities and nullifies EITF Issue No. 94-3, "Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity." The provisions of SFAS No. 146 were effective for exit or disposal activities initiated after December 31, 2002, with early application encouraged. The adoption of SFAS No. 146 did not have any impact on the Company's financial statements.

In November 2002, FASB Interpretation No. 45, "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others," was issued. This Interpretation enhances the disclosures to be made by a guarantor in its interim and annual financial statements about its obligations under guarantees it has issued. The Interpretation also clarifies that a guarantor is required to recognize, at inception of a guarantee, a liability for the fair value of the obligation undertaken. The initial recognition and measurement provisions of the Interpretation were applicable to guarantees issued or modified after December 31, 2002 and the disclosure requirements were effective for financial statements of interim or annual periods ending after December 15, 2002. The adoption of FASB Interpretation No. 45 did not have any impact on the Company's financial statements.

In December 2002, SFAS No. 148 was issued. SFAS No. 148 amends SFAS No. 123 to provide alternative methods of transition for a voluntary change to the fair value method of accounting for stock-based employee compensation. In addition, SFAS No. 148 amends the disclosure requirements of SFAS No. 123 to require prominent disclosures in both annual and interim financial statements. Disclosures required by this standard are included in the notes to these financial statements.

2. Sale of the Domestic CRO Operation

On December 31, 1999, the Company sold the business and certain of the assets of its domestic CRO operation (the "Division"), which consisted of clinical trial management and clinical data management operations. The Company received cash consideration of \$1,000,000 on December 31, 1999 and \$8,000,000 on

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January 31, 2000, with additional consideration, if any, payable over time, subject to adjustments and earn-outs. In addition, certain specific liabilities of the Division were assumed by the buyer as part of the transaction. During the years ended December 31, 2001 and 2002, the Company recognized additional pre-tax gain of \$1,422,000 and \$35,000, respectively, related to the disposition. During the first quarter of 2002, the Company finalized the accounting for the disposition related to certain earn-outs. The escrow account that was established in connection with the transaction has been closed effective as of the last income distribution received by the Company during the first quarter of 2002.

3. Accounts Receivable

The components of accounts receivable are as follows:

	December 31,	
	2002	2003
Billed	\$ 7,344,000	\$ 14,074,000
Unbilled	49,000	240,000
Allowance for doubtful accounts	(439,000)	(367,000)
	<u>\$ 6,954,000</u>	<u>\$ 13,947,000</u>

4. Property and Equipment

The components of property and equipment are as follows:

	December 31,	
	2002	2003
Computer and other equipment	\$ 12,855,000	\$ 20,383,000
Furniture and fixtures	2,620,000	2,742,000
Leasehold improvements	1,491,000	1,543,000
System development costs	4,717,000	6,327,000
	<u>21,683,000</u>	<u>30,995,000</u>
Less-Accumulated depreciation	(9,096,000)	(14,579,000)
	<u>\$ 12,587,000</u>	<u>\$ 16,416,000</u>

5. Line of Credit

The Company has a line of credit with a bank, through June 30, 2004, that provides for borrowings up to \$3,000,000 at an interest rate of prime minus 35 basis points. 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, the Company has not borrowed any amounts under its line of credit.

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

The income tax provision (benefit) consists of the following:

	Year Ended December 31,		
	2001	2002	2003
Current provision (benefit):			
Federal	\$ (133,000)	\$ □	\$ 8,752,000
State and local	□	182,000	900,000
Foreign	219,000	995,000	1,933,000
	<u>86,000</u>	<u>1,177,000</u>	<u>11,585,000</u>
Deferred provision (benefit):			
Federal	(198,000)	1,185,000	(3,166,000)
State and local	□	(932,000)	76,000
Foreign	□	166,000	322,000
	<u>(198,000)</u>	<u>419,000</u>	<u>(2,768,000)</u>
	<u>\$ (112,000)</u>	<u>\$ 1,596,000</u>	<u>\$ 8,817,000</u>

Foreign income before income taxes was \$730,000, \$3,318,000 and \$6,443,000 for the years ended December 31, 2001, 2002 and 2003, respectively.

