ERESEARCHTECHNOLOGY INC /DE/
Form 10-K
March 03, 2010

Table of Contents

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K

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

For the Fiscal Year ended December 31, 2009

or

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

For the transition period from _____ to _____

Commission File No. 0-29100

eResearchTechnology, Inc.

(Exact name of issuer as specified in its charter)

Delaware	**22-3264604**
(State of Incorporation)	(I.R.S. Employer Identification No.)
1818 Market Street Philadelphia, PA	**19103**
(Address of Principal Executive Offices)	(Zip Code)

(215) 972-0420

Registrant s telephone number, including area code

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

Title of Class	**Name of Each Exchange on Which Registered**
Common Stock, $.01 par value	**The Nasdaq Stock Market LLC**

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No þ

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes o No þ

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 þ No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes o No o

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. o

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

Large accelerated filer o	Accelerated filer þ
Non-accelerated filer o	Smaller reporting company o
(Do not check if a smaller reporting company)	

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

As of June 30, 2009, the aggregate market value of the registrant s common stock held by non-affiliates of the registrant was $290,875,796 based on the closing sale price as reported on the Nasdaq Global Select Market.

Table of Contents

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

Class	Outstanding at February 19, 2010
Common Stock, $.01 par value per share	48,610,757 shares

DOCUMENTS INCORPORATED BY REFERENCE

The information required by Part III (Items 10, 11, 12, 13 and 14) is incorporated by reference from the registrant s definitive proxy statement for its 2010 Annual Meeting of Stockholders, to be filed with the Commission pursuant to Regulation 14A.

TABLE OF CONTENTS

Table of Contents

Cautionary Statement for Forward-Looking Information

Except for historical matters, the matters discussed in this Form 10-K are forward-looking statements that involve risks and uncertainties. Forward-looking statements include, but are not limited to, statements within the meaning of the Private Securities Litigation Reform Act of 1995 that reflect our current views as to future events and financial performance with respect to our operations. These statements can be identified by the fact that they do not relate strictly to historical or current facts. They use words such as aim, anticipate, are confident, estimate, expect, wi will continue, will likely result, project, intend, plan, believe, look to and other words and terms of similar conjunction with a discussion of future operating or financial performance.

These statements are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied in the forward-looking statements. Factors that might cause such a difference include: unfavorable economic conditions; our ability to obtain new contracts and accurately estimate net revenues due to variability in size, scope and duration of projects and internal issues at the sponsoring client; our ability to successfully integrate acquisitions; competitive factors in the market for centralized cardiac safety services; changes in the pharmaceutical, biotechnology and medical device industries to which we sell our solutions; technological development; and market demand. There is no guarantee that the amounts in our backlog will ever convert to revenue. Should the current economic conditions continue or deteriorate further, the cancellation rates that we have historically experienced could increase. Further information on potential factors that could affect the Company s financial results can be found in Item 1A Risk Factors and in the reports we file with the Securities and Exchange Commission.

Forward-looking statements speak only as of the date made. We undertake no obligation to update any forward-looking statements, including prior forward-looking statements, to reflect the events or circumstances arising after the date as of which they were made. As a result of these risks and uncertainties, readers are cautioned not to place undue reliance on any forward-looking statements included in this discussion or that may be made in our filings with the Securities and Exchange Commission or elsewhere from time to time by, or on behalf of, us.

Table of Contents

PART I

ITEM 1. BUSINESS

General

eResearchTechnology, Inc. (ERT[tm]), a Delaware corporation, was founded in 1977 to provide Cardiac Safety solutions to evaluate the safety of new drugs. ERT and its consolidated subsidiaries collectively are referred to as the Company or we. We provide technology and service solutions 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 solutions (Cardiac Safety solutions) and a provider of technology solutions that streamline the clinical trials process by enabling our clients to evolve from traditional, paper-based methods to electronic processing using our electronic patient reported outcomes (ERT ePRO[tm]) solutions.

Our solutions improve the accuracy, timeliness and efficiency of trial set-up, data collection from sites worldwide, data interpretation, and new drug, biologic and device application submissions. We offer Cardiac Safety solutions, which are utilized by pharmaceutical, biotechnology and medical device companies, clinical trial sponsors and clinical research organizations (CROs) during the conduct of clinical trials. Our Cardiac Safety solutions include the collection, interpretation and distribution of electrocardiographic (ECG) data and images and are performed during clinical trials in all phases of the clinical research process. The ECG provides an electronic map of the heart s rhythm and structure, and is performed in most clinical trials. Our Cardiac Safety solutions permit assessments of the safety of therapies by documenting the occurrence of cardiac electrical change. Specific trials, such as a Thorough QTc study, focus on the cardiac safety profile of a compound. Thorough QTc studies are comprehensive studies that typically are of large volume and short duration and are recommended by the United States Food and Drug Administration (FDA) under guidance issued in 2005 by the International Committee on Harmonization (ICH E14). We also offer site support, which includes the rental and sale of cardiac safety equipment along with related supplies and logistics management. We also offer ePRO solutions along with proprietary clinical assessments.

On June 23, 2009, we completed the sale of certain assets relating to our electronic data capture (EDC) operations. Under the terms of the transaction, OmniComm Systems, Inc. issued to us 8.1 million shares of common stock and assumed certain liabilities including deferred revenue relating to our EDC operations in exchange for our EDC assets which primarily included our EDC software, applications and fixed assets and $1.15 million in cash we paid. During the year ended December 31, 2009, we recorded a gain on the sale of these assets of $0.5 million within general and administrative expenses in the consolidated statement of operations. The revenue and cost of revenue of our former EDC operations have been reclassified from the licenses and services categories to the EDC category on the consolidated statements of operations for all periods presented. Additionally, the remaining revenues and costs of sales in licenses, related to cardiac safety reporting and ePRO, were reclassified to the services category on the consolidated statements of operations for all periods presented.

Cardiac Safety Market in Clinical Trials

Diagnostic tests are employed in clinical trials to measure the effect of the drug on certain body organs and systems in order to determine the product s safety. Cardiac safety testing is a critical component of diagnostic testing. The collection of cardiac safety data (primarily ECGs) can be performed using a decentralized collection method or in a centralized cardiac safety laboratory environment which ERT and other centralized cardiac safety laboratories provide.

Decentralized ECG collection is performed at investigative sites using local ECG equipment with ECGs read by local physicians using a paper ECG output. Different ECG machines, which often use different algorithms to measure the ECG, may be utilized at the various trial sites which may create variability in the ECG measurements. Variability may result in the inability to identify cardiac safety signals. The use of paper based ECGs also limits the degree of detailed analysis of the ECG versus a digital representation of the ECG. Further, the use of multiple physicians, many of whom may not be cardiologists, to interpret the ECGs at individual sites may also create variability.

Under centralized ECG collection, most of the work that would otherwise be done at the local site level is performed by centralized cardiac safety laboratories. ECGs are administered at the local site using a standard set of

Table of Contents

protocols and homogenous equipment. The digital ECG data is then transmitted to the centralized cardiac safety laboratory where it is subject to a standardized set of operational processes.

We estimate that centralized ECG collection is used in about one third of ECGs collected in clinical trials, and this use is growing due to the benefits over paper based decentralized collection. The primary benefit is the creation of a higher quality of data, in part because resolution of digital data is greater than that of paper based ECGs. It is also due to the standardization of cardiologist review and the use of a common operational framework, independent third party evaluation and repeatable project management and work flow processes. We also believe use of centralized cardiac safety laboratories is more efficient and provides the customer with an overall lower cost. We are participating in the development of a low-cost cardiac safety equipment solution to further incent clinical trial sponsors to transition from decentralized to centralized collection and analysis of ECGs.

The primary techniques used by core laboratories for interval duration measurements and morphology evaluations include a fully manual and a semi-automated methodology. The fully manual measurement, as performed by ERT, involves human analyzers (a cardiac safety specialist for interval duration measurements of the intervals and a cardiologist for quality control and interpretation) who perform on-screen measurements of the intervals, without the use of a computer algorithm to identify interval onsets and offsets. The advantage of this approach is that the readers are not biased or influenced by the computer algorithm. The semi-automated methodology (also called manual adjudication), as performed by ERT, utilizes a computer algorithm to generate the initial on-screen placement of electronic calipers at the beginning and end of each interval requiring measurement, such as the QT interval. This is followed by the review of the caliper placement and manual adjustments, as necessary, which are performed by human analyzers (a cardiac safety specialist and an over-read by a cardiologist, who also performs the interpretation). The advantage of this approach is less measurement variability and the ability to correct automated measurements that are believed to be inaccurate by the analyzers. We provide both the fully manual and semi-automated reading methodology to our customers. Over the past several years we have experienced an increase in the use of semi-automatic reading as compared to fully manual reading of ECGs.

