ERESEARCHTECHNOLOGY INC /DE/
Form 10-K
March 02, 2012
Table of Contents

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF**

THE SECURITIES EXCHANGE ACT OF 1934

For the Fiscal Year ended December 31, 2011

or

¨ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE**

SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File No. 0-29100

eResearchTechnology, Inc.

(Exact name of issuer as specified in its charter)

Delaware	**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 ¨ No x

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

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 x No ¨

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 x No ¨

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

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 ¨	Accelerated filer x
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	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 ¨ No x

As of June 30, 2011, the aggregate market value of the registrant s common stock held by non-affiliates of the registrant was $370,226,190 based on the closing sale price as reported on the Nasdaq Global Select Market.

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 17, 2012**
Common Stock, $.01 par value per share	49,241,633 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 2012 Annual Meeting of Stockholders, to be filed with the Commission pursuant to Regulation 14A.

Table of Contents

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, will be, will continue, will likely result, project, intend, plan, believe, look to and other words and terms of similar mean 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, variability in size, scope and duration of projects and internal issues at the sponsoring customer; our ability to successfully integrate any future acquisitions; competitive factors in the market for our centralized services; changes in the bio-pharmaceutical and healthcare 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 economic conditions deteriorate, the cancellation rates that we have historically experienced could increase. Further information on potential factors that could affect our financial results can be found in Item 1A Risk Factors as well as the other sections of this annual Report on Form 10-K.

Table of Contents

PART I

ITEM 1. BUSINESS

General

eResearchTechnology, Inc. (ERT®), a Delaware corporation, was founded in 1977. ERT and its consolidated subsidiaries collectively are referred to as the Company or we. We are a global technology-driven provider of services and customizable medical devices primarily to biopharmaceutical organizations and, to a lesser extent, healthcare organizations. We are the market leader for centralized cardiac safety (Cardiac Safety solutions) and respiratory efficacy services (Respiratory solutions) in drug development and also collect, analyze and distribute electronic patient reported outcomes (ePRO) in multiple modalities across all phases of clinical research.

Clinical trials employ diagnostic tests to measure the effect of the drug on certain body organs and systems to determine the product s safety and efficacy. Our technology-based services 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. Our Cardiac Safety solutions include the collection, interpretation and distribution of electrocardiographic (ECG) data and images and are utilized during clinical trials in all phases of the clinical research process. Our Respiratory solutions are utilized by biopharmaceutical and healthcare organizations and CROs that are developing new compounds for the treatment of asthma, emphysema, cystic fibrosis and chronic obstructive pulmonary disease (COPD) to assess the efficacy of a drug or to evaluate compounds that have an effect on pulmonary function. Our ePRO solutions electronically capture patient self-reported data pertaining to their quality of life and is utilized by sponsors of clinical trials. In addition, we also offer site support, which includes the rental and sale of devices to support cardiac and respiratory services and ePRO, along with related supplies and logistics management.

Service Offerings

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

	Year Ended December 31,		
	2009	2010	2011
Net revenues:			
Services	68.9%	60.8%	53.7%
Site support	28.4	39.2	46.3
EDC licenses and services	2.7		
Total net revenues	100.0	100.0	100.0

Our services revenues consist primarily of our services offered under our Cardiac Safety, Respiratory and, to a lesser extent, our electronic patient reported outcomes (ePRO) solutions that we provide on a fee for services basis. We recognize the related revenues as the services are performed. We also provide consulting services on a time and materials basis and recognize revenues as we perform the services. Our site support revenue, consisting of equipment rentals and sales along with related supplies and logistics management, are recognized at the time of sale or over the rental period. Our former electronic data capture (EDC) operations, which we sold in June 2009, are included in EDC licenses and services revenue and included license revenue, technology consulting and training services and software maintenance services.

We offer the following products and services on a global basis:

Cardiac Safety Solutions

We provide centralized cardiac safety testing which is a critical component of diagnostic testing in clinical trials. Our Cardiac Safety solutions include the collection, interpretation and distribution of ECG data and images

Table of Contents

and are utilized 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).

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 we 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 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 forty percent 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 that the use of centralized cardiac safety laboratories is more efficient and provides the customer with an overall lower cost. We have introduced a low-cost cardiac safety equipment solution to further incent clinical trial sponsors to transition from decentralized to centralized collection and analysis of ECGs.

Our Cardiac Safety solutions, including our proprietary EXPERT® technology platform, provide for workflow-enabled cardiac safety data collection, interpretation and distribution of ECG data and images as well as for analysis and cardiologist interpretation of ECGs performed on research subjects in connection with our customers 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.

As part of our Cardiac Safety solutions, we offer continuous digital 12-lead ECG recording and longer-term Holter recording. For 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, we can evaluate 12-lead ECGs 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 presence of arrhythmias, cardiac ischemia and/or heart rate variability findings. Holter recording 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 primarily the incidence of arrhythmias, but also cardiac ischemia and/or heart rate variability.

Our Cardiac Safety solutions also include FDA XML delivery, which provides for the delivery of ECGs in a format compliant with the United States Food and Drug Administration s XML standard for digital ECGs for

Table of Contents

submission to the FDA ECG Warehouse. We also provide ECG equipment through rental and sales to customers to perform the ECG recordings and give them means to send such recordings to us. Our portal product, MyStudy Portal , 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.

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. The primary techniques core laboratories use for interval duration measurements and morphology evaluations include a fully manual and a semi-automated methodology. The fully manual measurement, as we perform it, 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 we perform it, 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.

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 may utilize cardiologists or other human readers to over-read a subset of the ECGs collected. We also offer 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, none of our customers have requested us to conduct a study using a fully- automated reading methodology for Thorough QTc trials 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 small 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 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 debate in that the addition of another algorithm to the entire core lab process would result in significant additional costs due to its licensing costs. 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 described above, 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 and the smaller Phase I 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 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

Respiratory Solutions

Spirometry is the most commonly performed pulmonary function test (PFT) today and measures the volume and/or flow of air that can be inhaled and exhaled. Sponsors developing new compounds for the treatment of asthma, emphysema, cystic fibrosis and COPD use this non-invasive, cost effective test to assess the efficacy of a drug. Lung diseases such as asthma, COPD and emphysema decrease a patient s air flow by narrowing or blocking the airways during exhalation. The most important parameters of spirometry are forced vital capacity (FVC) and the forced expiratory volume (FEV). The FVC is the volume delivered during maximal expiration (or peak flow) starting from a deep inspiration. The FEV is the volume delivered in the first second of the FVC maneuver. Peak flow is a simple, non-invasive and inexpensive method to measure the function of the airway and we provide a unique electronic peak flow meter with integrated diary for clinical trials capturing peak flow data at home.

The diffusing capacity of the lung related to carbon monoxide, which is known as DLCO, measures the extent to which oxygen passes from the air sacs of the lungs into the blood and involves measuring the partial pressure difference between inspired and expired carbon monoxide. Our centralized DLCO testing offers sponsors the advantage of being able to diagnose and treat lung disorders not found by either spirometry or chest x-ray. DLCO testing is also described as single-breath determination of carbon monoxide uptake in the lung in clinical research and is used to determine if new drugs being inhaled for pain, diabetes or multiple sclerosis may have an effect on the lung, e.g. if the diffusion of oxygen into the bloodstream is affected or not.

In the study of respiratory drugs, the validity of spirometry values is highly dependent on the cooperation of the subject, the interaction of the subject with the study coordinator and the influences of the surrounding environment. The analysis of any parameter without considering these factors could result in faulty or erroneous conclusions. We offer centralized and standardized respiratory services which enables each site to receive the exact same equipment with the same protocol specific software for the clinical trial and the electronic transfer of the data to a centralized database, where spirometry overread is performed and feedback to the sites regarding the quality of the spirometry is given.

In 1979, the American Thoracic Society (ATS) issued its first statement on the standardization of spirometry. The standards were updated in 1987 and again in 1994. In parallel, a similar initiative by the European Community for Steel and Coal, resulted in the first European standardization document in 1983. These standards were then updated in 1993 as the official statement of the European Respiratory Society (ERS). The new ATS/ERS Standardization of Spirometry 2005 document aligns the views of the ATS and ERS in an attempt to publish standards that can be applied more globally. Our medical devices pertaining to spirometry meet these standards.

We provide biopharmaceutical and healthcare organizations a one-stop-shop clinical evaluation for respiratory data which may also include additional testing for cardiac safety and related ePRO analysis in a fully integrated system. We have established a preferred centralized respiratory vendor status with several of the top 20 pharmaceutical companies. Our staff of medical doctors, exercise physiologists and respiratory therapists are trained and certified to over-read data from pulmonary function and cardio-pulmonary stress tests.

Electronic Patient Reported Outcomes (ePRO)

We offer electronic patient report outcomes (ePRO) solutions which refer to the electronic capture of patient self-reported data pertaining to their quality of life. ePRO solutions offer our customers higher quality data with accurate timestamps and real-time data access compared to existing practice of using paper based diaries and assessments. ePRO provides less variable and more reliable data, enabling smaller trials and better scientific conclusions.

Our ePRO solutions include both products and services for clinical trials. We manufacture devices such as handheld electronic diaries that are designed exclusively for clinical research, including our VIAPad eDiary handheld device which enables high resolution, remote collection, memory and automatic data transmission, and

Table of Contents

our electronic digital VIAPen . We also provide an Interactive Voice Response (IVR) system accessible through standard telephone lines and offer device customization, worldwide logistics and our in-house global and local support to ensure comprehensive and efficient trial management. Diaries, screening, recruitment and all clinical assessments can be completed directly by the subject without requiring clinician involvement.

In December 2009, the FDA finalized PRO Guidance for Label Claims, which outlines the steps required to develop a PRO instrument from hypothesis of a concept or claim through data item evaluation, collection, cognitive debriefing, interpretation, revision and finalization. We believe that our devices conform to this guidance.

Increased suicidality risk with novel compounds is a growing concern. Suicidality monitoring is now a requirement in an increasing number of drug-development efforts to ensure effective drug-profiling and patient-safety monitoring. In September 2010, the FDA released Draft Guidance on Prospective Assessment of Suicidality in Clinical Trials. The guidance contains recommendations for prospectively querying for suicidality to identify patients at risk and collect complete, timely data to be completed at baseline and all subsequent visits in all psychiatric indications and neurological compounds.

We offer an electronic self-rated version of the FDA accepted Columbia Suicide Severity Rating Scale (C-SSRS) to facilitate compliance with regulatory requirements for prospective monitoring of suicidal ideation and behaviors. The validated eC-SSRS solution, developed in collaboration with the scale author and Columbia University, is a cost-effective method of prospectively monitoring for suicidality. We believe the eC-SSRS conforms to the FDA guidance.

Consulting

We have industry-leading experts who are readily available for the benefit of our customers. Our Clinical Consulting Group offers the scientific and regulatory expertise that biopharmaceutical and healthcare organizations and contract research organizations (CROs) need to successfully run their clinical trials. We understand the importance of regulatory compliance and data accuracy, and we work directly with our customers to ensure quality outcomes right from the start. We are committed to transforming the way clinical trials are run and empowering our customers expert decisions that help bring safe drugs and devices to market.

The centralization of diagnostic services 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 regulatory guidelines and, as a result, sponsors look to their vendors to provide key scientific input into the overall process. Our consulting service aids sponsors in the design of protocols and the creation and analysis of statistical plans and by providing an expert medical report which interprets the clinical 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 solutions.

Project Assurance

We provide a full spectrum of project assurance services that augment the study management and implementation efforts of customers in support of their clinical research requirements. Our project assurance methodology is a consistent framework through which we can efficiently manage the delivery of all data, from study initiation to completion. It also provides our customers with the standards, guidelines and services that allow us to effectively anticipate their needs and ensure proactive communication to meet and exceed their goals.

Integrated Product Offering

We offer a fully integrated set of products and services for centralized cardiac safety, respiratory, and ePRO and a single point of contact for all aspects of the electronic data collection process in clinical trials. Our technology platform also supports the integration of other devices to integrate additional key safety data to support cardiac and respiratory trials.