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

	Year Ended December 31,		
	2001	2002	2003
Tax at federal statutory rate	\$ (1,282,000)	\$ 2,634,000	\$ 8,148,000
Increase (decrease) in valuation allowance	2,935,000	(1,074,000)	133,000
State and local taxes, net of federal	(1,002,000)	182,000	976,000
Change in effective rate for deferred assets	486,000	□	□
Federal tax credits	(807,000)	(172,000)	(587,000)
Foreign pre-tax income	(29,000)	33,000	□
Tax-free interest income	(75,000)	(24,000)	(18,000)
Other	(338,000)	17,000	165,000
	<u>\$ (112,000)</u>	<u>\$ 1,596,000</u>	<u>\$ 8,817,000</u>

The components of the Company's net deferred tax asset are as follows:

	December 31,	
	2002	2003
Goodwill amortization	\$ 2,099,000	\$ 1,982,000
Capitalized R&D expenses	□	3,200,000
Tax credit carryforwards	1,352,000	2,041,000
Net operating loss carryforwards	1,151,000	926,000
Investment impairment	1,791,000	1,845,000

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Repatriation of UK earnings	(166,000)	(107,000)
Depreciation	(1,689,000)	(2,419,000)
Reserves and accruals	424,000	395,000
	<u> </u>	<u> </u>
Deferred tax asset before valuation allowance	4,962,000	7,863,000
Valuation allowance	(2,145,000)	(2,278,000)
	<u> </u>	<u> </u>
Net deferred tax asset	\$ 2,817,000	\$ 5,585,000
	<u> </u>	<u> </u>

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At December 31, 2003, the Company had net operating loss carryforwards for state and local tax purposes of approximately \$15,500,000, which will begin to expire in 2004. A valuation allowance of \$2,278,000 has been provided as of December 31, 2003 for the capital loss on the investment impairment as well as certain of the Company's state net operating loss carryforwards because of the uncertainty of their realization. At December 31, 2003, the Company had alternative minimum tax credit carryforwards of \$188,000, which have no expiration date, and net research and development tax credits of \$1,484,000, which begin to expire in 2018. The Company began recognizing a deferred tax liability for undistributed earnings of its UK subsidiary beginning in 2002.

Based on the Company's 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; therefore, no valuation allowance is necessary with the exception of the capital loss and certain New Jersey state net operating loss carryforwards. New Jersey has suspended the use of net operating loss carryforwards through at least 2003 and management believes it is appropriate to maintain a valuation allowance on these items.

7. Employee Retirement Plan

The Company sponsors 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 \$245,000 in 2003, \$200,000 in 2002 and \$178,000 in 2001.

8. Related Party Transactions

The Company's 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 2001, 2002 and 2003 (see Note 10). Fees incurred under this consulting arrangement approximated \$255,000, \$389,000 and \$394,000 for the years ended December 31, 2001, 2002 and 2003, respectively. At December 31, 2002 and 2003, \$245,000 and \$76,000, respectively, was owed to the professional corporation in connection with the consulting agreement. The Company amended its consulting agreement with the professional corporation in January 2003 and 2004 (see Note 10).

The Company recognized \$180,000 of software maintenance service revenues associated with an agreement with DAC in the year ended December 31, 2001 which was included in the Company's consolidated services revenues.

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 \$84,000, \$61,000 and \$75,000 for the years ended December 31, 2001, 2002 and 2003, respectively.

9. Stock Option Plans

In August 1993, the Company established a nonqualified stock option plan (the "1993 Plan") authorizing the grant of options to acquire up to 4,952,250 shares of the Company's 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 the Company's 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, the Company adopted a stock option plan (the "1996 Plan") that authorized the grant of both incentive and non-qualified options to acquire up to 2,250,000 shares of the Company's common stock. The Company's 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 2,700,000 to 4,950,000

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and provided for an annual option grant of 15,000 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 1,350,000 to 6,300,000. No additional options will be granted under this plan in 2004 and 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 2,550,000 shares of the Company's common stock. The Compensation Committee of the Company's Board of Directors determines the exercise price 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 the Company's plans is as follows:

	Outstanding Shares	Option Price Per Share	Weighted Average Exercise Price
Balance, December 31, 2000	3,342,213	\$ 0.51-3.96	\$ 2.08
Granted	2,484,519	0.97-2.53	1.45
Exercised	(90,000)	1.33-2.23	1.87
Cancelled	(118,800)	0.97-3.96	2.66
Balance, December 31, 2001	5,617,932	0.51-3.61	1.79
Granted	883,875	3.56-6.32	4.34
Exercised	(678,575)	0.51-4.51	1.72
Cancelled	(452,772)	0.51-4.51	2.72
Balance, December 31, 2002	5,370,460	0.83-6.32	2.15
Granted	1,164,000	8.79-28.96	9.76
Exercised	(2,106,452)	0.83-4.51	1.85
Cancelled	(122,147)	0.97-9.43	5.00
Balance, December 31, 2003	4,305,861	0.83-28.96	4.27

As of December 31, 2003, 1,633,386 options with a weighted average exercise price of \$2.91 per share were exercisable and 1,567,500 options were available for future grants under the 2003 Plan.