Certain providers of cardiac safety services have been developing software algorithms which enable more highly, or in some cases fully, automated reads. Fully-automated readings rely entirely on computer algorithms generated by the ECG machine to measure the QT interval and eliminate the cardiac safety specialist and cardiologist review of the underlying interval duration measurement data. Highly-automated readings utilize cardiologists or other human readers to over-read a subset of the ECGs collected. ERT offers a fully-automated reading methodology in addition to our fully-manual and semi-automatic methodologies. While the FDA potentially could accept highly- or fully-automated ECG data for submittal, we have not been requested by our customers to conduct a study using a fully-automated reading methodology which would be used for submission of data to the FDA. We consider the risk of taking the human oversight of a cardiac safety specialist or a cardiologist out of the reading process, especially in trials populated with sick patients, to be too high to offset the potential cost savings that could be experienced should a fully-automated read be performed.

The anticipated cost savings of using a highly- or fully-automated approach are subject to much professional debate. The main savings anticipated from using a highly- or fully-automated approach come from a reduced number of subjects required to run the trial, due to an assumed lower variance from using highly- or fully-automated readings. However, there are published peer-reviewed articles that indicate that fully- or highly-automated approaches actually lead to increases in variance (and hence would potentially require more subjects) in some cases. The second potential area of cost-savings the lower amount of time that cardiologists or other humans would be required to spend doing over-reads of the ECGs is also subject to much debate in that the addition of another algorithm to the entire core lab process would result in significant additional costs due to licensing costs of using such an algorithm. We estimate that our costs related to cardiologist or other technical specialist over-reads of ECGs is less than 20% of the total costs that we incur in our processing of a cardiac safety trial. Moreover, all other procedures and processes we provide as part of

our cardiac safety services product offering, as noted in the Service Offerings section of this 10-K, would continue to be required under any alternative ECG reading methodology. Should the pharmaceuticals industry adopt a highly- or fully-automated reading methodology as a preferred method, we believe it would only be adopted in Thorough QTc trials, as these trials utilize healthy patients only. In addition the ICH E-14 guidance continues to recommend that ECGs in Thorough QTc studies be read by a few skilled readers. As a result of the factors above, we believe that the impact of any significant shift to a highly- or fully-automated reading methodology would have a limited impact on our operations or financial results.

Table of Contents

Operations

We conduct our operations through offices in the United States (U.S.) and the United Kingdom (UK). Our international net revenues represented approximately 23%, 21% and 24% of total net revenues for the years ended December 31, 2007, 2008 and 2009, respectively. The majority of our revenues are allocated based upon the profit split transfer pricing methodology. The profit split methodology equalizes gross margins for each legal entity, based upon its respective direct revenue or direct costs, as determined by the relevant revenue source.

Service Offerings

Our revenues by service solution as a percentage of total revenues are as follows:

	Year Ended December 31,		
	2007	2008	2009
Net revenues:			
EDC licenses and services	6.4%	4.4%	2.7%
Services	66.8	72.5	68.9
Site support	26.8	23.1	28.4
Total net revenues	100.0	100.0	100.0

Our EDC licenses and services revenues consisted of license fees for perpetual license sales and monthly and annual term license sales for our software products, technology consulting and training services and software maintenance services offered under our former EDC solutions. Our services revenues consist of our services offered under our Cardiac Safety and to a lesser extent, ePRO[tm] solutions. Our site support revenue consists of cardiac safety equipment rentals and sales along with related supplies and logistics management.

Service Solutions	Description
Cardiac Safety	ERT provides a highly scalable set of Cardiac Safety solutions centered on our regulatory compliant (Title 21 CFR, Part 11) EXPERT® Technology Platform. EXPERT® provides for workflow enabled cardiac safety data collection, interpretation and distribution of ECG data and images. EXPERT® also enables analysis and cardiologist interpretation of ECGs performed on research subjects in connection with our clients clinical trials. EXPERT® is designed specifically to address global regulatory guidance and technical standards for digital ECG processing to include digital collection, waveform measurements and annotations, review and output to the regulatory standard file format. EXPERT® 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. EXPERT® further enhances our ECG solutions by permitting cardiologists, with training in our ECG interpretation guidelines and proper security access, to perform

telecardiology, which is the ability to access and evaluate ECGs electronically in remote locations. Our EXPERT® solution supports a wide variety of workflows and rules that in turn provides us the flexibility to accommodate the unique needs of individual sponsors and studies.

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

Digital ECG Services. Allows the investigator to transmit, via modem or Internet, 12-lead ECG data directly to us for interpretation and rapid return of results to the investigator and the sponsor. ECGs are measured using a manual

Table of Contents

method or a semi-automatic method. Under the manual method, ECGs are measured by our cardiac safety specialists utilizing an on screen, high-resolution caliper placement system, and are then interpreted by a cardiologist. Under the semi-automatic method, ECGs are measured by a cardiac safety specialist and cardiologist adjudication of software algorithm placed measurements where appropriate and as desired by our clients.

Continuous Digital 12-lead ECG Recording. The 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 cardiologist. Continuous digital 12-lead ECG recordings can also be used for studies assessing the incidence of arrhythmias, cardiac ischemia and/or heart rate variability findings.

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

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

FDA XML ECG Services. This 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 XML standard for digital ECGs.

MyStudy Portal™. This is a hosted solution, which provides sponsors and investigator sites with the ability to order supplies, gain real time reports and respond to queries via a secure web portal in lieu of less efficient means such as faxing and telephone calls.

Cardiac Safety Equipment. We provide ECG equipment to clients to perform the ECG and Holter recordings and give them the means to send such recordings to ERT. The service comprises equipment rental and sales, along with related supplies and logistics management.

Cardiac Safety Consulting

The centralization of electrocardiograms in clinical research has become increasingly important to organizations involved in the development of new drugs. Global regulators each apply their own slightly different interpretation of the ICH E14 guidelines and, as a result, sponsors look to their vendors to provide key scientific input into the overall process. Our cardiac safety consulting service aids sponsors in the development of protocol synopses, the creation and analysis of statistical plans as well as the provision of an expert medical report with regard to the cardiac findings. We are involved in all phases of clinical development from a consultancy point of view. We offer this service both as a stand-alone service and

integrated with our full suite of Cardiac Safety solutions.

Table of Contents

ePRO	Data is collected during clinical trials allowing sponsors to gauge the efficacy of the compounds they are testing. Collecting data directly from the patient can be performed in a number of different methods, including electronically. We provide an electronic patient reported outcome (ePRO) service that allows subjects to easily and quickly report data for a clinical trial. Because it can be accessed from a standard phone, our ePRO system is cost effective while being extremely scalable and suitable from Phase I through Phase IV. Diaries, screening, recruitment and all clinical assessments can be completed directly by the subject without requiring clinician involvement. Our solution consists of the following tools and services: Data Collection Our ePRO solution is an Interactive Voice Response (IVR) system that allows subjects in a clinical trial to call into the system via a telephone and enter their reported data directly into the system. Data Management Once the data has been entered into the ePRO system there are a number of data management functions that can be performed depending on the requirements of the sponsor. This includes sending call reports to the sites, sending call reports to the sponsor, alerting the sites if data is outside specifically set boundaries, web access to the data by the sponsor, and cleaning of data per the specs provided by the sponsor. Data Delivery At the conclusion of the study, the data is compiled and then delivered according to the sponsor requirements. This can include SAS exports, ASCII exports, electronic file transfers and data delivery on digital media.
Project Assurance	We provide a full spectrum of consulting services for all of our solutions that augment the study management and implementation efforts of clients in support of their clinical research requirements. The methodology provides a consistent framework through which we can effectively manage the delivery of all service solutions and 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.

Research and Development

Overview

As of December 31, 2009, we had 26 employees engaged in research and development. The central approach of our research and development team is to foster a close relationship with our customers and internal users to ensure we continue to deliver industry leading capabilities across all our offerings.

Our proprietary and patented technology is designed to materially enhance the abilities of our customers and internal users to efficiently and securely capture and process clinical data, to ensure regulatory compliance and to offer scalability to support the largest of clinical studies in a timely manner.

Our technology initiatives continue to focus on the dual need of enabling unique configurations to meet the varying clinical trial requirements of each of our customers and doing so in a highly automated manner to enable continued strong financial performance.

Table of Contents

Technology

ERT s technology strategy centers on a corporate-wide approach to ensuring we extend our current market leadership in cardiac safety and capture market leadership in new areas, such as electronic Patient Reported Outcomes and suicidality assessments. In addition, during 2009, we have centralized all systems and technology activities to drive further automation and efficiencies.

2009 Research and Development Initiatives

During 2009, we undertook a series of major initiatives to launch new customer facing products, introduce sophisticated Customer Relationship Management capabilities, retire older and less capable systems, and to further integrate and upgrade our internal systems. A brief outline of these initiatives follows:

MyStudy Portal™

We launched a new portal product to provide our cardiac safety and ePRO customers with a variety of self-service features intended to shift work from manual faxing and telephone-based processes to more efficient, automated e-commerce based processes. Features of MyStudy Portal™ include:

Scalability, to not only support our sponsor customers, but also to enable access for our 25,000+ investigator site locations,

Electronic site qualification process,

On Demand, real time reporting,

Ordering of supplies, and

Electronic query management.