Table of Contents

The protocols of many of the respiratory trials in which we participate often also require ECGs and/or Holter monitoring and ePRO solutions. Our flagship investigator site device, MasterScope® CT, is a comprehensive solution for standardized and centralized spirometry, full PFT, ECG and ePRO in clinical trials. Using customized software, this innovative system combines protocol-driven workflows (with many diagnostic applications) into a single easy-to-use clinical trial workstation. These workflows can be specially tailored for multi-center studies. We believe our customers and their users consider the availability of a fully integrated platform for respiratory, cardiac safety and ePRO to be a major advantage that has enabled us to establish a preferred centralized respiratory vendor status with several of the top 20 pharmaceutical companies.

Operations

We conduct our operations through offices in the United States (U.S.), Germany and the United Kingdom (U.K.). Our international net revenues represented approximately 24%, 57% and 65% of total net revenues for the years ended December 31, 2009, 2010 and 2011, respectively. A large portion of our revenues are allocated among our geographic segments based upon the profit split transfer pricing methodology which equalizes gross margins for each relevant legal entity based upon its respective direct revenue or direct costs, as determined by the relevant revenue source. See Note 15 to our consolidated financial statements for additional information about geographic operations.

On May 28, 2010, we acquired Research Services Germany 234 GmbH (Research Services or RS). RS is comprised of the research services division of CareFusion Germany 234 GmbH and certain research operations of CareFusion Corporation. RS is the source of our Respiratory solutions business and also provides Cardiac Safety and ePRO services. In addition, RS is a manufacturer of diagnostic devices we rent or sell to customers in connection with our services. See Note 2 to our consolidated financial statements for additional disclosure on the RS acquisition.

During the latter half of 2010, we recognized the need to modify the operations work flow processes and infrastructure of our RS operations to expand capacity to support customer requirements for active and new studies. This did impact our ability to contract for new business with certain customers who required faster commencement of studies than our standard delivery time would allow and still maintain our desired level of quality. We added new staff in Germany during the fourth quarter of 2010 and into our first quarter of 2011 and continued the development of our new integrated data handling platform, EXPERT 3. The EXPERT 3 platform, the first phase of which went live in January 2012, will further expand the capacity by improving the efficiency and reducing the complexity of our processes. In 2011, we made investments to complete the integration of the RS business and strengthened our infrastructure and piloted expansion projects of our products and services into adjacent markets. During 2012, we will be updating and enhancing our medical devices, enhancing our ePRO capabilities, starting the development of a global rollout of an ERP system and making further enhancements to our EXPERT 3 platform. We believe that these investments will better position us for improved growth and profitability in 2013 and beyond.

Research and Development

Overview

As of December 31, 2011, we had 116 employees and 82 independent consultants 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 our entire suite of services. For the years ended December 31, 2009, 2010 and 2011, our research and development expenses were $3.9 million, $5.1 million and $7.4 million, respectively. 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

Table of Contents

unique configurations to meet the varying clinical trial requirements of each of our customers and doing so in a highly automated manner. Our technology strategy centers on a corporate-wide approach to ensuring we extend our current market leadership in cardiac safety and respiratory services and capture market leadership in new areas, such as ePRO and suicidality assessments. Following the RS acquisition, we began to integrate the technology assets we acquired throughout our operations.

2011 Research and Development Initiatives

During 2011, we undertook a series of major new technology initiatives:

- We established a globally integrated Customer Care infrastructure providing our customers with one phone number for any type of support and we provided our customer care employees with a single global system for capturing all customer care tickets;
- We launched a new Disaster Recovery data center providing full redundancy in case of a catastrophic failure at our primary operational data center;
- We launched a major new release of our ePRO system supporting studies with VIAPhone or VIAWeb modalities;
- We launched a major new release of the MasterScope platform, MasterScope 32, providing enhanced user interfaces and a more efficient means to setup studies;
- We completed the first release of EXPERT 3 in January 2012, which features a major new Protocol Designer capability and will enable the migration of our nearly 1,000 active ECG and ViaPhone based ePRO studies. Another release of EXPERT 3 will occur later in the first quarter of 2012 to support respiratory and VIAPen and VIAPad based ePRO studies;

Our Customers

We serve primarily biopharmaceutical organizations and CROs and, to a lesser extent, healthcare organizations. We have agreements that establish the overall contractual relationship between us and our customers with approximately 269 customers for active or upcoming projects. We provide our solutions to 39 of the 50 largest biopharmaceutical companies globally including all of the top 10. Novartis accounted for 18%, 28% and 19% of our consolidated net revenues in 2009, 2010 and 2011, respectively. In 2011, GlaxoSmithKline and Boehringer Ingelheim each accounted for 13% of our consolidated net revenues. No other customer accounted for 10% or more of our consolidated net revenues during these periods.

Sales and Marketing

We market and sell our solutions primarily through our global direct sales, sales support and professional services organizations. As of December 31, 2011, our business development team consisted of 54 sales, marketing and consulting professionals worldwide, which included a direct sales force of 31 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 customers 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 contract research organization (CRO) for a proposal to address a customer-specific research requirement. We then engage in a series of meetings, consultations,

10

Table of Contents

workshops, implementation reviews, final proposals and contract negotiations prior to the time when the prospective customer 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.

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 or equipment are provided. Backlog at December 31, 2010 was $302.9 million, compared to $357.4 million at December 31, 2011. Contracts included in backlog are subject to termination by our customers at any time, and our annualized cancellation rate over 2010 and 2011 has ranged from 9.7% to 24.6% 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 50% of our backlog as of December 31, 2011 will convert into revenue during the 2012 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 for any particular periods 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 further 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:

- customer service;
- a significant base of reference customers;

Table of Contents

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;

cost of services and products;

financial and organizational stability; and

ability to adapt to changing regulatory guidance.

We believe that our solutions, particularly our Cardiac Safety and Respiratory function 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.

The FDA has 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 FDA has 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

Table of Contents

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.

In December 2009, the FDA issued guidance related to ePRO. The guidance covered a number of concepts from instrument use and modification, content validity and reliability, clinical trial design and data analysis. In addition, the FDA has issued guidance specifically related to clinical trials regarding pulmonary disease and suicidality assessment testing for certain neurological drugs under development. We must continue to adapt our processes in accordance with FDA guidance to meet our growth expectations.

Our medical devices are subject to regulation by numerous government agencies, including the FDA and comparable foreign agencies, including agencies in Germany where our manufacturing operations are located. To varying degrees, each of these agencies requires us to comply with laws and regulations governing the development, testing, manufacturing, labeling, marketing and distribution of our medical devices. In particular, the International Electrotechnical Commission (IEC) 60601-1:2005 (3rd edition) was published in December 2005. In this publication, standards are listed as general requirements concerning basic safety and the essential performance of equipment. These new standards must be in place by June 1, 2012 in Europe and June 1, 2013 in the United States. Other countries such as Japan, China and Brazil continue to accept the 2nd edition of IEC 60601-1 without defining transition dates for the 3rd edition. The IEC 60601-2-27 standard for ECG equipment has not yet been adapted to the structure of the third edition. The second edition of the general standard continues to be binding.

Authorization to commercially distribute a new medical device in the U.S. is generally received in one of two ways. The first, known as pre-market notification or the 510(k) process, requires us to demonstrate that our new medical device is substantially equivalent to a legally marketed medical device. In this process, we must submit data that supports our equivalence claim. If human clinical data is required, it must be gathered in compliance with FDA investigational device exemption regulations. We must receive an order from the FDA finding substantial equivalence to another legally marketed medical device before we can commercially distribute the new medical device. Modifications to cleared medical devices can be made without using the 510(k) process if the changes do not significantly affect safety or effectiveness. The second, more rigorous process, known as pre-market approval (PMA), requires us to independently demonstrate that the new medical device is safe and effective. We do this by collecting data regarding design, materials, bench and animal testing and human clinical data for the medical device. The FDA will authorize commercial release if it determines there is reasonable assurance that the medical device is safe and effective. This determination is based on the benefit outweighing the risk for the population intended to be treated with the device. This process is much more detailed, time-consuming and expensive than the 510(k) process.

Both before and after a product is commercially released, we have ongoing responsibilities under FDA regulations. The FDA reviews design and manufacturing practices, labeling and record keeping and manufacturers required reports of adverse experiences and other information to identify potential problems with marketed medical devices. We are also subject to periodic inspection by the FDA for compliance with the FDA s quality system regulations among other FDA requirements, such as restrictions on advertising and promotion. The quality system regulations govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging and servicing of all finished medical devices intended for human use. If the FDA were to conclude that we are not in compliance with applicable laws or regulations, or that any of our medical devices are ineffective or pose an unreasonable health risk, the FDA could require us to notify health professionals and others that the devices present unreasonable risks of substantial harm to the public health, order a recall, repair, replacement or refund of such devices, detain or seize adulterated or misbranded medical devices or ban such medical devices. The FDA may also impose operating restrictions, enjoin and restrain certain conduct resulting

Table of Contents

in violations of applicable law pertaining to medical devices and assess civil or criminal penalties against our officers, employees or us. The FDA may also recommend prosecution to the Department of Justice.

The FDA, in cooperation with U.S. Customs and Border Protection (CBP), administers controls over the import of medical devices into the U.S. The CBP imposes its own regulatory requirements on the import of our products, including inspection and possible sanctions for noncompliance. We are also subject to foreign trade controls administered by several U.S. government agencies, including the Bureau of Industry and Security within the Commerce Department and the Office of Foreign Assets Control within the Treasury Department.

In the European Union, a single regulatory approval process exists, and conformity with the legal requirements is represented by the CE Mark. To obtain a CE Mark, defined products must meet minimum standards of performance, safety and quality (i.e., the essential requirements) and then, according to their classification, comply with one or more of a selection of conformity assessment routes. A notified body assesses the quality management systems of the manufacturer and the product conformity to the essential and other requirements within the medical device directive. We are subject to inspection by notified bodies for compliance. The competent authorities of the European Union countries, generally in the form of their ministries or departments of health, oversee the clinical research for medical devices and are responsible for market surveillance of products once they are placed on the market. We are required to report device failures and injuries potentially related to product use to these authorities in a timely manner. Various penalties exist for non-compliance with the laws transcribing the medical device directives.

To be sold in Japan, most medical devices must undergo thorough safety examinations and demonstrate medical efficacy before they are granted approval, or shonin. The Japanese government, through the Ministry of Health, Labour and Welfare (MHLW), regulates medical devices under the Pharmaceutical Affairs Law (PAL). Oversight for medical devices is conducted with participation by the Pharmaceutical and Medical Devices Agency (PMDA), a quasi government organization performing many of the review functions for MHLW. Penalties for a company s noncompliance with PAL could be severe, including revocation or suspension of a company s business license and criminal sanctions. MHLW and PMDA also assess the quality management systems of the manufacturer and the product conformity to the requirements of the PAL. We are subject to inspection for compliance by these agencies.

Foreign governmental regulations have become increasingly stringent and more common, and we may become subject to more rigorous regulation by foreign governmental authorities in the future. We believe that we have designed our service and product solutions to be consistent with the recommendations of the relevant regulatory bodies as referred to above and to comply with applicable regulatory requirements.

Federal and state laws protect the confidentiality of certain patient health information, including patient medical records, and restrict the use and disclosure of patient health information by healthcare providers. In particular, in April 2003, the U.S. Department of Health and Human Services (HHS) published patient privacy rules under the Health Insurance Portability and Accountability Act of 1996 (HIPAA privacy rule) and, in April 2005, published security rules for protected health information. The HIPAA privacy and security rules govern the use, disclosure and security of protected health information by covered entities, which are healthcare providers that submit electronic claims, health plans and healthcare clearinghouses. In 2009, Congress passed the HITECH Act, which modified certain provisions of the HIPAA privacy and security rules for covered entities and their business associates (which is anyone that performs a service on behalf of a covered entity involving the use or disclosure of protected health information and is not a member of the covered entity s workforce).These included directing HHS to publish more specific security standards, and increasing breach notification requirements, as well as tightening certain aspects of the privacy rules. In addition, the HITECH Act provided that business associates will now be subject to the same security requirements as covered entities, and that with regard to both the security and privacy rule, business associates will be subject to direct enforcement by HHS, including civil and criminal liability, just as covered entities are.