The following table summarizes information about stock options outstanding at December 31, 2003:

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
\$0.00 - \$2.89	2,541,575	6.8	\$ 1.77	1,259,975	\$ 1.96
\$2.90 - \$5.79	532,786	7.7	4.05	199,036	3.59
\$5.80 - \$8.69	97,500	8.8	6.32	24,375	6.32
\$8.70 - \$11.58	1,101,000	9.3	9.34	150,000	9.43
\$14.48 - \$17.38	12,000	9.6	16.24	-	-
\$26.06 - \$28.96	21,000	9.8	28.96	-	-

4,305,861	7.6	4.27	1,633,386	2.91
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10. Commitments and Contingencies

Leases

The Company leases 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

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all operating leases for the years ended December 31, 2001, 2002 and 2003 was \$1,687,000, \$2,319,000 and \$3,149,000, respectively.

The Company leases approximately 39,000 square feet of office space in Philadelphia, Pennsylvania, of which approximately 840 square feet is subleased to a third party. This lease expires in August 2008. The Company leases approximately 31,000 square feet of office space in Bridgewater, New Jersey, which expires in January 2011. The Company leases approximately 9,000 square feet of office space in Peterborough, United Kingdom, which expires in September 2009.

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

Future minimum lease payments as of December 31, 2003 are as follows:

	Capital Leases	Gross Operating Leases	Sublease Income
2004	\$ 691,000	\$ 3,950,000	\$ 328,000
2005	134,000	3,700,000	324,000
2006	□	2,853,000	104,000
2007	□	1,900,000	□
2008	□	1,497,000	□
2009 and thereafter	□	1,957,000	□
	<u>\$ 825,000</u>	<u>\$ 15,857,000</u>	<u>\$ 756,000</u>
Less imputed interest	(50,000)		
Net present value of capital lease obligations	775,000		
Less current installments	(644,000)		
Long-term capital lease obligations, excluding current installments	<u>\$ 131,000</u>		

Agreements with the Company's Management

In addition to an employment agreement with the Company's Chairman and Chief Scientist, the Company 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 the Company's 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 the Company's Board of Directors.

The Company has entered into an employment agreement with the Company's Chief Executive Officer effective January 1, 2004. Under this agreement, his employment may be terminated with or without cause (as defined therein) by the Company at any time. In the event that the Company terminates Mr. Esposito's employment other than for cause or in the event of Mr. Esposito's death or disability (as defined therein), the Company is obligated to (i) pay Mr. Esposito, in lump sum, one year salary and bonus; (ii) to continue Mr. Esposito's benefits (as defined therein) for one year; and (iii) accelerate the vesting of all of Mr. Esposito's stock options, not otherwise vested, to

purchase the Company's Common Stock. The agreement provides that, upon a change of control (as defined therein) of the Company, Mr. Esposito may resign (i) if he is not offered a position

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that includes comparable responsibilities, location or compensation or (ii) in Mr. Esposito's sole discretion, within one year after the first anniversary of accepting any position, regardless of the responsibilities, location or compensation of such position. The fact that Mr. Esposito 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. If Mr. Esposito resigns under such circumstances, the Company will be obligated to provide the same benefits to Mr. Esposito as if he was terminated other than for cause. 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 the Company; and (ii) interfering with the Company's business by soliciting customers or employees.