Cardiac Safety

We delivered a major new release of our EXPERT® 2 platform adding further automation across all cardiac safety components, including:

Protocol setup,

Query management,

Analysis,

Cardiology review and

New reporting features.

We developed a new web service to enable EXPERT® 2 to integrate with new generations of ECG machines that are expected to reach the market in 2010.

Electronic Patient Reported Outcomes (ePRO)

We launched a series of upgrades to enhance our current voice-technology based ePRO platform, including:

New, innovative patient enrollment feature,

Launch of suicidality assessments,

Integration with MyStudy Portal[tm], and

New reports.

Table of Contents

Customer Relationship Management (CRM)

We implemented a corporate-wide customer relationship management system to materially increase automation and integration across several organizations and to significantly reduce and eliminate standalone systems. The capabilities include:

Sales and marketing automation,

Customer Care Functionality,

Contracts and proposal management, and

Forecasting.

Our new CRM system, using Salesforce.com and tailored to our unique needs, enabled us to retire our older, standalone systems.

Our Clients

We serve pharmaceutical, biotechnology, medical device companies and clinical trial sponsors as well as CROs. We have agreements that establish the overall contractual relationship between us and our clients with approximately 207 customers for active or upcoming projects. We provide our solutions to 39 of the 50 largest pharmaceutical companies globally and all of the top 10 pharmaceutical companies globally. In 2009, Novartis AG, at 18%, was the only client that accounted for 10% or more of our consolidated net revenues. Novartis accounted for 24% and 23% of our consolidated net revenues in 2007 and 2008, respectively.

Sales and Marketing

We market and sell service solutions primarily through our global direct sales, sales support and professional services organizations. As of December 31, 2009, our business development team consisted of 43 sales, marketing and consulting professionals worldwide, which included a direct sales force of 23 sales professionals located globally.

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

Our sales cycle generally begins with proactive business development within our active customer base as well as outreach to new customers identified through prospecting and marketing efforts. The sales process may include 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 meetings, consultations, workshops, implementation reviews, final proposals and contract negotiations prior to the time when the prospective client has any obligation to purchase our service solutions. During this process, we involve our sales, professional services and senior management personnel in a collaborative approach. Our sales cycle can vary from a few weeks to greater than one year, depending upon the scope of the clinical trial or program, the sponsor s budgeting process, the service solutions being sold, and the final agreed-upon solution required to support the clinical trial or program.

The acquisition of Covance Cardiac Safety Services, Inc. (CCSS), the centralized ECG business of Covance Inc. (Covance) that we acquired in November 2007, included a marketing agreement under which Covance is obligated to

use us as its provider of centralized cardiac safety solutions, and to offer these solutions to Covance s clients, on an exclusive basis, for a 10-year period, subject to certain exceptions. Since the acquisition, we have expanded our customer base and realized new bookings as a result of this expanded relationship.

Since the latter portion of 2008, we have experienced an increase in awards of new and expanded exclusive or near-exclusive long-term enterprise contracts with large pharmaceutical companies, including several with which we had very little business in the past or that we acquired through the Covance relationship. Partially as a result of these long-term commitments, in 2009 we invested in our sales and marketing functions and our internal IT infrastructure.

Table of Contents

Partnerships

We have formalized agreements with clinical pharmacology units (CPUs), CROs, imaging core laboratories and other third-party service providers around the globe, including geographic and cultural specialization in Asia. We structure our integrated partnership offering to provide meaningful service enhancements for partners and sponsors. Enhanced communications and experienced collaboration with numerous partners promote speed, accuracy and reliability of data collection and reporting and quality study conduct.

Backlog

Backlog represents anticipated revenue from work not yet completed or performed under signed contracts, letters of intent or, in some cases, other written acknowledgements from the customer of awarded business. Once work commences, revenue is generally recognized over the life of the contract as services are or equipment is provided. Backlog at December 31, 2009 was $170 million, compared to $166.5 million at December 31, 2008. Contracts included in backlog are subject to termination by our customers at any time, and our annualized cancellation rate over 2008 and 2009 has ranged from 15% to 21% of backlog. In the event of termination, we would be entitled to receive payment for all services performed up to the cancellation date, and in some instances we may be entitled to receive a cancellation penalty. The duration of the projects included in our backlog range from less than 3 months to approximately 5 years.

We cannot provide assurance that we will be able to realize all or most of the revenues included in backlog. We estimate that approximately 40% to 45% of our backlog as of December 31, 2009 will convert into revenue during the 2010 calendar year. Although backlog can provide meaningful information to our management with respect to a particular project or study and is used for operational planning, we believe that our aggregate backlog as of any date is not necessarily a meaningful indicator of our future results as studies may vary in duration; the scope of studies may change, which may increase or decrease their value; and studies may be terminated, reduced in scope or delayed at any time by the customer or regulatory authorities. Any of these factors, in addition to others, can affect our ability to convert our backlog into revenue and the timing of any such conversion.

Competition

While there has been some consolidation in our industry, the market for our service solutions remains extremely fragmented, with hundreds of companies providing niche solutions to satisfy small parts of the clinical research process. Additionally, we were the first company to utilize specifically developed technology to address the digital regulatory initiative in providing ECG solutions.

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

scientific expertise;

consulting capabilities;

quality and performance;

core technology underlying our service offerings;

ability to implement solutions;

capacity;

Table of Contents

price;

financial and organizational stability; and

ability to adapt to changing regulatory guidance.

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

Government Regulation

Human pharmaceutical products, biological products and medical devices are subject to rigorous government regulation. In the United States, the principal federal regulatory agency is the 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 service solutions assist the sponsor or CRO in conducting the trial and preparing the new drug, biologic or device application, we must comply with these requirements. We also must comply with similar regulatory requirements in foreign countries. These foreign regulations vary somewhat from country to country, but generally establish requirements similar to those of the FDA.

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

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

In November 2001, the FDA held a public meeting at which it proposed requiring sponsors of new drugs to submit ECG raw data in digital format and annotated digital ECG waveforms. Annotated waveforms include definition of measurement points that are used to create ECG analysis data. A subsequent meeting held in January 2003, which was supported by a preliminary concept paper issued in November 2002, further discussed the trial design, ECG acquisition, analysis and reporting for digital ECGs. Following a meeting in June 2004, the International Conference on Harmonization (ICH) released to the public in September 2004 the following guidelines at Step 3, S7B: Safety Pharmacology Studies for Assessing the Potential for Delayed Ventricular Repolarization (QT Interval Prolongation) by Human Pharmaceuticals and E14: The Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs (ICH E14). The objective of these guidelines is to recommend the design and timing of studies in the clinical development process and provide general recommendations on available non-clinical methodologies to assess the potential risk of QT interval prolongation of a pharmaceutical product. On May 12, 2005, the ICH ratified and recommended for implementation the cardiac safety monitoring guidance provided in ICH E14 (step 4). The guidance was implemented by the FDA in October 2005 and adopted by the European Union in

November 2005. On October 23, 2009, ICH E14 was ratified by the Japanese Ministry of Health. The guidance confirms previous guidance reinforcing the need for routine cardiac safety testing as well as Thorough QTc testing for all compounds entering the blood stream commencing early in clinical development to provide maximum guidance for later trials, as well as testing for all compounds in Phase III prior to submission for approval.

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

Table of Contents

Potential Liability and Insurance

We attempt to manage our risk of liability for personal injury or death to study subjects from administration of products under study through contractual indemnification provisions with clients and through insurance maintained by our clients and us. Contractual indemnification generally does not protect us against certain of our own actions, such as negligence. The terms and scope of such indemnification vary from client to client and from trial to trial. Although most of our clients are large, well-capitalized companies, the financial viability of these indemnification provisions cannot be assured. Therefore, we bear the risk that the indemnifying party may not have the financial ability to fulfill its indemnification obligations to us. We maintain errors and omissions liability insurance in the amount of $10 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 solutions have been enhanced by significant investment in information technology. Our research and development organization is committed to achieving operating efficiencies through technological advances. We have developed certain computer software and technologically derived procedures, as well as created internal operational processes, which we seek to protect through a combination of contract law and trade secrets, including seeking patent protection in several jurisdictions. We believe that our technological capabilities and operational processes provide significant benefits to our clients.

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

On February 2, 2010, we were issued U.S. Patent No. 7,654,965 by the U.S. Patent Office, which further extends our existing patent protection for the processes embedded in our EXPERT™ 2 technology platform. These new patent claims span a series of innovative and automated processes furthering the science of cardiac safety.

We have also filed patent applications in Canada, India and the European Patent Office. We continue to pursue patent protection of new technology advances and production.