Table of Contents

We are generally not a covered entity. However, we operate as a business associate to covered entities in some instances as a provider of clinical research services. In those cases, the patient data that we receive and analyze may include protected health information. We are committed to maintaining the security and privacy of patients health information and believe that we meet the expectations of the HIPAA rules. Some modifications to our systems and policies may be necessary, but the framework is already in place. However, the potential for enforcement action against us is now greater, as HHS can take action directly against business associates. Thus, while we believe we are and will be in compliance with all HIPAA standards, there is no guarantee that the government will not disagree. Enforcement actions can be costly and interrupt regular operations of our business.

The European Union Data Protection Directive regulates the processing and dissemination of personal data of individuals in the European Union. The U.S. Department of Commerce, in consultation with the European Commission, has developed a safe-harbor framework to provide a streamlined means for U.S. entities to comply with the directive. In order to rely upon the safe-harbor framework, an entity must certify (and periodically recertify) to the Department of Commerce that its data privacy policy satisfies the requirements of the safe-harbor framework regarding notice, choice regarding disclosure of personal data, restrictions on transfers of such data to third parties, rights of access to the data by affected individuals, security controls, data integrity and the adequacy of mechanisms to enforce the policy. Although it is not clear that the clinical trial data we process in providing our services to our customers is regulated by the directive, many of our customers have requested assurances that our privacy policy complies with the directive. To address these concerns, we became a signatory to the safe-harbor framework, as a result of which our privacy policy is deemed to be in compliance with the requirements of the directive.

The delivery of our devices is subject to regulation by HHS and comparable state and foreign agencies responsible for reimbursement and regulation of healthcare items and services. U.S. laws and regulations are imposed primarily in connection with the Medicare and Medicaid programs, as well as the government s interest in regulating the quality and cost of healthcare. Foreign governments also impose regulations in connection with their healthcare reimbursement programs and the delivery of healthcare items and services.

Federal healthcare laws apply when we or our customers submit claims for items or services that are reimbursed under Medicare, Medicaid or other federally-funded healthcare programs. The principal federal laws include: (1) the False Claims Act which prohibits the submission of false or otherwise improper claims for payment to a federally-funded health care program; (2) the Anti-Kickback Statute which prohibits offers to pay or receive remuneration of any kind for the purpose of inducing or rewarding referrals of items or services reimbursable by a Federal healthcare program; (3) the Stark law which prohibits physicians from referring Medicare or Medicaid patients to a provider that bills these programs for the provision of certain designated health services if the physician (or a member of the physician s immediate family) has a financial relationship with that provider; and (4) healthcare fraud statutes that prohibit false statements and improper claims to any third-party payor. There are often similar state false claims, anti-kickback and anti-self referral and insurance laws that apply to state-funded Medicaid and other healthcare programs and private third-party payors. In addition, the U.S. Foreign Corrupt Practices Act can be used to prosecute companies in the U.S. for arrangements with physicians, or other parties outside the U.S. if the physician or party is a government official of another country and the arrangement violates the law of that country.

The laws applicable to us are subject to change, and to evolving interpretations. If a governmental authority were to conclude that we are not in compliance with applicable laws and regulations, ERT and its officers and employees could be subject to severe criminal and civil penalties including substantial penalties, fines and damages and exclusion from participation as a supplier of product to beneficiaries covered by Medicare or Medicaid.

We are also subject to various environmental laws and regulations both within and outside the U.S. Like other medical device companies, our operations involve the use of substances regulated under environmental

Table of Contents

laws, primarily manufacturing and sterilization processes. To the best of our knowledge at this time, we do not expect that compliance with environmental protection laws will have a material impact on our consolidated results of operations, financial position or cash flows.

Potential Liability and Insurance

We operate in an industry characterized by extensive patent litigation, product liability and personal injury claims. Patent litigation can result in significant damage awards and injunctions that could prevent the manufacture and sale of affected products or result in significant royalty payments in order to continue selling the products. Product liability claims may be brought by individuals seeking relief on their own behalf or purporting to represent a class. In addition, product liability claims may be asserted against us in the future based on events we are not aware of at the present time. Personal liability claims may be asserted for personal injury or death to study subjects from the administration of products in clinical studies in which we provide services. While it is not possible to predict the outcome of patent litigation, product liability or personal injury claims incident to our business, we believe the costs associated with this type of litigation could have a material adverse impact on our consolidated results of operations, financial position or cash flows.

We attempt to manage our risk of potential liability through contractual indemnification provisions with customers and through insurance maintained by our customers and us. Contractual indemnification generally does not protect us against certain of our own actions, such as patent infringement or negligence. The terms and scope of such indemnification vary from customer to customer and from trial to trial. Although most of our customers 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 customer or where the indemnifying party does not fulfill its indemnification obligations to us.

Intellectual Property

Our solutions have been enhanced by significant investments in research and development and strategic acquisitions and licensing arrangements, which have allowed us to develop an intellectual property portfolio consisting of computer software and technologically derived procedures, internal operating processes and proprietary medical devices. While we rely upon confidentiality agreements to protect trade secrets, manufacturing know-how and similar proprietary rights, we also hold numerous patents and have numerous patent applications pending in the United States, the European Union and various other jurisdictions to protect our intellectual property.

We hold United States patents for various methods and systems for processing electrocardiograms directed to various features of our EXPERT® workflow enabled data handling technology and processes embedded in our EXPERT® 2 technology platform. We also hold a United States patent and two Japanese patents related to interactive annotation and measurement of time series data, such as electrocardiograms, with automatic marker sequencing. Finally, we hold a United States patent and a German patent for the maximum expiratory flow measuring device used in our Respiratory solutions.

We file patent applications in the United States and other jurisdictions when we consider it commercially beneficial to do so. While we believe our patents help provide a competitive benefit for us, we do not believe that the success of our business is dependent upon any particular patent.

We also hold a number of trademarks that we use in conducting our operations, some of which are registered in the United States and other jurisdictions and others of which unregistered common law trademarks.

Table of Contents

The more significant trademarks we use include ERT®, EXPERT®, our corporate logo, Getting it Done. Right.®, CorScreen®, SpiroPro®, VIApen®, VIAphone , VIAPad , FlowScreen®, AsthmaMonitor MasterScope and My Study Portal .

Employees

At December 31, 2011, we had a total of 680 employees, with 280 employees (271 full-time, 9 part-time) at our locations in the United States, 304 employees (all full-time) at our locations in Germany and 94 employees (86 full-time, 8 part-time) at our location in the U.K. We also had 2 full-time employees in Sweden. We had 418 employees performing services directly for our customers, 116 employees in research and development, 54 employees in sales and marketing and 92 employees in general and administrative functions. We supplement our work force with contract employees as necessary. 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. In Germany, our employees are represented by work councils. 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 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. Our business, financial condition, cash flows and/or results of operations could be materially adversely affected by any of these risks. The trading price of our common stock could decline due to any of these risks. 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 customers;
- our sales cycles can be lengthy and variable; 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 researching and manufacturing certain diagnostic devices and educating and providing

Table of Contents

information to our customer base, via consultations, without any obligation by our customer to purchase our product and 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 product and 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. 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. On May 28, 2010, we acquired RS for $82.7 million in cash. The acquisition and related transaction costs were financed from our existing cash and a portion of the $23.0 million drawn from our $40.0 million revolving credit facility. Future acquisitions or investments may reduce our readily available capital and require us to obtain additional financing. If we are unable to obtain any 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 customers may be unable to get the necessary financing to conduct business and existing customers may fail to make timely payments for products we have sold or 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 customers, and in particular, development stage biopharmaceutical 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 customers 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 products we have sold or 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.

The ongoing uncertainty and volatility in the financial markets related to the U.S. budget deficit, the European sovereign debt crisis and the state of the U.S. economic recovery may adversely affect the Company s operating results.

Global financial markets continue to experience disruptions, including increased volatility, and diminished liquidity and credit availability. In particular, developments in Europe have created uncertainty with respect to the ability of certain European countries to continue to service their sovereign debt obligations. This debt crisis and related European financial restructuring efforts may cause the value of the Euro to deteriorate, reducing the purchasing power of our European customers and reducing the translation of Euro based revenues into U.S. dollars. In the event that one or more countries were to replace the Euro with their legacy currency, then the Company s sales into such countries, or Europe generally, would likely be adversely affected until stable exchange rates are established. In addition, the European crisis is contributing to instability in global credit

Table of Contents

markets. If global economic and market conditions, or economic and financial market conditions in Europe, the United States or other key markets, remain uncertain, persist, or deteriorate further, our customers may respond by suspending, delaying or reducing their capital expenditures, which may adversely affect our cash flows and results of operations. In addition, these conditions may affect the ability of our suppliers to provide goods and materials to us on a consistent and timely basis which may adversely affect our operations.

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 Covance Cardiac Safety Services, Inc. (CCSS) and entered into a long-term strategic relationship with Healthcare Technology Systems, Inc. (HTS) in 2007 and acquired RS in 2010. 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, such as the respiratory services and device manufacturing markets we entered as a result of the RS acquisition;
- 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 RS, 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 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.

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

Our customer base could decline because of consolidation, and we may not be able to expand sales of our product and service solutions to new customers. Consolidation among biopharmaceutical and healthcare organizations and among CROs has continued in recent years. In addition, in times of a weakened economy, less

19

Table of Contents

stable companies, such as smaller biotechnology companies, may be at risk of being acquired. Our profitability will also 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 product and 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 product and 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 product and service solutions. Also, if consolidation of larger customers 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 biopharmaceutical and healthcare organizations conduct. Our revenues and profitability will decline if there is less competition among biopharmaceutical and healthcare organizations, 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 biopharmaceutical and healthcare 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 our product and services solutions are delayed or postponed resulting in lower than expected revenues.

We depend on the need for clinical trials in the area of pulmonary disease and a downturn in this specific therapeutic area could cause our revenues and profitability to decrease.

We provide biopharmaceutical and healthcare organizations an integrated set of products and services for the clinical evaluation of respiratory data. We have a preferred centralized spirometry vendor status with several of the top 20 biopharmaceutical companies where we provide respiratory, cardiac safety and ePRO products and services primarily in the therapeutic area for respiratory drugs. If there were significant developments in pharmacology or government regulation that significantly reduced or eliminated the need for further clinical trials for pulmonary disease, our revenue, net income and workforce would be adversely affected.

Extensive governmental regulation of the clinical trial or device manufacturing processes could require costly modifications to our technology, adversely affect prospective customers willingness to use our product and service solutions and increase competition and reduce our market share.

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

Table of Contents

Our customers and prospective customers will be less likely to use our product and service solutions if the product and 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. Our failure to maintain revenue and gross profit per transaction may affect our ability to achieve growth in services 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 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.

In December 2009, the FDA issued guidance related to ePRO. The guidance covered a number of concepts from instrument use and modification, content validity and reliability, clinical trial design and data analysis. In addition, the FDA has issued guidance specifically related to clinical trials regarding pulmonary disease. We must continue to adapt our processes in accordance with FDA guidance to meet our growth expectations. If we are unable to adapt our processes in accordance with FDA guidance, our service offerings will become obsolete, which would adversely affect our revenue and net income growth. In addition, if the FDA finds we are not operating in accordance with its guidance, the FDA may impose operating restrictions, enjoin and restrain certain violations of applicable law pertaining to our clinical research services and assess civil or criminal penalties against our officers, employees or us. The FDA may also recommend prosecution to the Department of Justice. Any adverse regulatory action, depending on its magnitude, may restrict us from effectively marketing and selling our products and services.

Our medical devices are subject to regulation by numerous government agencies, including the FDA and comparable foreign agencies, including agencies in Germany where our manufacturing operations are located. To varying degrees, each of these agencies requires us to comply with laws and regulations governing the development, testing, manufacturing, labeling, marketing and distribution of our medical devices. We cannot guarantee that we will be able to obtain marketing clearance for our new products, or enhancements or modifications to existing products, and if we do, such approval may:

take a significant amount of time,

require the expenditure of substantial resources,

involve stringent clinical and pre-clinical testing,

involve modifications, repairs or replacements of our products; and

result in limitations on the proposed uses of our products.