The Company has entered into employment agreements with each of the other executive officers. Under these agreements, their employment may be terminated with or without cause (as defined therein) by the Company at any time. In the event that the Company terminates an officer's employment other than for cause or in the event of the officer's death or disability (as defined therein), the Company is obligated to continue base salary payments and benefits for between six months and one year. These agreements provide that, upon a change of control (as defined therein) of the Company the officer may resign (i) if the officer is not offered a position that includes comparable responsibilities, authority, location or compensation or (ii) in the officer's sole discretion, within one year after accepting any position, regardless of the responsibilities, authority, location or compensation of such position. If the officer resigns under such circumstances, the Company will be obligated to provide up to one year's base salary and prorated bonus, in one lump sum payment. 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 the Company; and (ii) interfering with the Company's business by soliciting customers or employees.

Contingencies

The Company is involved in legal proceedings from time to time in the ordinary course of its business. The Company believes that none of these legal proceedings will have a material adverse effect on its financial condition or results of its operations.

11. Fair Value of Financial Instruments

The Company's 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

Commencing in 2003, the Company considers its operations to consist of one segment. The development of the one segment approach corresponds to the implementation of the Company's refinement in strategic focus in late 2002, and represents management's view of the Company's operations. Prior to 2003, the Company's reportable segments were Cardiac Safety and Clinical Research Technology and Services. All prior periods have been restated to conform to the current-year presentation.

The Company operates on a worldwide basis with two locations in the United States and one location in the United Kingdom, which is categorized below as North America and Europe, respectively.

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Geographic information is as follows:

Year Ended December 31, 2001			
	North America	Europe	Total
License revenues	\$ 1,282,000	\$ 90,000	\$ 1,372,000
Service revenues	20,701,000	5,924,000	26,625,000
Net revenues from external customers	\$ 21,983,000	\$ 6,014,000	\$ 27,997,000
Income (loss) from operations	\$ (1,161,000)	\$ 714,000	\$ (447,000)
Identifiable assets	\$ 39,201,000	\$ 1,799,000	\$ 41,000,000
Year Ended December 31, 2002			
	North America	Europe	Total
License revenues	\$ 2,022,000	\$ 97,000	\$ 2,119,000
Service revenues	29,608,000	9,799,000	39,407,000
Net revenues from external customers	\$ 31,630,000	\$ 9,896,000	\$ 41,526,000
Income from operations	\$ 3,542,000	\$ 3,301,000	\$ 6,843,000
Identifiable assets	\$ 47,368,000	\$ 6,024,000	\$ 53,392,000
Year Ended December 31, 2003			
	North America	Europe	Total
License revenues	\$ 4,974,000	\$ 764,000	\$ 5,738,000
Service revenues	47,022,000	14,082,000	61,104,000
Net revenues from external customers	\$ 51,996,000	\$ 14,846,000	\$ 66,842,000
Income from operations	\$ 16,574,000	\$ 6,396,000	\$ 22,970,000
Identifiable assets	\$ 83,834,000	\$ 8,144,000	\$ 91,978,000

13. Quarterly Financial Data (Unaudited)

The quarterly data below includes all adjustments (consisting only of normal recurring adjustments with the exception of those indicated below) that the Company considers necessary for a fair presentation (in thousands, except per share data).

	March 31,		June 30,		September 30,		December 31,	
	2002	2003	2002	2003	2002	2003	2002	2003
Net revenues	\$ 8,361	\$ 13,583	\$ 10,104	\$ 14,776	\$ 10,924	\$ 17,464	\$ 12,137	\$ 21,019
Gross margin	4,826	8,252	5,946	8,958	5,872	10,973	6,869	13,918
Operating income (a)	850	3,856	1,534	4,325	1,945	6,089	2,514	8,700
Net income (a) (b)	709	2,455	1,170	2,769	1,362	3,873	2,909	5,366
Basic net income per share	\$ 0.02	\$ 0.08	\$ 0.04	\$ 0.08	\$ 0.04	\$ 0.12	\$ 0.09	\$ 0.16
Diluted net income per share	\$ 0.02	\$ 0.07	\$ 0.03	\$ 0.08	\$ 0.04	\$ 0.11	\$ 0.08	\$ 0.15

-
- (a) Includes gains on the sale of the Company's domestic CRO of \$35 in the quarter ended March 31, 2002.
- (b) Includes gain on the sale of marketable securities of \$2, \$73 and \$344 in the quarters ended March 31, 2002, June 30, 2002 and December 31, 2002, respectively.

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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, 2001	\$ 833	□	\$ 383	\$ 450
December 31, 2002	\$ 450	□	\$ 11	\$ 439
December 31, 2003	\$ 439	□	\$ 72	\$ 367

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