We hold U.S. Registration No. 2.843,409 for our EXPERT® trademark. We use the EXPERT® trademark to identify our services for clinical trials of medical and clinical diagnostic products. In addition, we hold many other unregistered trademarks including EXPeRT® Direct™, EXPeRT® ePRO™, ePRO Solutions™, My Study Portal™, EXPERT® Technology Platform™, Cardiac Safety Solutions™, Clinical Research Consulting Group™ and ERT WebService™.

Employees

At December 31, 2009, we had a total of 353 employees, with 266 employees (253 full-time, 13 part-time) at our locations in the United States and 87 employees (82 full-time, 5 part-time) at our location in the United Kingdom. We had 230 employees performing services directly for our clients, 26 employees in research and development, 43 employees in sales and marketing and 54 employees in general and administrative functions.

We are not a party to any collective bargaining agreements covering any of our employees, nor have we ever experienced any material labor disruption. We are not aware of any current efforts or plans to unionize our employees. We consider our relationship with our employees to be good.

Available Information

Our website address is www.ert.com. We make available on our website our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports as soon as reasonably

Table of Contents

practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission. You may access and print these forms free of charge from our website.

In addition, we provide notifications of news or announcements regarding our financial performance, including SEC filings, investor events, press and earnings releases, as part of our investor relations web site, which can be located through www.ert.com. The contents of our web site are not intended to be incorporated by reference into this report or in any other report or document we file and any reference to these web sites are intended to be inactive textual references only.

ITEM 1A. RISK FACTORS

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

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

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

- we generate a significant percentage of our revenues from a limited number of clients;
- our sales cycles can be lengthy and variable;
- Thorough QTc studies are typically of large volume and of short duration; and
- 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, via consultations, without any obligation by our client to purchase our service solutions. Because many of our expenses are fixed and we are committed to making a significant investment in our organization and in marketing our service solutions, delays in recognizing revenues could cause our operating results to fluctuate from period to period. If we fail to generate the contract signings that we expect or the anticipated revenues from such signings, we may fail to meet financial guidance that we have provided, or may provide in the future, to the public. Failure to meet financial guidance could cause the market price of our common stock to decline and affect our ability to raise capital which could reduce our cash reserves and limit our capital spending.

If general economic conditions deteriorate or fail to improve, our operations may be affected and/or we may be unable to secure future financing to make the necessary investments to grow our business.

General business and economic conditions have deteriorated globally and to date there has only been moderate relief. Since the fourth quarter of 2008, we have experienced a significant increase in Phase III bookings, a decline in Thorough QTc bookings, and a delay in starts for Thorough QTc trials. Although we believe the fundamental drivers of our core business remain positive, a continued weakened global economy could have an impact on our future results of operations. There is no guarantee that the amounts in our backlog will ever convert to revenue. Should the current economic conditions continue or deteriorate further, the cancellation rates that we have historically experienced could continue or increase.

While we believe our current financial condition is very strong and liquid, we have made in the past, and may make in the future, acquisitions or significant investments in other businesses. Future acquisitions or investments may reduce our readily available capital and require us to obtain additional financing. If we are unable to obtain any

Table of Contents

financing necessary to make investments in our technology and workforce, we may be unable to achieve the market growth that such investments were intended to generate.

If general economic conditions deteriorate or fail to improve, potential clients may be unable to get the necessary financing to conduct business and existing clients may fail to make timely payments for services that we have performed, which could adversely affect our ability to maintain or increase overall revenues and our overall financial position.

Many of our existing and potential clients, and in particular, development stage pharmaceutical or biotechnology companies, depend on financing to conduct clinical trials and may be affected by poor economic conditions. If financing is unattainable or business is otherwise affected by a troubled economy, clinical trials may be delayed, which could affect our ability to sign new contracts and maintain or increase revenues. In addition, while we take reasonable precautions to avoid credit risk, some clients may have financial difficulties as a result of the lack of financing or the general poor economic conditions, which could result in delayed payments to us for the services we performed. Such delays in payments would result in higher accounts receivable balances and lower liquidity. In addition, this could result in us recording additional expense to write-off the accounts receivable balances remaining if payment is not likely.

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

Our client base could decline because of consolidation, and we may not be able to expand sales of our service solutions to new clients. Consolidation in the pharmaceutical, biotechnology and medical device industries and among CROs has accelerated in recent years, and we expect this trend to continue. In addition, in times of a weakened economy, less stable companies, such as smaller biotechnology companies, may be at risk of being acquired. In addition, our profitability will suffer if we reduce our prices in response to competitive pressures without achieving corresponding reductions in our expenses.

New companies or organizations that result from such consolidation may decide that our service solutions are no longer needed because of their own internal processes or the use of alternative systems. As these industries consolidate, competition to provide service solutions 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 service solutions. Also, if consolidation of larger clients occurs, the combined organization may represent a larger percentage of business for us and, as a result, we would be likely to rely more significantly on the combined organization s revenues to achieve expected future growth.

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

Our business depends entirely on the clinical trials that pharmaceutical, biotechnology and medical device companies conduct. Our revenues and profitability will decline if there is less competition in the pharmaceutical, biotechnology or medical device industries, which could result in fewer products under development and decreased pressure to accelerate a product approval. Our revenues and profitability will also decline if the FDA or similar agencies in foreign countries modify their requirements, thereby decreasing the need for our solutions. Any other developments that adversely affect the pharmaceutical, biotechnology or medical device industries generally, including federal or state health care reform, product liability claims, new technologies or products or general business conditions, could also decrease the volume of our business. From time to time studies for which we are contracted to provide Cardiac Safety solutions are delayed or postponed resulting in lower than expected revenues.

15

Table of Contents

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

We may incur increased expenses or suffer a reduction in revenues if our service solutions do not comply with applicable government regulations or if regulations allow more competition in the marketplace. Conforming our service solutions 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 service solutions 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.

Our clients and prospective clients will be less likely to use our service solutions if the service solutions do not comply with regulatory requirements in all countries where clinical trials are expected to take place or if we are precluded from participating in clinical trials in countries where trials will be conducted. In addition, changing regulatory requirements could provide an advantage to our competitors if our competitors are able to meet the requirements more rapidly or at lower cost. For example, in the May 12, 2005 ICH release, it was suggested that semi-automated processing of electrocardiograms may be found acceptable in certain instances and thereby replace the manual processing method. Semi-automated processing uses software algorithm-placed measurements that are later adjudicated by a cardiac specialist or physician with overall interpretation by a physician. Manual processing includes manually placed calipers to obtain interval duration measurements interpreted by a cardiologist. Since the 2005 release of the ICH guidance, drug sponsors have shifted towards semi-automated processing allowing more competitors to compete with us in offering this service and, as a result, we have reduced pricing to remain competitive. The effect of such actions has reduced our revenue and gross profit per transaction in prior years and could adversely affect us in the future.

The ICH E14 guidance contained in the May 2005 release recommends either fully manual or manual adjudication (semi automatic) approaches for clinical trials in which the assessment of ECG safety is an important objective, such as the Thorough QTc study. If the Thorough QTc study is negative (i.e. the drug has no QT effect), routine ECG safety assessments in late phase clinical trials using fully automated readings may be adequate. If the Thorough QTc study is positive, (i.e. the drug has a QT effect), then intensive ECG monitoring should take place in future clinical trials. If drug sponsors shift towards fully-automated processing for routine or Thorough QTc studies, our future results of operations may be adversely affected as pricing may decline and additional competitors could enter the market.

Our failure to maintain revenue and gross profit per transaction may affect our ability to achieve growth in cardiac safety revenues and overall profitability from year to year. Our failure to show growth may also prevent us from meeting the expectations of securities analysts and investors, which would likely cause the market price of our common stock to decline.

The FDA may recommend a different approach to measure drug effects on the QT interval of an ECG which could make our systems and processes obsolete and adversely affect revenue and profitability.

The FDA has provided guidance reinforcing the need for routine cardiac safety testing as well as Thorough QTc testing for all compounds entering the blood stream. This testing is accomplished by measuring the QT/QTc interval

prolongation on an ECG. We function as an ECG core lab and have developed our EXPERT® system and processes to receive the ECGs and obtain and report these measurements. It is possible that, in the future, the FDA may recommend different approaches to measuring drug effects on the QT interval which may diminish the need for an ECG core lab. This would considerably reduce the value of our existing systems and processes and would substantially decrease our revenues and profitability.

Table of Contents

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

We have one client that represented approximately 18% of our total revenues for 2009, a decrease from 23% of our total revenues for 2008. While no other client represented more than 10% of our 2009 revenues, our next five largest clients in the aggregate represented approximately 25% of our total revenues for 2009. If we lose all or a material amount of our revenues from any significant clients and do not replace them with revenues from new clients, our revenues will decrease and they may not be sufficient to cover our costs. We currently derive and expect to continue to derive a significant portion of our revenues and profitability from a limited number of clients.

Our failure to continue 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 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 and our operations organization, 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, if any, in the use of our service solutions 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.