Table of Contents

Both before and after a product is commercially released, we have ongoing responsibilities under FDA regulations. We are also subject to periodic inspections by the FDA to determine compliance with the FDA s requirements, including primarily the quality system regulations and medical device reporting regulations. The results of these inspections can include inspectional observations on FDA s Form-483, warning letters or other forms of enforcement. Since 2009, the FDA has significantly increased its oversight of companies subject to its regulations, including medical device companies, by hiring new investigators and stepping up inspections of manufacturing facilities. The FDA has recently also significantly increased the number of warning letters issued to companies. If the FDA were to conclude that we are not in compliance with applicable laws or regulations, or that any of our medical devices are ineffective or pose an unreasonable health risk, the FDA could ban such medical devices, detain or seize adulterated or misbranded medical devices, order a recall, repair, replacement, or refund of such devices, refuse to grant pending premarket approval applications or require certificates of foreign governments for exports and/or require us to notify health professionals and others that the devices present unreasonable risks of substantial harm to the public health. The FDA may also impose operating restrictions, enjoin and restrain certain violations of applicable law pertaining to medical devices and assess civil or criminal penalties against our officers, employees or us. The FDA may also recommend prosecution to the Department of Justice. Any adverse regulatory action, depending on its magnitude, may restrict us from effectively marketing and selling our products and may affect our ability to offer our clinical research services related to such products.

Foreign governmental regulations have become increasingly stringent and more common, and we may become subject to more rigorous regulation by foreign governmental authorities in the future. Penalties for a company s noncompliance with foreign governmental regulation could be severe, including revocation or suspension of a company s business license and criminal sanctions. Any domestic or foreign governmental law or regulation imposed in the future may have a material adverse effect on us.

The FDA may recommend a different approach to measuring 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 may recommend different approaches to pulmonary function testing which may make our current devices and processes obsolete and considerably decrease our revenues and profitability.

The FDA has provided guidance reinforcing the need for routine cardiac safety 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. In addition, it is possible that, in the future, the FDA may recommend different approaches to pulmonary function testing which may make our current devices and processes obsolete and considerably decrease our revenues and profitability.

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

We have one customer that represented approximately 18%, 28% and 19% of our total revenues for the years ended December 31, 2009, 2010 and 2011, respectively. We have two other customers that each represented 13% of our total revenues for the year ended December 31, 2011. If we lose all or a material amount of our revenues from any significant customers and do not replace them with revenues from new customers, 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 customers.

Table of Contents

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 product and 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 product and service solutions, which could reduce our revenues, profitability and market share.

If our product and service solutions do not achieve widespread acceptance by our customers, our revenues, profitability and market share will likely decline. Our competitors include other centralized clinical research diagnostic laboratories and CROs. Our targeted customers may decide to choose other product and 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 customer bases than we do. Further, certain drug development organizations may decide not to outsource all or a significant portion of the clinical research diagnostic 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 product and service solutions, cause us to lose customers 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 customers that our solutions do not address and by providing us access to their customers 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 diagnostic analysis and interpretation services.

We provide products for respiratory, cardiac safety and ePRO measurements as well as services that collect, transmit, analyze and process such data in connection with our customers clinical trials. It is possible that liability may be asserted against us and the physicians who provide services for us for failing to accurately diagnose a medical problem indicated by such diagnostic services or for failing to disclose a medical problem to the investigator responsible for the subject being tested. In addition, product liability claims could be asserted against us if our diagnostic devices fail to perform to their specification or to the expectation of our customers or their patients. 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 customer 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.

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 product and service solutions. We may increase our dependence on certain suppliers as we continue to develop and enhance our product and

Table of Contents

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, Respiratory and ePRO 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 service 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 and are dependent on the Internet to transfer this data. Consequently, the occurrence of a natural disaster, misconduct, technical or service lapses or other unanticipated problems at the facilities of our third-party providers, including Internet service providers, could result in unanticipated interruptions in our access and/or our customers access to their data from software hosted at these facilities. 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 damages, customer credits and termination of these customer contracts.

Problems with Internet security could expose customer data to the public and result in significant liability to us and could affect our ability to retain existing customers and obtain new customers.

Our software and customer data may 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. Since we receive and process personal information of clinical trial participants over the Internet, there is a risk that if customer data was unsecure while processed through the Internet and exposed to the public, we could be liable 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. Further, if we fail to protect confidential customer data as required by contractual terms between us and our customers, we could be subjected to damages and such failures could affect our ability to retain existing customers and obtain new customers.

The equipment that we manufacture, acquire and lease could malfunction or become obsolete due to technological advance. Malfunctions in the equipment may result in inaccurate or lost data. If we experience malfunctions or obsolescence, we may not be able to provide the quantity of equipment needed to service our customers. We may fail to obtain the necessary certifications for use of the equipment. Any such development would reduce our revenues and profitability and/or subject us to third party claims.

We manufacture, acquire and lease equipment, which we provide to our customers to perform our service solutions. This equipment may malfunction resulting in inaccurate data or lost data. Such occurrence could cause significant study delays or possible discontinuance and may result in a third party claim against us. In addition,

Table of Contents

our equipment could 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 and failing to meet equipment demands. In addition, certifications are required for the use of certain 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 customers, which may jeopardize our business relationship and our ability to continue providing products and services. As a result, we may lose clinical customers if adequate equipment is not available, resulting in reduced revenues and profitability and we may be subject to third party claims if we are unable to perform under existing contracts.

Our equipment is subject to governmental regulation. In particular, the IEC 60601-1:2005 (3rd edition) was published in December 2005. In this publication, standards are listed as general requirements concerning basic safety and the essential performance of equipment. These new standards must be in place by June 1, 2012 in Europe and June 1, 2013 in the United States. If we are unable to adhere to this or other regulations, we will be unable to use our equipment for our clinical trials. As a result, we could be found in breach of existing customer contracts and/or unable to obtain new contracts, both of which will have a negative impact on earnings.

Capacity constraint or system or device failures could result in the loss of or liability to customers, 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 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 customers experience any significant level of problems with our technology, we may become liable to those customers, we may be unable to persuade our customers to change from a manual, paper-based process and we may lose customers. The success of our product and service solutions depends on the ability to protect against:

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

- rapid technological change;

changing customer needs;

frequent new product introductions; and

evolving industry standards.

Table of Contents

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 product and 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 subjects. 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 product and service solutions.

We depend on certain key executives. If we lose the services of any of these executives or are unable to fill open positions existing for these key 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. We also depend on our key technical, customer 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, including both software and devices, 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 customers and experience a decline in sales of our solutions. To protect our intellectual property rights, we rely on a combination of confidentiality agreements and similar restrictions on disclosure as well as patent protection. Despite our efforts to protect our proprietary rights, unauthorized parties may copy or otherwise obtain and use our products and technology. In addition, our patents 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.

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

We have recorded approximately $72.9 million in goodwill primarily as a result of the RS and CCSS acquisitions. 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, 2011, if we determine in connection with future tests that the carrying value of goodwill may not

Table of Contents

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 product and 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, and the RS acquisition has substantially increased our operations in Europe. 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

difficulties in staffing and managing foreign operations.

We are subject to a variety of government regulations in the countries where we market our product and service solutions. We currently operate in the U.K. and Germany through foreign subsidiaries and may operate in the future in other countries through additional foreign subsidiaries. If we form foreign subsidiaries outside of the U.K. and Germany, 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.

Table of Contents

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. We enter into foreign exchange contracts to mitigate such foreign exchange fluctuations. These contracts are not designated as hedging instruments and changes in fair value are immediately recognized into earnings in the line item foreign exchange gain (losses). As of December 31, 2011, there were no contracts remaining.

The agreements that we sign with customers outside the United States may be governed by the laws of the countries where we provide our product and 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.

Our revenue and earnings are exposed to foreign exchange rate fluctuations, which has substantially affected our operating results.

We conduct a significant portion of our operations in foreign countries. Because our financial statements are denominated in U.S. dollars, changes in foreign currency exchange rates could have and have had a significant effect on our operating results.

While a majority of the 2011 revenue of our foreign operations are denominated in U.S. dollars, foreign revenue will increase in 2012 and most of the expenses of our foreign operations are generally denominated in local currencies, primarily the pound sterling and the euro, and are translated into U.S. dollars for financial reporting purposes. Accordingly, changes in exchange rates between foreign currencies and the U.S. dollar will affect the translation of foreign results into U.S. dollars for purposes of reporting our consolidated results.

Our effective income tax rate may fluctuate from quarter to quarter, which may affect our earnings and earnings per share.

Our quarterly effective income tax rate is influenced by our projected profitability in the various taxing jurisdictions in which we operate. Changes in the distribution of profits and losses among taxing jurisdictions may have a significant impact on our effective income tax rate, which in turn could have a material adverse effect on our net income and earnings per share. Factors that affect the effective income tax rate include, but are not limited to:

- the possibility that an income tax benefit may not be realized with respect to losses in certain jurisdictions as a result of historical losses or local tax laws;
- actual and projected full year pretax income;
- transfer pricing;
- changes in tax laws in various taxing jurisdictions;
- audits by taxing authorities; and
- the establishment of valuation allowances against deferred tax assets if it is determined that it is more likely than not that future tax benefits will not be realized.

Any potential changes in either the U.S., U.K. or German tax law could cause fluctuations in our effective income tax rate that could cause fluctuations in our earnings and earnings per share, which can affect our stock price.

Table of Contents

Our existing credit facility contains covenants that limit our flexibility and prevent us from taking certain actions.

The agreement in connection with our credit facility requires us to maintain a maximum senior leverage ratio of 2.0 to 1.0 and a minimum debt service coverage ratio of 1.5 to 1.0. The agreement contains other customary affirmative and negative covenants including, but not limited to, limitations upon our ability to:

- incur liens or indebtedness;
- merge, consolidate or dispose of assets;
- make loans or investments;
- pay dividends or other distributions;
- engage in certain transactions with affiliates; and
- change our business or amend our organizational documents.

The agreement contains events of default customary for facilities of this type including, but not limited to:

- nonpayment of principal, interest, fees or other amounts when due;
- breach of any representations or warranties;
- breach of any affirmative or negative covenants, subject to any applicable cure periods;
- default in respect of any indebtedness of us or any of our subsidiaries in an amount in excess of $1.0 million;
- bankruptcy, insolvency or similar events involving us or any of our subsidiaries;
- entry of a judgment against us or any of our subsidiaries of at least $750,000;
- a change of control;
- certain adverse events under our ERISA plans or those of our subsidiaries; and

the occurrence of any event that has or could reasonably be expected to have a material adverse effect as defined in the agreement.

These covenants may limit our operating and financial flexibility and limit our ability to respond to changes in our business or competitive activities. Our failure to comply with these covenants could result in an event of default, which, if not cured or waived, could result in our being required to repay these borrowings before their scheduled due date.

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

Table of Contents

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.

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;

Table of Contents

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. Some existing stockholders many need to liquidate our common stock in order to meet certain requirements of the funds which hold the shares. 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 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 61,000 square feet. Our lease expires in October 2019. We lease approximately 45,000 square feet of office and warehouse space in Höchberg, Germany, which expires in December 2012 and 35,000 square feet of office space in Würzburg, Germany, which expires in August, 2013. In February 2012, we executed a lease to move our German offices and warehouse space to a new facility in Estenfeld, Germany. The facility will shortly be under construction and we anticipate moving in the first quarter of 2013. The new lease provides for the rental of approximately 90,000 square feet, compared to the approximately 80,000 square feet in our current German locations. For more details on the lease, see the discussion under Liquidity and Capital Resources. We also lease approximately 19,000 square feet of office space in Bridgewater, New Jersey, under a sublease which expires January 2013 and a direct lease which will begin in February 2013 and will expire in January 2021. This replaced a lease of approximately 31,000 square feet which expired in January 2011. We lease approximately 18,000 square feet of office space in Peterborough, U.K., 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 share the payment obligations on the Reno lease equally with Covance until November 28, 2012, to the extent such obligations are not covered by a new tenant, after which we will be solely responsible for all payment obligations until the lease expires.

Table of Contents

ITEM 3. LEGAL PROCEEDINGS

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

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
Jeffrey S. Litwin, MD	53	President, Chief Executive Officer and a Director
Keith D. Schneck	56	Executive Vice President, Chief Financial Officer, Secretary and Treasurer
John M. Blakeley	44	Executive Vice President and Chief Commercial Officer
Thomas P. Devine	59	Executive Vice President and Chief Information Officer
Amy Furlong	39	Executive Vice President and Chief Operations Officer
Joel Morganroth, MD	66	Executive Vice President, Chief Scientific Officer and a Director
Achim Schuelke	50	Executive Vice President and Chief Technology Officer

Dr. Litwin has served on our board of directors and as our President and Chief Executive Officer since May 2011. Dr. Litwin is a cardiologist and previously served as our Executive Vice President and Chief Medical Officer from December 2005 to April 2011. He served as our Senior Vice President and Chief Medical Officer from July 2000 until December 2005. Dr. Litwin serves on the DIA Annual Meeting planning committee, the Applied Clinical Trials Editorial Board, and the Board of Directors of the Metrics Champion Consortium.

Mr. Schneck has been our Executive Vice President, Chief Financial Officer, Secretary and Treasurer 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. Blakeley has been our Executive Vice President and Chief Commercial Officer since October 2010. Mr. Blakeley served as Executive Vice President, Sales and Marketing from February 2008 to October 2010 and 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. Devine has been our Executive Vice President and Chief Information Officer since October 2010. Mr. Devine served as our Executive Vice President and Chief Development Officer from December 2005 to October 2010 and 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 and Chief Operations Officer since October 2010. Ms. Furlong served as our Executive Vice President, Cardiac Safety Operations from December 2005 to October 2010 and 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. Morganroth has served as a member of our Board of Directors since 1997 and as our Chief Scientific Officer since April 2006. He previously served as the Chairman of our Board of Directors from 1999 to April 2011 and interim President and Chief Executive Officer from December 2010 to April 2011. Dr. Morganroth also

Table of Contents

served as our Chief Scientist from March 2001 to December 2005 and our Chief Executive Officer from 1993 to March 2001. In addition, Dr. Morganroth has consulted for us since 1977. Dr. Morganroth is a globally recognized cardiologist and clinical researcher who served for over ten years as a Medical Review Officer/Expert for the U.S. Food and Drug Administration.

Mr. Schuelke has been our Executive Vice President and Chief Technology Officer since October 2010. Mr. Schuelke joined us in May 2010 following our acquisition of RS and held the position of Vice President until October 2010. Prior to joining us, Mr. Schuelke held various leadership positions in healthcare technology within CareFusion Corporation, including Vice President of CareFusion from September 2009 until May 2010, Vice President of Cardinal Health from July 2008 to September 2009 and Vice President of VIASYS Healthcare from 2001 to 2007.

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 ERT. 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
2010		
First Quarter	$ 6.93	$ 5.34
Second Quarter	8.73	6.37
Third Quarter	8.95	6.42
Fourth Quarter	8.59	5.36
2011		
First Quarter	$ 7.60	$ 5.91
Second Quarter	6.98	5.43
Third Quarter	6.95	4.25
Fourth Quarter	5.55	3.86

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 17, 2012, there were 45 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, 2006 and ending December 31, 2011. 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.

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 and RS operating results in our Consolidated Statements of Operations from the dates of acquisition, November 28, 2007 and May 28, 2010, respectively.

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

	Year Ended December 31,				
	2007	2008	2009	2010	2011
Net revenues:					
Services	$ 55,309	$ 96,567	$ 64,655	$ 85,718	$ 99,289
Site support	28,042	30,679	26,667	55,274	85,633
EDC licenses and services	3,017	5,894	2,501		
Total net revenues	86,368	133,140	93,823	140,992	184,922
Costs of revenues:					
Cost of services	25,431	38,609	29,886	43,403	56,063
Cost of site support	18,821	18,445	13,544	30,212	53,056
Cost of EDC licenses and services	286	1,843	863		
Total costs of revenues	44,538	58,897	44,293	73,615	109,119
Gross margin	41,830	74,243	49,530	67,377	75,803
Operating expenses:					
Selling and marketing	11,051	13,273	12,905	16,064	17,888
General and administrative	14,668	18,181	14,859	30,607	31,011
Research and development	4,146	4,394	3,853	5,089	7,397
Total operating expenses	29,865	35,848	31,617	51,760	56,296
Operating income	11,965	38,395	17,913	15,617	19,507
Foreign exchange (losses) gains	(154)	832	(618)	(956)	171
Other income (expense), net	1,404	898	183	(239)	(1,256)
Income before income taxes	13,215	40,125	17,478	14,422	18,422
Income tax provision	4,905	15,123	6,791	4,551	4,694
Net income	$ 8,310	$ 25,002	$ 10,687	$ 9,871	$ 13,728
Basic net income per share	$ 0.17	$ 0.49	$ 0.22	$ 0.20	$ 0.28
Diluted net income per share	$ 0.16	$ 0.48	$ 0.22	$ 0.20	$ 0.28

Consolidated Balance Sheet Data (in thousands)

	December 31,				
	2007	2008	2009	2010	2011
Cash, cash equivalents and short-term investments	$ 46,879	$ 66,426	$ 78,761	$ 30,393	$ 38,978
Working capital	45,594	75,289	82,950	47,819	64,017

Total assets	147,696	169,122	164,861	214,835	240,368
Long-term debt				21,000	21,000
Total stockholders equity	113,512	137,428	137,672	150,655	169,677

Table of Contents

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

Overview

eResearchTechnology, Inc. (ERT®), a Delaware corporation, was founded in 1977. ERT and its consolidated subsidiaries collectively are referred to as the Company or we. We are a global technology-driven provider of services and customizable medical devices to biopharmaceutical organizations and, to a lesser extent, healthcare organizations. We are the market leader for centralized cardiac safety (Cardiac Safety) and respiratory efficacy (Respiratory) services in drug development and also collect, analyze and distribute electronic patient reported outcomes (ePRO) information in multiple modalities across all phases of clinical research.

Clinical trials employ diagnostic tests to measure the effect of a drug or device on certain body organs and systems to determine the product s safety and efficacy. Our technology-based services are utilized by biopharmaceutical and healthcare organizations and CROs to 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. Our Cardiac Safety solutions include the centralized collection, interpretation and distribution of electrocardiographic (ECG) data and images and are utilized during clinical trials in all phases of the clinical research process. Customers use our centralized Respiratory solutions when they are developing new compounds for the treatment of asthma, emphysema, cystic fibrosis and chronic obstructive pulmonary disease (COPD) in order to assess the efficacy of a drug or to evaluate compounds that have an effect on pulmonary function. We also offer ePRO solutions along with proprietary clinical assessments to enable customers to efficiently collect and analyze patient-reported feedback during a clinical trial. In addition, we offer site support, which includes the rental and sale of devices to support Cardiac Safety, Respiratory, and ePRO services along with related supplies and logistics management.

On May 28, 2010, we acquired Research Services Germany 234 GmbH (Research Services or RS). RS is comprised of the research services division of CareFusion Germany 234 GmbH and certain research operations of CareFusion Corporation. RS is the source of our Respiratory solutions business and also provides Cardiac Safety and ePRO services. In addition, RS is a manufacturer of diagnostic devices we rent or sell to customers in connection with our services. We paid $82.7 million for RS. The acquisition and related transaction costs were financed from our existing cash and a portion of the $23.0 million drawn from our $40.0 million revolving credit facility through Citizens Bank of Pennsylvania. The RS operations have been included in our financial results from the acquisition date of May 28, 2010. As such, only seven months of RS operations were included in our results for the year ended December 31, 2010.

Service Offerings

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

	Year Ended December 31,		
	2009	2010	2011
Net revenues:			
Services	68.9%	60.8%	53.7%
Site support	28.4	39.2	46.3
EDC licenses and services	2.7		
Total net revenues	100.0	100.0	100.0

Our services revenues consist primarily of our services offered under our Cardiac Safety, Respiratory and, to a lesser extent, our ePRO solutions that we provide on a fee for services basis. We recognize the related revenues as the services are performed. We also provide consulting services on a time and materials basis and recognize revenues as we perform the services. Our site support revenue, consisting of equipment rentals and sales along with related supplies and logistics management, are recognized at the time of sale or over the rental period.

Table of Contents

We provide biopharmaceutical and healthcare organizations a fully integrated solution for clinical services in connection with respiratory trials, including Respiratory efficacy services and devices, centralized Cardiac Safety and related ePRO services and devices in a fully integrated solution, plus a single point of contact for all aspects of the electronic data collection process in clinical trials. Our technology platform also supports the integration of other devices to integrate additional key safety data to support cardiac, respiratory and other trials.

The protocols of many of the respiratory trials in which we participate often also require ECGs and/or Holter monitoring and ePRO solutions. Our flagship investigator site device, MasterScope® CT, is a comprehensive solution for standardized and centralized spirometry, full PFT, ECG and ePRO in clinical trials. Using customized software, this innovative system combines protocol-driven workflows (with many diagnostic applications) into a single easy-to-use clinical trial workstation. These workflows can be specially tailored for multi-center studies. We believe our customers and their users consider the availability of a fully integrated platform for respiratory, cardiac safety and ePRO to be a major advantage that has enabled us to establish a preferred centralized respiratory vendor status with several of the top 20 pharmaceutical companies.

Results of Operations

Executive Overview

Net revenues were $141.0 million in 2010 as compared to $184.9 million in 2011, an increase of $43.9 million or 31.2%. This increase was primarily due to the acquisition of RS, which contributed $47.2 million of revenues during 2010 after the May 2010 acquisition date and $87.9 million for the full year 2011. Revenues from our legacy business, which primarily includes our cardiac safety business, grew $3.2 million, or 3.4%, primarily due to increased demand for our Thorough QTc cardiac safety product offering. Our legacy business experienced revenues of $27.7 million in the fourth quarter of 2011, its highest quarterly level since the fourth quarter of 2008. New bookings were $212.2 million for the year ended December 31, 2010 as compared to a record $303.5 million for the year ended December 31, 2011, and backlog was $357.4 million as of December 31, 2011.

Gross margin percentage was 47.8% in 2010 compared to 41.0% in 2011. Gross margin percentage in 2011 was impacted by the full year results of RS. The RS operations have historically generated a lower margin than our legacy business due to their higher proportion of lower margin site related revenue, higher services costs due to the more labor intensive delivery and the overall impact of integration expenses. Gross margin was also negatively impacted in both years by amortization of acquired intangible assets directly related to the RS acquisition, which totaled $5.6 million and $7.6 million in 2010 and 2011, respectively.

Operating expenses were $51.8 million in 2010 as compared to $56.3 million for 2011, an increase of $4.5 million or 8.8%. Operating expenses for 2010 included $5.9 million of costs associated with acquisition and other related costs, which included a $0.6 million payment to our Chief Executive Officer upon his retirement in 2010. In 2011, operating expenses included $0.3 million of costs associated with the acquisition and other related costs. In 2011, other income (expense), net included a provision of $0.7 million to recognize an other-than-temporary impairment of marketable securities that we received as part of our 2009 sale of the EDC business.

Our effective income tax rate for 2010 was 31.6% as compared to 25.5% in 2011, with the reduction due to a greater proportion of income being generated from lower tax rate countries, primarily from Germany, and from internal structural changes which had the benefit of lowering our U.S. income tax rate.

Net income for 2010 was $9.9 million, or $0.20 per diluted share, compared to $13.7 million, or $0.28 per diluted share, in 2011.

During the latter half of 2010, we recognized the need to modify the RS operations work flow processes and infrastructure to expand capacity to support customer requirements for active and new studies. We added new staff in Germany during the fourth quarter of 2010 and into our first quarter of 2011 to expand our capacity to

Table of Contents

handle new business and we continued the development during 2011 of our new integrated data handling platform, EXPERT 3. The EXPERT 3 platform will further expand the RS capacity by improving the efficiency and reducing the complexity of our processes. We began utilizing the EXPERT 3 system for new studies in the first quarter of 2012. We believe that these investments will better position us for improved growth and profitability in 2013 and beyond.