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

If our service solutions do not achieve widespread acceptance by our clients, our revenues, profitability and market share will likely decline. Our competitors include other centralized cardiac safety laboratories and CROs. Our targeted clients may decide to choose other service solutions generated internally by them or from another source. Some of our competitors have substantially greater financial and other resources, greater name recognition and more extensive client bases than we do. Further, certain drug development organizations may decide not to outsource all or a significant portion of the cardiac safety activities associated with their clinical research programs, which could reduce our revenues, profitability and market share.

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

We have relationships with providers of clinical pharmacology services, hardware and software systems, telecommunications, web-hosting and development services, 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 incur liability as a result of providing consulting and Cardiac Safety analysis and interpretation services.

We provide consulting and centralized analysis and interpretation of ECGs in connection with our clients clinical trials. It is possible that liability may be asserted against us and the physicians who interpret the ECGs for us for failing to accurately diagnose a medical problem indicated by the ECG or for failing to disclose a medical problem to

the investigator responsible for the subject being tested. If we are found liable, we may be forced to pay fines and damages and to discontinue a portion of our operations. The contractual protections included in our client contracts and our insurance coverage may not be sufficient to protect us against such liability. If the protections are not adequate, our profitability would be negatively impacted and also our stock price would likely fall.

Table of Contents

Our business could be seriously harmed by our dependence on a limited number of suppliers.

We depend upon a limited number of suppliers for specific components of our service solutions. We may increase our dependence on certain suppliers as we continue to develop and enhance our service solutions. Our dependence on a limited number of suppliers leaves us vulnerable to having an inadequate supply of required components, reduced services capacity, price increases, delayed supplier performance and poor component and services quality. For instance, we rely on a limited number of providers to supply ECG equipment, software applications designed for the on-screen measurement of ECG signals and server facilities. If we are unable to obtain products and services from third-party suppliers in the quantities and of the quality that we need, on a timely basis or at acceptable prices, we may not be able to deliver our cardiac safety and ePRO solutions on a timely or cost-effective basis to our customers, and our business, results of operations and financial condition could be seriously harmed. Moreover, delays or interruptions in our service, including without limitation delays or interruptions resulting from a change in suppliers, may reduce our revenues, cause customers to terminate their contracts and adversely affect our customer renewals. If these companies were to terminate their arrangements with us or we were otherwise required to find alternative suppliers to provide the required capacity and quality on a timely basis, sales of our solutions would be delayed. To qualify a new supplier and familiarize it with our solutions, quality standards and other requirements is a costly and time-consuming process. We cannot assure you that we would be able to establish alternative relationships on acceptable terms.

Interruptions or delays in service from our third-party providers could impair the delivery of customer data and harm our business.

We host some of our software at third-party facilities. Consequently, the occurrence of a natural disaster, technical or service lapses or other unanticipated problems at the facilities of our third-party providers could result in unanticipated interruptions in our access and/or our customers access to their data from software hosted at these facilities. Our software and customer data may also be subject to sabotage, intentional acts of malfeasance and similar misconduct due to the nature of the Internet. In the past, Internet users have occasionally experienced difficulties with Internet and online services due to system or security failures. We cannot assure you that our business interruption insurance will adequately compensate our customers or us for losses that may occur. Even if covered by insurance, any failure or breach of security of our systems could damage our reputation and cause us to lose customers. Further, in the event that we fail to meet the service requirements under our agreements with our customers, whether resulting from an interruption in service caused by our technology or that of a third-party provider, we could be subject to customer credits or termination of these customer contracts.

The cardiac safety equipment that we own and lease could become obsolete due to technological advance. We may not be able to provide the quantity of equipment needed to service our clients. We may fail to obtain the necessary certifications for use of the equipment. Any such development would reduce our revenues and profitability.

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 of the equipment. In addition, certifications are required for the use of certain ECG equipment. We have been able to maintain such certifications in the past, but if the requirements for these certifications change or other factors lead to our failure to be compliant, we will lose the certifications and may not be able to satisfy the equipment needs of our clients, which may jeopardize our business relationship and our ability to continue providing services. As a result, we may lose clinical clients if adequate equipment is not available, resulting in reduced revenues and profitability.

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

In the past, we have been able to staff for increasing workload demands in an expeditious manner. However, there may not be a sufficient and suitable group of potential employees available if rapid growth occurs in a short

Table of Contents

period of time. If we are unable to hire suitable employees to adequately meet market demand for our solutions, it could affect our ability to bid on this business or to meet existing contractual turnaround times.

If our clients experience any significant level of problems with our technology, we may become liable to those clients, we may be unable to persuade our clients to change from a manual, paper-based process and we may lose clients. The success of our service solutions 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; and

natural disasters.

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 service solutions could cause us to lose clients and prevent us from successfully marketing our solutions to prospective clients. As a result, our revenues and profitability would likely decline. Because our business relies on technology, we are susceptible to:

rapid technological change;

changing client needs;

frequent new product introductions; and

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. We must develop and introduce new or enhanced service solutions 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.

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

If participants conducting clinical trials are unwilling to adopt our technology solutions and new ways of conducting business, our revenues may not be sufficient to achieve our expected growth rate. Our efforts to establish a standardized, electronic process to collect, manage and analyze clinical trial and cardiac safety data are a significant departure from the traditional clinical research process. We estimate that the majority of clinical trials today use manual, paper-based data entry, management and analysis tools. Each clinical trial can involve a multitude of participants, including the sponsor, a CRO, regional site managers, investigators and patients. With so many participants involved in a clinical trial, it may be difficult to convince a sponsor or CRO to accept new methods of

conducting a clinical trial. We may not be successful in persuading these participants to change the manner in which they have traditionally operated and to use our service solutions.

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

The loss of the services of one or more of our key executives could negatively affect our ability to achieve our business goals. 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 Scientific Officer, and Dr. Michael McKelvey, our President and Chief Executive Officer. We also depend on our key

Table of Contents

technical, client support, sales and other managerial employees. We believe that it would be costly and time consuming to find suitable replacements for our key 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. To protect our intellectual property rights, we rely on a combination of copyright and trade secret laws and restrictions on disclosure. In addition, in 2004 we were issued a U.S. Patent on over 50 claims directed to various features of our EXPERT® workflow enabled data handling technology. On February 2, 2010, we were issued a series of new claims under the same U. S. Patent, which further extends our existing patent protection for the processes embedded in our EXPERT™ 2 technology platform. These new patent claims span a series of innovative and automated processes furthering the science of cardiac safety. We also have filed continuation-in-part applications in the United States Patent and Trademark Office pursuing alternative claim coverage and pursuing claim coverage specific to enhancements in our EXPERT® workflow enabled handling technology that is imbedded in our EXPERT® Technology Platform. Despite our efforts to protect our proprietary rights, unauthorized parties may copy or otherwise obtain and use our products and technology. In addition, our U.S. Patent could be successfully challenged as invalid. Monitoring unauthorized use of our solutions is difficult and the steps we have taken may not prevent unauthorized use of our technology, particularly in foreign countries where the laws may not protect our proprietary rights as fully as in the United States.

We may acquire or make investments in companies or technologies that could cause disruption of our business and loss of value or dilution to our stockholders.

From time to time, we evaluate potential investments in, and acquisitions of, complementary technologies, services and businesses. We have made in the past, and may make in the future, acquisitions or significant investments in other businesses. For example, we acquired CCSS and entered into a long-term strategic relationship with Healthcare Technology Systems, Inc. (HTS) in 2007. Entering into an acquisition entails many risks, any of which could harm our business, including:

- managing the risks and challenges of entering markets or types of businesses in which we have limited or no direct experience;
- difficulties in integrating the operations, technologies, products, existing contracts and personnel of the target company and realizing the anticipated synergies of the combined businesses;
- the price we pay, the expense that we incur or other resources that we devote may exceed the value we eventually realize or the value we could have realized if we had allocated the purchase price or other resources to another opportunity;
- potential loss of key employees, customers and strategic alliances from either our current business or the target company s business;
- failure of a party to perform ancillary contractual obligations related to the acquisition;
- the diversion of management s attention from other business concerns; and

assumption of unanticipated problems or latent liabilities, such as problems with the quality of the target company s products.

In addition, we could discover deficiencies withheld from us in an acquisition due to fraud or otherwise not uncovered in our due diligence prior to the acquisition. These deficiencies could include problems in internal controls, data adequacy and integrity, product quality and regulatory compliance, any of which could result in us becoming subject to penalties or other liabilities. Acquisitions also frequently result in the recording of goodwill, as in the case of CCSS, and other intangible assets which are subject to potential impairments in the future that could harm our financial condition and operating results. If any of the foregoing were to occur, our financial condition and results of operations could be materially adversely impacted. In addition, if we finance any future acquisitions by

Table of Contents

issuing equity securities or convertible debt, our existing stockholders may be diluted or the market price of our stock may be adversely affected. The failure to successfully evaluate and execute acquisitions or investments or otherwise adequately address these risks could materially harm our business and financial results.