The following table presents certain financial data as a percentage of total net revenues (except for the gross margin for each product line which is a percentage of that product line s revenue):

	Year Ended December 31,		
	2009	2010	2011
Net revenues:			
Services	68.9%	60.8%	53.7%
Site support	28.4%	39.2%	46.3%
EDC licenses and services	2.7%	0.0%	0.0%
Total net revenues	100.0%	100.0%	100.0%
Costs of revenues:			
Cost of services	31.9%	30.8%	30.3%
Cost of site support	14.4%	21.4%	28.7%
Cost of EDC licenses and services	0.9%	0.0%	0.0%
Total costs of revenues	47.2%	52.2%	59.0%
Gross margin:			
Gross margin services	53.8%	49.4%	43.5%
Gross margin site support	49.2%	45.3%	38.0%
Gross margin EDC licenses and services	65.5%	N/A	N/A
Total gross margin	52.8%	47.8%	41.0%
Operating expenses:			
Selling and marketing	13.8%	11.4%	9.7%
General and administrative	15.8%	21.7%	16.8%
Research and development	4.1%	3.6%	4.0%
Total operating expenses	33.7%	36.7%	30.4%
Operating income	19.1%	11.1%	10.6%
Foreign exchange (losses) gains	(0.7)%	(0.7)%	0.1%
Other income (expense), net	0.2%	(0.3)%	(0.7)%
Income before income taxes	18.6%	10.2%	10.0%
Income tax provision	7.2%	3.2%	2.6%
Net income	11.4%	7.0%	7.4%

Table of Contents

Year Ended December 31, 2010 Compared to the Year Ended December 31, 2011

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

	Year Ended December 31,			
	2010	2011	Increase (Decrease)	
Services:				
Net revenues	$ 85,718	$ 99,289	$ 13,571	15.8%
Costs of revenues	43,403	56,063	12,660	29.2%
Gross margin	$ 42,315	$ 43,226	$ 911	2.2%
Site support:				
Net revenues	$ 55,274	$ 85,633	$ 30,359	54.9%
Costs of revenues	30,212	53,056	22,844	75.6%
Gross margin	$ 25,062	$ 32,577	$ 7,515	30.0%
Total				
Net revenues	$ 140,992	$ 184,922	$ 43,930	31.2%
Costs of revenues	73,615	109,119	35,504	48.2%
Gross margin	67,377	75,803	8,426	12.5%
Operating expenses:				
Selling and marketing	16,064	17,888	1,824	11.4%
General and administrative	30,607	31,011	404	1.3%
Research and development	5,089	7,397	2,308	45.4%
Total operating expenses	51,760	56,296	4,536	8.8%
Operating income	15,617	19,507	3,890	24.9%
Foreign exchange (losses) gains	(956)	171	1,127	N.M.
Other expense , net	(239)	(1,256)	(1,017)	425.5%
Income before income taxes	14,422	18,422	4,000	27.7%
Income tax provision	4,551	4,694	143	3.1%
Net income	$ 9,871	$ 13,728	$ 3,857	39.1%

N.M. Not meaningful

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
	2010	2011	(Decrease)
Costs of revenues:			
Cost of services	50.6%	56.5%	5.9%

Cost of site support	54.7%	62.0%	7.3%
Total costs of revenues	52.2%	59.0%	6.8%
Operating expenses:			
Selling and marketing	11.4%	9.7%	(1.7)%
General and administrative	21.7%	16.8%	(4.9)%
Research and development	3.6%	4.0%	0.4%
Total operating expenses	36.7%	30.4%	(6.3)%

Table of Contents

Revenues

Revenues from RS operations were $47.2 million for the post-acquisition seven months ended December 31, 2010 as compared to $87.9 million in 2011. RS operations had revenues of $28.3 million for the first five months of 2010 prior to the acquisition. Annual RS revenue increased $12.4 million or 16.4% as compared to 2010 pro-forma amounts due to an increase in demand for respiratory services and an expansion of the internal capacity to handle new business.

Services revenues included $21.1 million and $33.0 million for the years ended December 31, 2010 and 2011, respectively, from the operations of RS. Apart from the impact of RS, services revenues increased $1.7 million in the year ended December 31, 2011 as compared to the year ended December 31, 2010 due to a $1.8 million increase in ECG transactions and corresponding project management fees as well as a $0.3 million increase in Cardiac Safety consulting revenue. Partially offsetting these increases was a decrease in study reporting revenue and a small decrease in average ECG revenue per transaction.

Site support revenues included $26.0 million and $54.9 million for the years ended December 31, 2010 and 2011, respectively, from the operations of RS. Apart from the impact of RS, site support revenues increased approximately $1.5 million in the year ended December 31, 2011 as compared to the year ended December 31, 2010. This increase was due to additional Cardiac Safety equipment rented along with related supplies and freight, partially offset by a decrease in the average rental revenue per unit.

Costs of Revenues

The cost of services revenues included $14.1 million and $25.6 million for the years ended December 31, 2010 and 2011, respectively, from the operations of RS. RS cost of services as a percentage of RS services revenue was 66.8% in 2010 and 77.6% in 2011. The higher percentage in 2011 was largely due to higher labor costs for study setup, customization, and other operations. We intentionally incurred these costs in order to deliver against aggressive study timelines for key strategic customers in our Respiratory and ePRO business lines. Apart from the impact of RS, the cost of services revenues increased $1.2 million for the year ended December 31, 2011 as compared to the year ended December 31, 2010. This increase, both in absolute terms and as a percentage of services revenues, was due to a $0.9 million increase in labor costs associated with additional headcount, a $0.4 million increase in consulting costs related to Cardiac Safety consulting revenue and ePRO translation services and $0.3 million increase in depreciation associated with new ePRO functionality for our EXPERT technology platform. These increases were partially offset by decreases in several areas including incentive compensation and amortization.

The cost of site support revenues included $17.4 million and $39.1 million for the years ended December 31, 2010 and 2011, respectively, from the operations of RS. RS cost of site support revenue as a percentage of RS site support revenue was 66.9% in 2010 and 71.2% in 2011. The higher percentage in 2011 was largely due to costs for freight and other pass-through items, which have little or no margins on the associated revenue, negative manufacturing variances and increased manufacturing activity. Apart from the impact of RS, there was a $1.5 million increase in the cost of site support for the year ended December 31, 2011 as compared to the year ended December 31, 2010. This increase, both in absolute terms and as a percentage of site support revenues, was primarily due to a $0.7 million increase in labor that was largely a result of a change in the classification of the costs associated with the customer support center to report these as additional costs of site support in 2010 to better align costs with related revenue. Also contributing to the increase was a $0.6 million increase in depreciation resulting from purchases of rental equipment and the implementation of a new logistics management system and $0.3 million of additional freight.

Operating Expenses

Selling and marketing expenses included $1.9 million and $3.3 million for the years ended December 31, 2010 and 2011, respectively, from the operations of RS. RS selling and marketing expense as a percentage of RS

Table of Contents

total revenue was 4.0% in 2010 and 3.8% in 2011. The lower percentage in 2011 reflects the fact that some of the costs do not necessarily change in direct relation with changes in revenue. Apart from the impact of RS, selling and marketing expenses increased $0.4 million for the year ended December 31, 2011 as compared to the year ended December 31, 2010. This increase was primarily due to an increase in commissions as a result of an increase in the number of staff qualifying for additional commissions as well as the impact of a significant increase in ePRO bookings and an increase in labor due to additional staff. Excluding the impact of RS, the small decrease in selling and marketing expenses as a percentage of total net revenues reflects the fact that some of the costs do not necessarily change in direct relation with changes in revenue.

General and administrative expenses included $6.8 million and $10.5 million for the years ended December 31, 2010 and 2011, respectively, from the operations of RS. RS general and administrative expense as a percentage of RS total revenue was 14.4% in 2010 and 11.9% in 2011. The higher percentage in 2010 was largely due to labor and severance for a former employee who was terminated in 2010. Apart from the impact of RS, general and administrative expenses decreased $3.3 million for the year ended December 31, 2011 as compared to the year ended December 31, 2010. This decrease, both in absolute terms and as a percentage of total revenues, was due primarily to $4.1 million of professional fees related to our acquisition of RS in 2010, for which there was no corresponding expense in 2011. Additionally, in 2010, we added $0.6 million to the reserve for losses on the lease of our Reno, Nevada facility. There was also a decrease in office rent of $0.7 million for the year ended December 31, 2011 as compared to the year ended December 31, 2010 due to the new facility in Bridgewater, NJ. Partially offsetting these decreases was a $0.7 million increase in labor costs resulting from a reduction in the capitalized labor for IT staff who worked on development projects in 2010 but not in 2011, an increase in 401(k) company matches due to the increase in incentive compensation payments in 2011, and the impact of salary merit increases. Other expense increases included $0.5 million for professional fees not related to the RS acquisition compared to 2010, $0.5 million of depreciation related to computer equipment and internal-use software that went into production in 2011 and $0.2 million for software licenses.

Research and development expenses included $1.5 million and $3.8 million for the years ended December 31, 2010 and 2011, respectively, from the operations of RS. Research and development expense as a percentage of RS total revenue was 3.2% in 2010 and 4.3% in 2011. The higher percentage in 2011 was largely due to more routine systems maintenance and product development work in 2011 as compared to 2010. Apart from the impact of RS, research and development expenses, both in absolute terms and as a percentage of total net revenues, were essentially unchanged.

Foreign exchange moved from a loss of $1.0 million for the year ended December 31, 2010 to a gain of $0.2 million for the year ended December 31, 2011, primarily due to the movement in the exchange rate between the euro and U.S. dollar that impacts our operations in Germany, particularly accounts receivable denominated in U.S. dollars, as well as movement in the exchange rate between the U.K. pound and U.S. dollar that impacts our operations in the U.K., particularly accounts receivable denominated in U.S. dollars. We entered into forward contracts to sell $35.7 million U.S. dollars and purchase euros at an average price of $1.42 U.S. dollars to 1 euro during the year ended December 31, 2011. The related losses were insignificant.

Other income (expense), net, changed as we recognized an other-than-temporary impairment loss of $0.7 million on our investment in marketable securities in 2011 and we incurred a full year of interest expense and commitment fees under our credit facility in 2011, while 2010 included only seven months of interest expense.

Our effective tax rate for the year ended December 31, 2010 was 31.6% compared to 25.5% for the year ended December 31, 2011. Our effective income tax rate for the year ended December 31, 2011 benefited from the lower tax rates applicable to the RS operations in Germany, organizational restructuring activities undertaken during the latter half of 2010, a $0.2 million reversal of the reserve for unrecognized tax benefits during the year ended December 31, 2011 as a result of the conclusion of the examination of our 2006 and 2007 U.K. income tax returns, and a reduction in the corporate tax rate in the U.K.

Table of Contents

Year Ended December 31, 2009 Compared to the Year Ended December 31, 2010

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

	Year Ended December 31, 2009	2010	Increase (Decrease)	
Services:				
Net revenues	$ 64,655	$ 85,718	$ 21,063	32.6%
Costs of revenues	29,886	43,403	13,517	45.2%
Gross margin	$ 34,769	$ 42,315	$ 7,546	21.7%
Site support:				
Net revenues	$ 26,667	$ 55,274	$ 28,607	107.3%
Costs of revenues	13,544	30,212	16,668	123.1%
Gross margin	$ 13,123	$ 25,062	$ 11,939	91.0%
EDC licenses and services				
Net revenues	$ 2,501	$	$ (2,501)	(100.0)%
Costs of revenues	863		(863)	(100.0)%
Gross margin	$ 1,638	$	$ (1,638)	(100.0)%
Total				
Net revenues	$ 93,823	$ 140,992	$ 47,169	50.3%
Costs of revenues	44,293	73,615	29,322	66.2%
Gross margin	49,530	67,377	17,847	36.0%
Operating expenses:				
Selling and marketing	12,905	16,064	3,159	24.5%
General and administrative	14,859	30,607	15,748	106.0%
Research and development	3,853	5,089	1,236	32.1%
Total operating expenses	31,617	51,760	20,143	63.7%
Operating income	17,913	15,617	(2,296)	(12.8)%
Foreign exchange gains (losses)	(618)	(956)	(338)	54.7%
Other income, net	183	(239)	(422)	N.M.
Income before income taxes	17,478	14,422	(3,056)	(17.5)%
Income tax provision	6,791	4,551	(2,240)	(33.0)%
Net income	$ 10,687	$ 9,871	$ (816)	(7.6)%

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
	2009	2010	(Decrease)
Costs of revenues:			
Cost of services	46.2%	50.6%	4.4%
Cost of site support	50.8%	54.7%	3.9%
Cost of EDC licenses and services	34.5%	N.M.	N.M.
Total costs of revenues	47.2%	52.2%	5.0%
Operating expenses:			
Selling and marketing	13.8%	11.4%	(2.4)%
General and administrative	15.8%	21.7%	5.9%
Research and development	4.1%	3.6%	(0.5)%
Total operating expenses	33.7%	36.7%	3.0%

EDC

On June 23, 2009, we completed the sale of certain assets relating to our EDC operations. 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.

Revenues

Services revenues for the year ended December 31, 2010 included $21.1 million from the operations of RS. Apart from the impact of RS, services revenues were essentially flat from 2009 to 2010, with a $3.0 million reduction in transaction revenue related to lower volume of transactions performed in the year ended December 31, 2010 as compared to the year ended December 31, 2009 being offset by a number of revenue increases totaling $3.0 million, primarily from our ePRO operations.

Site support revenues for the year ended December 31, 2010 included $26.0 million from the operations of RS. Apart from the impact of RS, the increase in site support revenue was primarily due to $2.9 million associated with an increase in the number of units rented in the year ended December 31, 2010 as compared to the year ended December 31, 2009, $0.3 million increase in equipment sales and $0.2 million increase in supplies revenue. Partially offsetting these increases was a $0.6 million decrease in revenue attributable to decreases in average rental per unit and a decrease of $0.2 million of other revenue items.

Costs of Revenues

The cost of services revenues for the year ended December 31, 2010 included $14.1 million from the operations of RS. Apart from the impact of RS, the decrease in the cost of services was primarily due to a $1.8 million reduction in labor costs, largely as a result of a change in the classification of the costs associated with the customer support center to report these as additional costs of site support in 2010 to better align costs with related revenue. We have also realized cost savings as a result of efficiency initiatives implemented in the latter part of 2009. Additionally, depreciation expense decreased by $0.4 million as computer equipment purchased for the development and implementation of the EXPERT 2 technology platform has become fully depreciated. Partially offsetting these decreases were increases in variable incentive compensation expenses of $1.2 million, $0.3 for consulting and $0.3 million for telephone and connectivity. The increase in cost of services revenues as a percentage of service revenues was due to the RS operations.

The cost of site support revenues for the year ended December 31, 2010 included $17.4 million from the operations of RS. Apart from the impact of RS, the decrease in the cost of site support was primarily due to a

Table of Contents

$1.5 million decrease in depreciation expense as older, more expensive ECG equipment has become fully depreciated and a $0.2 million decrease in freight. Partially offsetting these decreases was a $1.1 million increase in labor costs in 2010, largely associated with the customer support center as discussed above. The increase in cost of site support revenues as a percentage of site support revenues was due to the RS operations.

Operating Expenses

Selling and marketing expenses for the year ended December 31, 2010 included $1.9 million from the operations of RS. Apart from the impact of RS, the increase in selling and marketing expenses was due primarily to $0.4 million in higher labor costs due to higher commissionable revenue, $0.5 million in higher variable incentive compensation expenses and $0.2 million each in higher marketing costs and royalties. These increases were partially offset by $0.2 million lower consulting costs. The decrease in selling and marketing expenses as a percentage of total net revenues reflects the fact that the costs do not necessarily change in direct relation with changes in revenue.

General and administrative expenses for the year ended December 31, 2010 included $6.8 million from the operations of RS. Apart from the impact of RS, the increase in general and administrative expenses, both in absolute terms and as a percentage of total net revenues, was due primarily to $4.0 million of professional fees incurred related to transaction costs associated with our acquisition of RS. Labor costs increased $1.1 million which included a payment to our Chief Executive Officer upon his retirement in 2010. We added $0.6 million to the reserve for losses on the lease of our former Reno, Nevada facility due to continued poor prospects for subleasing that facility. We recognized a $0.5 million gain on sale of our former EDC business in the second quarter of 2009 which decreased our expenses in 2009. Additionally, software costs increased $0.6 million and consultant costs increased $0.3 million as a result of an information technology modernization and virtualization project started in late 2009 and continuing in 2010. There was a $0.9 million increase in variable incentive compensation expenses. Travel costs increased $0.4 million as a result of continuing integration costs associated with the RS acquisition.

Research and development expenses for the year ended December 31, 2010 included $1.5 million from the operations of RS. Apart from the impact of RS, the decrease in research and development expenses was primarily due to a $0.2 million reduction in labor costs as a result of the sale of our former EDC operations in June 2009 and a $0.4 million increase in the capitalization of salaries and consultant fees associated with internal-use software development projects during 2010. These decreases were partially offset by a $0.4 million increase in variable incentive compensation expenses. The decrease in research and development expenses as a percentage of total net revenues reflects the fact that the costs do not necessarily change in direct relation with changes in revenue.

Foreign exchange losses increased primarily due to the movement in the exchange rate between the euro, British pound sterling and U.S. dollar that impacts our operations in Germany and in the U.K.

Other income (expense), net, changed as we incurred interest expense on advances under our line of credit in 2010 that we used to purchase RS and to fund related acquisition expenses and working capital needs, while 2009 included a small amount of interest income on our cash balance, a substantial portion of which we used to purchase RS.

Our effective tax rate for the year ended December 31, 2009 was 38.9% compared to 31.6% for the year ended December 31, 2010. Through September 30, 2009, we calculated our transfer pricing for Cardiac Safety services using a profit split methodology based on cost. Subsequent to September 30, 2009, the profit split transfer pricing methodology was modified for Cardiac Safety services to allocate costs based on revenue instead of allocating revenue based on costs. Our effective tax rate for the year ended December 31, 2010 included the impact of the RS acquisition, which operates primarily in Germany which has a lower tax rate than our historic effective tax rate. However, acquisition costs are not deductible for tax purposes which increased the effective

Table of Contents

tax rate for the year ended December 31, 2010 by approximately nine percentage points. Additionally, as of July 1, 2010, we reorganized our operations in the United States to align our corporate structure along departmental business lines which has reduced our effective tax rate. The effective tax rate for the year ended December 31, 2010 also includes the impact of U.K. research and development credits for 2008 and 2009 not previously claimed and a reserve for a U.K. tax audit.

Liquidity and Capital Resources

At December 31, 2011, we had $39.0 million of cash, cash equivalents and short-term investments, primarily invested in money market funds and commercial bank accounts. Of the $39.0 million, $14.9 million and $9.1 million was held by our U.K. and German subsidiaries, respectively. Although a portion of our U.K. subsidiary s and all of our German subsidiary s current undistributed net earnings, as well as any future net earnings of our U.K. and German subsidiaries, will be permanently reinvested, we believe that this does not have a material impact on our overall liquidity.

For the year ended December 31, 2010, our operations provided cash of $35.9 million as compared to $42.5 million during the year ended December 31, 2011, an increase of $6.6 million compared. The increase was primarily the result of a $10.3 million increase for the year ended December 31, 2011 as compared to the year ended December 31, 2010 in net income before depreciation and amortization. Additionally, changes in deferred income taxes and deferred revenue had a positive impact on cash of $3.4 million and $1.9 million, respectively, in 2011 and a negative impact on cash of $0.7 million and $0.4 million, respectively, in 2010. A number of items partially offset this increase, primarily decreases in the impact of accounts payable and accrued expenses. There was a $4.1 million and an $8.1 million increase in accounts payable and accrued expenses, respectively, in 2010 and a $0.1 decrease and $0.6 million increase, respectively in 2011. The increases in 2010 were largely due to the addition of RS. While inventory increased $4.2 million at December 31, 2011 as compared to December 31, 2010, only $1.9 million of the change resulted in a negative cash impact. The remainder of the inventory increase was primarily related to non-cash transfers from rental equipment into inventory for decommissioned device components.

For the year ended December 31, 2010, our investing activities used cash of $94.8 million, which included $82.8 million used for the RS acquisition, as compared to $33.8 million during the year ended December 31, 2011. Proceeds from sales of investments, net of purchases, were $9.7 million during the year ended December 31, 2010, with no activity during the year ended December 31, 2011.

During the years ended December 31, 2010 and 2011, we capitalized $21.7 million and $33.7 million, respectively, of property and equipment. Included in property and equipment acquisitions was $6.2 million and $15.1 million for the year ended December 31, 2010 and 2011, respectively, of internal use software. The increase was largely due to the development of our new integrated data handling platform, EXPERT 3. The balance of the change was primarily due to an increase in purchases of rental equipment. The purchase of rental equipment included the activity of RS for only seven months in the year ended December 31, 2010.

For the year ended December 31, 2010, our financing activities provided cash of $21.3 million as compared to $0.7 million for the year ended December 31, 2011. The year ended December 31, 2010 included proceeds from long-term debt, net of debt repayment, of $21.0 million associated with the RS acquisition.

We have a revolving line of credit arrangement with Citizens Bank of Pennsylvania in the aggregate amount of $40.0 million, with an additional $10.0 million increase option subject to bank approval. As of December 31, 2011, we had outstanding $21.0 million under our line of credit and $19.0 million remained available for us to borrow. The line has a three-year term which expires May 27, 2013 and annual interest rates equal to LIBOR plus a margin of 1.00% to 1.75% based upon a total leverage ratio and unused commitment fees of 0.10% to 0.20% based upon the same total leverage ratio. For the year ended December 31, 2011, the annual interest rate ranged from 1.19% to 1.51% and the unused commitment fee ranged from 0.10 to 0.15%. Financial covenants

Table of Contents

include maximum total senior funded debt to earnings before interest, income taxes, depreciation and amortization (EBITDA) of 2.0 and minimum debt service coverage ratio of 1.5. At December 31, 2011, we were in compliance with all debt covenants. Borrowings under the line of credit are secured by 65% of the capital stock in certain of our foreign subsidiaries.

On February 2, 2012, one of our indirect wholly owned German subsidiaries entered into a lease for a new facility in Estenfeld, Germany. This new facility will replace our two existing facilities in Hoechberg, Germany and Wuerzburg, Germany. We anticipate that the new lease will commence on February 1, 2013, and the lease includes delay damages provisions if the facility is not ready for occupancy by that date. The current leases for the Hoechberg and Wuerzburg facilities expire on December 31, 2012 and August 31, 2013, respectively. We anticipate entering into an extension of the Hoechberg lease to cover the period until the new facility is completed.

The new lease provides for the rental of approximately 90,000 square feet compared to approximately 80,000 square feet combined in the current facilities, and includes manufacturing, warehouse, office and other space in addition to parking for 200 vehicles. The initial term of the lease is 12 years, with three successive five-year renewal options. In addition, there are two separate expansion options, one for approximately 11,000 additional square feet and the other for approximately 30,000 additional square feet. If either expansion option is exercised, the term of the lease for both the initial leased premises and the expansion space will extend for ten years from the date the expansion space is available for occupancy, and any remaining renewal options will be available thereafter and will cover the entire leased premises, as expanded.

The initial base rent under the lease will be approximately $142,000 per month, and we will also be responsible for operating expenses that we estimate will be approximately $16,000 per month, in each case plus statutory value added tax (currently a 19% rate). The initial base rent will be subject to adjustment if the facility, which will be newly constructed, varies by more than 3% from the anticipated square footage, subject to a maximum increase of 10%, or if we request changes in the construction materials to be used in the facility from those upon which the initial base rent was calculated. In addition, the base rent is subject to adjustment for consumer price index changes under certain situations.

As security for the lease obligations, we are obligated to provide the landlord a letter of credit or bank guarantee in the amount of approximately $393,000 and we have agreed to deliver a letter of comfort to the landlord that effectively guarantees our subsidiary s performance of its financial obligations under the lease.

In December 2011, we entered into a commitment to purchase $3.6 million of equipment from a manufacturer over a 10-month period beginning in January 2012. We expect to purchase this cardiac safety equipment in the normal course of business and thus this commitment does not represent a significant commitment above our expected routine purchases of ECG equipment during this period. We have a prior commitment to purchase approximately $5.1 million of private label cardiac safety equipment from the same manufacturer over a 15-month period ending in the first quarter of 2012. As of December 31, 2011, substantially all of the equipment was purchased under the $5.1 million commitment.

In March 2010, the Patient Protection and Affordable Care Act and the Health Care and Education Act of 2010 became law. The provisions of the Acts have not had, and are not expected to have, a significant impact on our consolidated financial statements.

We expect that existing cash and cash equivalents, cash flows from operations and amounts available under our credit facility as discussed above will be sufficient to meet our foreseeable cash needs for at least the next year. In addition, there may be acquisition and other growth opportunities that require additional external financing and we may from time to time seek to obtain additional funds from the public or private issuances of equity or debt securities. There can be no assurance that any such acquisitions will occur or that such financing will be available or available on terms acceptable to us, particularly in view of current capital market uncertainty.