Specifically, if the market does not embrace the IVR clinical assessments and system we licensed from HTS, we will not be able to achieve the higher revenues and profitability that we had anticipated that this transaction would allow us to generate.

Goodwill is subject to impairment which could result in a significant expense.

As a result of the CCSS acquisition, we carry a significant amount of goodwill. Goodwill is not amortized but is subject to an impairment test at least annually. We perform the impairment test annually as of December 31 or more frequently if events or circumstances indicate that the value of goodwill might be impaired. Although we made no adjustments as a result of the impairment test as of December 31, 2009, if we determine in connection with future tests that the carrying value of goodwill may not be recoverable, we will base the measurement of any impairment on a projected discounted cash flow method using a discount rate commensurate with the risk inherent in our current business model. An impairment could result in a write-off of goodwill which would reduce our profitability in the period of the write-off.

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 product or service solutions that incorporate it;
- obtain a license to use the challenged intellectual property or to sell product or service solutions that incorporate it, which could be costly or unavailable; and
- redesign those product or service solutions 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 and profitability.

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; and

Table of Contents

difficulties in staffing and managing foreign operations.

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

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

The agreements that we sign with clients outside the United States may be governed by the laws of the countries where we provide our service solutions. 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.

In the event we are unable to satisfy regulatory requirements relating to internal control over financial reporting, or if these internal controls are not effective, our business and financial results may suffer.

Effective internal controls are necessary for us to provide reasonable assurance with respect to our financial reports and to effectively prevent fraud. If we cannot provide reasonable assurance with respect to our financial reports and effectively prevent fraud, our brand and operating results could be harmed. Pursuant to the Sarbanes-Oxley Act of 2002, we are required to furnish a report by management on internal control over financial reporting, including management s assessment of the effectiveness of such control. Internal control over financial reporting may not prevent or detect misstatements because of its inherent limitations, including the possibility of human error, the circumvention or overriding of controls, or fraud. Therefore, even effective internal controls can provide only reasonable assurance with respect to the preparation and fair presentation of financial statements. In addition, projections of any evaluation of the effectiveness of internal control over financial reporting to future periods are subject to the risk that the control may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. If we fail to maintain the adequacy of our internal controls, including any failure to implement required new or improved controls, or if we experience difficulties in their implementation, our business and operating results could be harmed, we could fail to meet our reporting obligations, and there could also be a material adverse effect on our stock price.

In the course of conducting our business, we possess or could be deemed to possess personal medical information in connection with the conduct of clinical trials. If we fail to keep this information properly protected we could be subject to significant liability.

Our software solutions are used to collect, manage and report information in connection with the conduct of clinical trial and safety evaluation and monitoring activities. This information is or could be considered to be personal medical information of the clinical trial participants or patients. Regulation of the use and disclosure of personal medical information is complex and growing. Increased focus on individuals rights to confidentiality of their personal information, including personal medical information, could lead to an increase of existing and future legislative or

regulatory initiatives giving direct legal remedies to individuals, including rights to damages, against entities deemed responsible for not adequately securing such personal information. In addition, courts may look to regulatory standards in identifying or applying a common law theory of liability, whether or not that law affords a private right of action. Since we receive and process personal information of clinical trial participants and patients from customers utilizing our hosted solutions, there is a risk that we could be liable if there were a breach of any obligation to a protected person under contract, standard of practice or regulatory requirement. If we fail to properly protect this personal information that is in our possession or deemed to be in our possession, we could be subjected to significant liability.

Table of Contents

The market price and trading volume of our common stock may be volatile, which could result in substantial losses for investors purchasing shares in the public markets and subject us to securities class action litigation. The current market price of our common stock may not be indicative of future market prices and we may be unable to sustain or increase the value of an investment in our common stock.

Market prices for securities of software, technology and health care companies have been volatile. The trading price of our common stock has fluctuated significantly and may continue to do so. Accordingly, the trading price for our common stock at any particular time may not be indicative of future trading prices and we may be unable to sustain or increase the value of an investment in our common stock. Some of the factors that may cause the market price of our common stock to fluctuate include:

- changes in estimates of our financial results or recommendations by securities analysts;
- financial results that are below estimate of such results;
- changes in general economic, industry and market conditions;
- sales or transfers of large blocks of stock by existing investors;
- investors general perception of us;
- period-to-period fluctuations in our financial results or those of companies that are perceived to be similar to us;
- changes in market valuations of similar companies;
- announcements by us or our competitors of significant products, contracts, acquisitions or strategic alliances;
- future issuances of securities or the incurrence of debt by us, or other changes in our capital structure;
- success of competitive products and technologies;
- the failure of any of our software products, services and hosted solutions to achieve or maintain commercial success;
- regulatory developments in the United States and foreign countries;
- changes in industry analyst recommendations;
- additions or departures of key personnel; and
- litigation involving our company or our general industry or both.

In addition, if the market for software, technology or health care stocks or the stock market in general experiences a loss of investor confidence, the trading price of our common stock could decline for reasons unrelated to our business, operating results or financial condition. If any of the foregoing occurs, it could cause our stock price to fall and may expose us to class action lawsuits that, even if unsuccessful, could be costly to defend and a distraction to management.

Sales of large blocks of our common stock could cause the market price of our common stock to drop significantly, even if our business is doing well.

Some stockholders may acquire or own large blocks of shares of our outstanding common stock. We cannot predict the effect that public sales of these shares or the availability of these shares for sale will have on the market price of our common stock, if any. If our stockholders, and particularly our directors and officers, sell substantial amounts of our common stock in the public market, or if the public perceives that such sales could occur, this could have an adverse impact on the market price of our common stock, even if there is no relationship between such sales and the performance of our business.

In the future, we may also issue additional shares to our employees, directors or consultants, in connection with corporate alliances or acquisitions, and issue additional shares in follow-on offerings to raise additional capital. Due

Table of Contents

to these factors, sales of a substantial number of shares of our common stock in the public market could occur at any time. Such sales could reduce the market price of our common stock.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our corporate headquarters is located at 1818 Market Street, Philadelphia, Pennsylvania, where we lease approximately 59,000 square feet. Our lease expires in October 2019. We also lease approximately 31,000 square feet of office space in Bridgewater, New Jersey, which expires in January 2011 and we lease approximately 18,000 square feet of office space in Peterborough, United Kingdom, which expires in June 2013. We believe that these facilities are adequate for our current and reasonably foreseeable operations and that we will be able to locate comparable space in these markets on terms acceptable to us if our business grows more rapidly than we currently anticipate.

We also lease approximately 51,000 square feet in Reno, Nevada, which expires in November 2013. We vacated the Reno location in September 2008 and we are seeking to sublease the property. We were responsible for all payment obligations on the Reno lease until November 28, 2008. From November 28, 2008 through November 28, 2012, we will equally share the payment obligations on the Reno lease with Covance, to the extent such obligations are not covered by a new tenant.

ITEM 3. LEGAL PROCEEDINGS

None.

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

None.

SPECIAL ITEM. EXECUTIVE OFFICERS OF REGISTRANT

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

Name	Age	Position
Michael J. McKelvey, Ph.D.	57	President, Chief Executive Officer and Director
Joel Morganroth, MD	64	Chairman of the Board of Directors and Chief Scientific Officer
Keith D. Schneck	54	Executive Vice President, Chief Financial Officer and Secretary
Thomas P. Devine	57	Executive Vice President and Chief Development Officer
Amy Furlong	37	Executive Vice President, Cardiac Safety Operations
Jeffrey S. Litwin, MD	51	Executive Vice President and Chief Medical Officer
John M. Blakeley	42	Executive Vice President, Sales and Marketing
Robert S. Brown	54	Senior Vice President, Strategic Partnerships
John B. Sory	44	Senior Vice President, Health Care Solutions
George Tiger	50	Senior Vice President, Global Sales

Dr. McKelvey has served as our President and Chief Executive Officer since June 2006 and has served on our Board of Directors since July 2006. Prior to joining us, Dr. McKelvey was employed for five years by PAREXEL International, one of the largest biopharmaceutical outsourcing organizations in the world, where he served as Corporate Senior Vice President, Clinical Research Services.

Dr. Morganroth has served as the Chairman of our Board of Directors since 1999 and a member of our Board of Directors since 1997. He has served as our Chief Scientific Officer since April 2006. Prior to that, he served as our Chief Scientist from March 2001 to December 2005 and our Chief Executive Officer from 1993 to March 2001. In

Table of Contents

addition, Dr. Morganroth has consulted for us since 1977. Dr. Morganroth is a globally recognized cardiologist and clinical researcher. Dr. Morganroth served for over ten years as a Medical Review Officer/Expert for the U.S. Food and Drug Administration.

Mr. Schneck has been our Executive Vice President, Chief Financial Officer and Secretary since July 2008. Prior to joining us, Mr. Schneck worked as a financial and operational consultant for various firms from December 2007 to July 2008. From April 2003 until December 2007, Mr. Schneck served as the Executive Vice President and Chief Financial Officer of Neoware, Inc. Mr. Schneck is a certified public accountant.

Mr. Devine has been our Executive Vice President and Chief Development Officer since December 2005. Previously, he served as our Senior Vice President and Chief Development Officer from April 2003 until December 2005. From August 2002 to April 2003, Mr. Devine was our Vice President of Research and Development. Prior to joining us, Mr. Devine was Chief Technology Officer for an electronic commerce company.

Ms. Furlong has been our Executive Vice President, Cardiac Safety Operations since December 2005. She served as our Senior Vice President, Regulatory Compliance from January 2004 until December 2005. From February 2001 to January 2004, Ms. Furlong served as our Vice President, Regulatory Compliance.

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

Mr. Blakeley has been our Executive Vice President, Sales and Marketing since February 2008. He served as our Senior Vice President, International Operations and Sales from September 2006 to February 2008. He served as our Group Vice President, International Business Development from January 2005 to August 2006 and as our Director of Business Development from May 2002 to December 2004. Prior to joining ERT, Mr. Blakeley was Managing Director of a medical devices specialist.

Mr. Brown has been our Senior Vice President, Strategic Partnerships since January 2010. He served as our Senior Vice President, Marketing, Planning and Partnerships from September 2006 to December 2009. He served as our Senior Vice President, Outsourcing Partnerships from July 2002 to August 2006. From January 2000 to June 2002, Mr. Brown was our Senior Vice President, Cardiac Safety.

Mr. Sory has been our Senior Vice President, Health Care Solutions since November 2009. Prior to joining ERT, Mr. Sory served as General Manager, Vice President of Pfizer Health Solutions from 2002 to 2009.

Mr. Tiger has been our Senior Vice President, Global Sales since January 2009. He served as Senior Vice President, Americas Sales from October 2006 to December 2008. He served as our Senior Vice President, International Sales and Operations from October 2005 to September 2006, Senior Vice President, International Operations from July 2004 to October 2005 and as Vice President, International Business Development from August 2002 to July 2004. Prior to joining ERT, Mr. Tiger held a series of sales and marketing management positions with Abbott Laboratories and Celsis, Inc.

Table of Contents

PART II

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

Our common stock is traded on the Nasdaq Global Select Market 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 Global Select Market.

Calendar Period	High	Low
2008		
First Quarter	$ 12.73	$ 8.94
Second Quarter	17.82	11.90
Third Quarter	18.85	9.81
Fourth Quarter	12.00	3.86
2009		
First Quarter	$ 7.50	$ 4.48
Second Quarter	6.68	4.90
Third Quarter	7.56	5.32
Fourth Quarter	8.50	5.74

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 and for the repurchase of common stock under our stock buy-back program.

As of February 19, 2010, there were 48 record holders of our common stock.

Table of Contents

Stockholder Return Performance Graph

The following graph compares the cumulative total stockholder return on our common stock against the cumulative total return on the Nasdaq Composite Index and the Nasdaq Health Services Index for the period commencing December 31, 2004 and ending December 31, 2009. The graph assumes that at the beginning of the period indicated, $100 was invested in our common stock and the stock of the companies comprising the Nasdaq Composite Index and the Nasdaq Health Services Index, and that all dividends, if any, were reinvested.

This stockholder return performance graph shall not be deemed filed with the Securities and Exchange Commission (SEC) as part of this Form 10-K or incorporated by reference into any filing by us under the Securities Act of 1933 or the Securities Exchange Act of 1934, except to the extent we specifically incorporate the performance graph by reference therein.

*$100 invested on 12/31/04 in stock or index, including reinvestment of dividends.
Fiscal year ending December 31.

Table of Contents

ITEM 6. SELECTED FINANCIAL DATA

The following selected consolidated financial data is qualified by reference to, and should be read in conjunction with, the consolidated financial statements, including the notes thereto, and Management s Discussion and Analysis of Financial Condition and Results of Operations included elsewhere in this Form 10-K. We have included CCSS s operating results in our Consolidated Statements of Operations from the date of the acquisition, November 28, 2007. The revenue and cost of revenue of our former EDC operations have been reclassified from the licenses and services categories to the EDC category on the consolidated statements of operations for all periods presented. Additionally, the remaining revenues and costs of sales in licenses, related to cardiac safety reporting and ePRO, were reclassified to the services category on the consolidated statements of operations for all periods presented.

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

	Year Ended December 31,				
	2005	2006	2007	2008	2009
Net revenues:					
EDC licenses and services	$ 6,063	$ 3,017	$ 6,331	$ 5,894	$ 2,501
Services	59,712	55,309	65,916	96,567	64,655
Site support	21,072	28,042	26,451	30,679	26,667
Total net revenues	86,847	86,368	98,698	133,140	93,823
Costs of revenues:					
Cost of EDC licenses and services	436	286	2,018	1,843	863
Cost of services	24,337	25,431	28,808	38,609	29,886
Cost of site support	13,965	18,821	17,808	18,445	13,544
Total costs of revenues	38,738	44,538	48,634	58,897	44,293
Gross margin	48,109	41,830	50,064	74,243	49,530
Operating expenses:					
Selling and marketing	9,122	11,051	11,222	13,273	12,905
General and administrative	11,458	14,668	12,258	18,181	14,859
Research and development	4,093	4,146	4,333	4,394	3,853
Total operating expenses	24,673	29,865	27,813	35,848	31,617
Operating income	23,436	11,965	22,251	38,395	17,913
Other income (expense), net	936	1,250	2,206	1,730	(435)
Income before income taxes	24,372	13,215	24,457	40,125	17,478
Income tax provision	9,007	4,905	9,205	15,123	6,791
Net income	$ 15,365	$ 8,310	$ 15,252	$ 25,002	$ 10,687
Basic net income per share	$ 0.31	$ 0.17	$ 0.30	$ 0.49	$ 0.22

Diluted net income per share	$ 0.29	$ 0.16	$ 0.29	$ 0.48	$ 0.22

Consolidated Balance Sheet Data (in thousands)

	December 31,				
	2005	**2006**	**2007**	**2008**	**2009**
Cash, cash equivalents and short-term investments	$ 52,001	$ 56,913	$ 46,879	$ 66,426	$ 78,761
Working capital	45,795	61,320	45,594	75,289	82,950
Total assets	104,766	115,064	147,696	169,122	164,861
Treasury stock	(56,387)	(62,190)	(62,190)	(64,763)	(79,883)
Total stockholders equity	79,973	93,622	113,512	137,428	137,672

Table of Contents

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

Overview

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

On June 23, 2009, we completed the sale of certain assets relating to our EDC operations. Under the terms of the transaction, OmniComm Systems, Inc. issued to us 8.1 million shares of common stock and assumed certain liabilities including deferred revenue relating to our EDC operations in exchange for our EDC assets which primarily included our EDC software, applications and fixed assets and $1.15 million in cash we paid. During the year ended December 31, 2009, we recorded a gain on the sale of these assets of $0.5 million within general and administrative expenses in the consolidated statement of operations. The revenue and cost of revenue of our former EDC operations have been reclassified from the licenses and services categories to the EDC category on the consolidated statements of operations for all periods presented. Additionally, the remaining revenues and costs of sales in licenses, related to cardiac safety reporting and ePRO, were reclassified to the services category on the consolidated statements of operations for all periods presented.

Our services revenues consist primarily of our services offered under our Cardiac Safety and, to a lesser extent, ePRO^{tm} solutions. Our site support revenue consists of cardiac safety equipment rentals and sales along with related supplies and logistics management.

We offer Cardiac Safety solutions, which are utilized by pharmaceutical companies, biotechnology companies, medical device companies, clinical trial sponsors and clinical research organizations (CROs) during the conduct of clinical trials. Our Cardiac Safety solutions include the collection, interpretation and distribution of electrocardiographic (ECG) data and images and are performed during clinical trials in all phases of the clinical research process. The ECG provides an electronic map of the heart s rhythm and structure, and is performed in most clinical trials. Our Cardiac Safety solutions permit assessments of the safety of therapies by documenting the occurrence of cardiac electrical change. Specific trials, such as a Thorough QTc study, focus on the cardiac safety profile of a compound. Thorough QTc studies are comprehensive studies that typically are of large volume and short duration and are generally required by the United States Food and Drug Administration (FDA) under guidance issued in 2005 by the International Committee on Harmonization (ICH E14). We also offer site support, which includes the rental and sale of cardiac safety equipment along with related supplies and logistics management. We also offer ePRO solutions along with proprietary clinical assessments.

Services revenues consist of Cardiac Safety and ePRO services that we provide on a fee for services basis and are recognized as the services are performed. We also provide Cardiac Safety consulting services on a time and materials basis and recognize revenues as we perform the services. Site support revenues are recognized at the time of sale or over the rental period.

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 one or more delivered elements is not known, revenue is allocated to each component of the arrangement using the residual method provided that the fair value of all undelivered elements is known. Fair values

for undelivered elements are based primarily upon stated renewal rates for future products or services.

We have recorded reimbursements received for out-of-pocket expenses incurred as revenue in the accompanying consolidated financial statements.

Unbilled revenue is revenue that is recognized but is currently not billable to the customer pursuant to contractual terms. In general, such amounts become billable in accordance with predetermined payment schedules,

Table of Contents

but recognized as revenue as services are performed. Amounts included in unbilled revenue are expected to be collected within one year and are included within current assets.

Our former EDC business is included in EDC licenses and services and included license revenue, technology consulting and training services and software maintenance services. We recognized up-front license fee revenues under the residual method when a formal agreement existed, delivery of the software and related documentation occurred, collectability was probable and the license fee was fixed or determinable. We recognized monthly and annual term license fee revenues over the term of the arrangement. Hosting service fees were recognized evenly over the term of the service. We recognized revenues from software maintenance contracts on a straight-line basis over the term of the maintenance contract, which was typically twelve months. We provided consulting and training services on a time and materials basis and recognized revenues as we performed the services.

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

Costs of our former EDC operations included primarily wages, fees paid to outside consultants and other direct operating costs related to our software licensing, consulting and client support functions.

We conduct our operations through offices in the United States (U.S.) and the United Kingdom (UK). Our international net revenues represented approximately 23%, 21% and 24% of total net revenues for the years ended December 31, 2007, 2008 and 2009, respectively. The majority of our revenues are allocated among our geographic segments based upon the profit split transfer pricing methodology. The profit split methodology equalizes gross margins for each legal entity, based upon its respective direct revenue or direct costs, as determined by the relevant revenue source.

Results of Operations

Executive Overview

Net revenues were $93.8 million for 2009, a decrease of $39.3 million or (29.5%) from $133.1 million in 2008 due primarily to the confluence of two key factors. The first factor was the deep recession of 2008-2009, which significantly affected our clients, both large and small. Large pharmaceutical, biotechnology and medical device companies became very conservative in their funding of research and development activities and our small to mid-sized clients were severely impacted by the tight credit conditions from the recession. The second factor was a very sharp decline in the demand for Thorough QTc studies from our clients. These studies performed by ERT are largely for small to mid-sized clients; it was this sector of the economy that was most severely impacted by the very tight credit conditions caused by the recession. Both of these factors resulted in significantly reduced demand for our cardiac safety services and a corresponding fall in our revenue.

In addition, revenue from the acquired backlog of Covance Cardiac Safety Services, Inc. (CCSS) totaled $10.1 million in 2008 and declined to $4.5 million in 2009 as this backlog nears completion. To a lesser degree, we also had lower

revenue from routine business. We also sold our EDC operation in June 2009 which contributed $2.5 million of revenue in 2009 compared to $5.9 million in 2008.

Gross margin percentage was 52.8% in 2009 compared to 55.8% in 2008. Gross margin percentage is significantly impacted by transaction volume which declined 32.9% in 2009 compared to 2008. We also experienced a slight decline in average transaction pricing in 2009 as compared to 2008. In the shorter term, costs do not necessarily change in direct relation with changes in revenue. We also experienced a slight decline in average transaction pricing in 2009 as compared to 2008. The decline in the gross margin percentage compared to 2008 was partially offset by the elimination of legacy and transition costs incurred during 2008 associated with processing the

Table of Contents

CCSS backlog during the nine-month period in 2008 during which we integrated the CCSS operations. In addition during 2009, we incurred lower depreciation and amortization expense as older, more expensive equipment became fully depreciated.

Operating income for 2009 was $17.9 million or 19.1% of total net revenues compared to $38.4 million or 28.8% of total net revenues in 2008. Total expenses were $75.9 million in 2009, a decrease of $18.8 million from $94.7 million in 2008. Overall expenses decreased primarily due to the elimination of transition costs related to the integration of the CCSS operations, which was completed in September 2008. We also had lower variable incentive compensation expense in 2009 consistent with our reduced operating results and lower depreciation as some of our EDC equipment was fully depreciated and the amortization of CCSS intangibles declined. Our effective income tax rate for 2009 was 38.9% compared to 37.7% in 2008.

Net income for 2009 was $10.7 million, or $0.22 per share, compared to $25.0 million, or $0.48 per share in 2008.

Commencing in the fourth quarter of 2008 and into 2009, general business and economic conditions deteriorated globally. During this time, we experienced an increased focus in Phase III opportunities, a decline in the number of Thorough QTc bookings along with a delay in starts for certain Thorough QTc trials, and these trends have continued through much of fiscal 2009. We believe the increase in Phase III opportunities will provide us with a strong base of business in the future; however, this business will take longer to turn into revenue. We believe that the delays in Thorough QTc trials are related to timing as the result of the uncertain economic environment, especially in small to mid-sized customers which have been negatively impacted by funding limitations. Thorough QTc trials are generally required to be performed due to regulatory guidance; however, the timing of when these trials are done is discretionary.

We also experienced an increase in awards of new and expanded exclusive or near-exclusive long-term enterprise relationships with large pharmaceutical companies during the latter portion of fiscal 2008 and continuing into 2009, including several with whom we had very little business in the past. In exchange for these long-term enterprise relationships with large pharmaceutical companies, which are targeted to generate larger volumes of business, we have made selective pricing concessions which we believe will have the effect of lowering overall average transaction pricing in the future as studies performed under these agreements become active and generate revenue. We have also recently implemented a series of cost reductions which we believe will lessen the impact of any prior pricing reduction on our gross margin percentage. Overall, we believe the fundamental drivers of our core business remain positive. We believe that we have sufficient operating and technology capacity to support significant future growth in our business if and when it should occur. However, a continued weakened global economy could have a negative impact on future results of operations.

Table of Contents

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

	Year Ended December 31,		
	2007	2008	2009
Net revenues:			
EDC licenses and services	6.4%	4.4%	2.7%
Services	66.8	72.6	68.9
Site support	26.8	23.0	28.4
Total net revenues	100.0	100.0	100.0
Costs of revenues:			
Cost of EDC licenses and services	2.0	1.4	0.9
Cost of services	29.2	29.0	31.9
Cost of site support	18.1	13.8	14.4
Total costs of revenues	49.3	44.2	47.2
Gross margin	50.7	55.8	52.8
Operating expenses:			
Selling and marketing	11.4	10.0	13.8
General and administrative	12.4	13.7	15.8
Research and development	4.4	3.3	4.1
Total operating expenses	28.2	27.0	33.7
Operating income	22.5	28.8	19.1
Other income (expense), net	2.3	1.3	(0.5)
Income before income taxes	24.8	30.1	18.6
Income tax provision	9.3	11.3	7.2
Net income	15.5%	18.8%	11.4%

Table of Contents

Year Ended December 31, 2008 Compared to the Year Ended December 31, 2009

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

	Year Ended December 31,			
	2008	**2009**	**Increase (Decrease)**	
EDC licenses and services				
Net revenues	$ 5,894	$ 2,501	$ (3,393)	(57.6%)
Costs of revenues	1,843	863	(980)	(53.2%)
Gross margin	$ 4,051	$ 1,638	$ (2,413)	(59.6%)
Services:				
Net revenues	$ 96,567	$ 64,655	$ (31,912)	(33.0%)
Costs of revenues	38,609	29,886	(8,723)	(22.6%)
Gross margin	$ 57,958	$ 34,769	$ (23,189)	(40.0%)
Site support:				
Net revenues	$ 30,679	$ 26,667	$ (4,012)	(13.1%)
Costs of revenues	18,445	13,544	(4,901)	(26.6%)
Gross margin	$ 12,234	$ 13,123	$ 889	7.3%
Total				
Net revenues	$ 133,140	$ 93,823	$ (39,317)	(29.5%)
Costs of revenues	58,897	44,293	(14,604)	(24.8%)
Gross margin	74,243	49,530	(24,713)	(33.3%)
Operating expenses:				
Selling and marketing	13,273	12,905	(368)	(2.8%)
General and administrative	18,181	14,859	(3,322)	(18.3%)
Research and development	4,394	3,853	(541)	(12.3%)
Total operating expenses	35,848	31,617	(4,231)	(11.8%)
Operating income	38,395	17,913	(20,482)	(53.3%)
Other income (expense), net	1,730	(435)	(2,165)	N.M.
Income before income taxes	40,125	17,478	(22,647)	(56.4%)
Income tax provision	15,123	6,791	(8,332)	(55.1%)
Net income	$ 25,002	$ 10,687	$ (14,315)	(57.3%)

N.M. Not meaningful

Table of Contents

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

	Year Ended December 31,		Increase
	2008	2009	(Decrease)
Cost of EDC licenses and services	31.3%	34.5%	3.2%
Cost of services	40.0%	46.2%	6.2%
Cost of site support	60.1%	50.8%	(9.3%)
Total costs of revenues	44.2%	47.2%	3.0%