Table of Contents

Our board of directors has authorized the repurchase of up to an aggregate of 12.5 million shares, of which 5.0 million shares remain available for purchase as of December 31, 2011. The stock buy-back authorization allows us, but does not require us, to purchase the authorized shares. The purchase of the remaining shares authorized could require us to use a significant portion of our cash, cash equivalents and investments and could also require us to seek additional external financing. No shares were purchased during the years ended December 31, 2011 or 2010. The 7,363 additional shares added to treasury shares in the year ended December 31, 2011 were the result of employee tax liabilities related to restricted stock awards that were funded by the employees surrendering their rights to the respective amount of vested shares.

The following table presents contractual obligations information as of December 31, 2011 (in thousands):

		Payments due by period			
Contractual Obligations	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Long-term debt(a)	$ 21,628	$ 262	$ 21,366	$	$
Purchase obligations(b)	3,636	3,636			
Operating leases	20,823	4,627	5,517	4,097	6,582
Total	$ 46,087	$ 8,525	$ 26,883	$ 4,097	$ 6,582

(a) Debt amounts include principal maturity and expected interest payments that reflects the year-end interest rate.

(b) Purchase obligations include agreements to purchase goods or services that are enforceable and legally binding on us and that specify all significant terms, including: fixed or minimum quantities to be purchased; fixed, minimum or variable price provisions; and the approximate timing of the transaction. We have excluded agreements that are cancelable without penalty. Purchase obligations relate to purchases of rental equipment.

The long-term portion of other liabilities is comprised of the present value of estimated lease costs for the Reno location. The gross amount of the payments associated with these liabilities is included in operating leases in the contractual obligations table above.

Inflation

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

Recent Accounting Pronouncements

In September 2009, the FASB issued a new accounting standard regarding revenue arrangements with multiple deliverables. As codified in ASC 605-25 (formerly Emerging Issues Task Force Issue No. 08-1, Revenue Arrangements with Multiple Deliverables), this accounting standard sets forth requirements that must be met for an entity to recognize revenue from the sale of a delivered item that is part of a multiple-element arrangement when other items have not yet been delivered. One of those current requirements is that there be objective and reliable evidence of the standalone selling price of the undelivered items, which must be supported by either vendor-specific objective evidence (VSOE) or third-party evidence (TPE).

This consensus eliminates the requirement that all undelivered elements have VSOE or TPE before an entity can recognize the portion of an overall arrangement fee that is attributable to items that already have been delivered. In the absence of VSOE or TPE of the standalone selling price for one or more delivered or undelivered elements in a multiple-element arrangement, entities will be required to estimate the selling prices of those elements. The overall arrangement fee will be allocated to each element (both delivered and undelivered

48

Table of Contents

items) based on their relative selling prices, regardless of whether those selling prices are evidenced by VSOE or TPE or are based on the entity s estimated selling price. Application of the residual method of allocating an overall arrangement fee between delivered and undelivered elements will no longer be permitted. The accounting standard was effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. The adoption of this consensus did not have a material impact on our consolidated financial statements.

In January 2010, the FASB issued Accounting Standard Update (ASU) 2010-06 which requires reporting entities to make new disclosures about recurring or nonrecurring fair-value measurements including significant transfers into and out of Level 1 and Level 2 fair-value measurements and information on purchases, sales, issuances and settlements on a gross basis in the reconciliation of Level 3 fair-value measurements. The FASB also clarified existing fair-value measurement disclosure guidance about the level of disaggregation, inputs and valuation techniques. Except for the detailed Level 3 roll forward disclosures, we adopted this standard effective January 1, 2010. The new disclosures about purchases, sales, issuances and settlements in the roll forward activity for Level 3 fair-value measurements were effective for interim and annual reporting periods beginning after December 15, 2010. The adoption of these requirements did not have a material impact on our consolidated financial statements.

In May 2011, the FASB issued ASU No. 2011-04 which represents the converged guidance of the FASB and the IASB (the Boards) on fair value measurements. The collective efforts of the Boards and their staffs, reflected in ASU 2011-04, have resulted in common requirements for measuring fair value and for disclosing information about fair value measurements, including a consistent meaning of the term fair value. The Boards have concluded the common requirements will result in greater comparability of fair value measurements presented and disclosed in financial statements prepared in accordance with GAAP and IFRSs. The amendments in this ASU are required to be applied prospectively, and are effective for interim and annual periods beginning after December 15, 2011. We do not expect that the adoption of ASU 2011-04 will have a material impact on our consolidated financial statements.

In June 2011, the FASB issued ASU 2011-05, which amends current comprehensive income guidance. This accounting update eliminates the option to present the components of other comprehensive income as part of the statement of shareholders equity. Instead, we must report comprehensive income in either a single continuous statement of comprehensive income which contains two sections, net income and other comprehensive income, or in two separate but consecutive statements. ASU 2011-05 will be effective for public companies during the interim and annual periods beginning after Dec. 15, 2011 with early adoption permitted. The adoption of ASU 2011-05 will not have an impact on our consolidated financial statements as it only requires a change in the format of the current presentation.

In September 2011, the FASB issued ASU 2011-08, which permits an entity to make a qualitative assessment of whether it is more likely than not that a reporting unit s fair value is less than its carrying value before applying the two-step goodwill impairment model that is currently in place. If it is determined through the qualitative assessment that a reporting unit s fair value is more likely than not greater than its carrying value, the remaining impairment steps would be unnecessary. The qualitative assessment is optional, allowing companies to go directly to the quantitative assessment. This update is effective for annual and interim goodwill impairment tests performed in fiscal years beginning after December 15, 2011, which will require us to adopt these provisions in fiscal 2012; however, early adoption is permitted. The adoption of ASU 2011-08 will not have an impact on our consolidated financial statements.

Critical Accounting Policies

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

Table of Contents

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

Revenue Recognition

Services revenues consist primarily of our services offered under our Cardiac Safety, Respiratory Services and, to a lesser extent, ePRO solutions that we provide on a fee for services basis. We recognized the related revenues as the services are performed. We also provide consulting services on a time and materials basis and recognize revenues as we perform the services. Our site support revenue, consisting of equipment rentals and sales along with related supplies and logistics management, are recognized at the time of sale or over the rental period.

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

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

For arrangements with multiple deliverables entered into prior to 2011, where the fair value of each element is known, the revenue is allocated to each component based on the relative fair value 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.

For arrangements with multiple deliverables entered into from and after January 1, 2011, the revenue is allocated to each element (both delivered and undelivered items) based on their relative selling prices or management s best estimate of their selling prices, when vendor-specific or third-party evidence is unavailable.

We have recorded reimbursements received for out-of-pocket expenses incurred as revenue in the accompanying consolidated financial statements. Revenue generally is recognized net of any taxes collected from customers and subsequently remitted to government authorities.

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, 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.

Business Combinations

On May 28, 2010, we acquired Research Services Germany 234 GmbH (Research Services or RS), which provides respiratory diagnostics services and is a manufacturer of equipment that also offers cardiac safety and ePRO services. We paid $82.7 million for RS. The acquisition and related transaction costs were financed from our existing cash and the $23.0 million drawn from our $40.0 million revolving credit facility through

Table of Contents

Citizens Bank of Pennsylvania. The credit facility was established on May 27, 2010. See Note 2 to our consolidated financial statements for additional disclosure on the RS acquisition and Note 7 for additional disclosure regarding the revolving credit facility.

We allocated the purchase price to the tangible and intangible assets we acquired and liabilities we assumed based on their estimated fair values. This valuation required management to make significant estimates and assumptions, especially with respect to long-lived and intangible assets.

Critical estimates in valuing certain of the intangible assets included but were not limited to: future expected cash flows from customer contracts, customer relationships, proprietary technology and discount rates. Our estimates of fair value were based upon assumptions we believed to be reasonable, but which are inherently uncertain and unpredictable. Assumptions may have been incomplete or inaccurate, and unanticipated events and circumstances may occur.

Capitalized Software Development

We capitalize costs associated with internally developed and/or purchased software systems for new products and enhancements to existing products that have reached the application development stage and meet recoverability tests. These costs are included in property and equipment. Capitalized costs include external direct costs of materials and services utilized in developing or obtaining internal-use software, and payroll and payroll-related expenses for employees who are directly associated with and devote time to the internal-use software project. Determining useful lives of internal-use software projects requires management judgment based upon a number of factors including historical useful lives of comparable products, scalability and flexibility of the product, expectations of customer and regulatory requirements and other considerations.

Goodwill

The carrying value of goodwill was $71.6 million as of December 31, 2010 and $72.9 million as of December 31, 2011. During the year ended December 31, 2010, goodwill increased $36.9 million with $36.8 million due to the acquisition of RS. See Note 2 to our consolidated financial statements for additional disclosure regarding the RS acquisition. The change in goodwill during the year ended December 31, 2011 was primarily due to foreign currency fluctuation. Goodwill is not amortized but is subject to an impairment test at least annually. We perform the impairment test using a two-step process annually as of December 31 or more frequently if events or circumstances indicate that the value of goodwill might be impaired. The first step is a comparison of the fair value of an internal reporting unit with its carrying amount, including goodwill. If the fair value of the reporting unit exceeds its carrying value, goodwill of the reporting unit is not considered impaired and the second step is unnecessary. If the carrying value of the reporting unit exceeds its fair value, a second test is performed to measure the amount of impairment by comparing the carrying amount of the goodwill to a determination of the implied value of the goodwill. If the carrying amount of the goodwill is greater that the implied value, an impairment loss is recognized for the difference.

The implied value of goodwill is determined as of the test date by performing a purchase price allocation, as if the reporting unit had just been acquired, using currently estimated fair values of the individual assets and liabilities of the reporting unit, together with an estimate of the fair value of the reporting unit taken as a whole. The estimate of the fair value of the reporting unit is based upon information available regarding prices of similar groups of assets, or other valuation techniques including present value techniques based upon estimates of future cash flow.

The results of our annual impairment test performed in 2011 indicated that our goodwill and intangible assets were not impaired. We used many assumptions and estimates that directly impacted the results of our impairment testing, including an estimate of future expected revenues, earnings and cash flows, and discount rates applied to such expected cash flows in order to estimate fair value. We had the ability to influence the outcome and ultimate results based on the assumptions and estimates we chose for testing. To mitigate undue

Table of Contents

influence, we set criteria that were reviewed and approved by various levels of management. The determination of whether or not goodwill has become impaired involves a significant level of judgment in the assumptions underlying the approach used to determine the value of our reporting unit. Changes in our strategy or market conditions could significantly impact these judgments and require adjustments to recorded amounts of intangible assets.

Accounting for Income Taxes

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

Significant management judgment is required in determining our provision for income taxes, deferred taxes and any valuation allowance recorded against deferred tax assets. As of December 31, 2011, we had a valuation allowance of $1.4 million related to the uncertain realization of certain deferred tax assets. See Note 8 to our consolidated financial statements for more information.

Depreciation and Amortization of Long-lived Assets

We compute depreciation on our property, plant and equipment on a straight-line basis over their estimated useful lives, which generally range from two to five years. Leasehold improvements are amortized using the straight-line method over the shorter of the estimated useful life of the asset or the remaining lease term. System development costs are amortized on a straight-line basis over their estimated useful lives, which generally range from two to five years or, in the case of enhancements which have no stand-alone use, the remaining life of the initial project.

We compute amortization on our intangible assets, other than goodwill, over their estimated useful lives, which generally range from one to ten years. Amortization of backlog from our recent acquisitions is recognized on an accelerated basis while other intangibles are amortized using the straight-line method.

Changes in the estimated useful lives or an impairment of long-lived assets could have a material effect on our results of operations.

Stock-Based Compensation

We follow the fair value method of accounting for stock-based compensation. We estimate the fair value of options using the Black-Scholes option-pricing model with assumptions based primarily on historical data. The assumptions used in the Black-Scholes option-pricing model require estimates of the expected term the stock-based awards are held until exercised, the estimated volatility of our stock price over the expected term and the number of options that will be forfeited prior to the completion of their vesting requirements. Changes in our assumptions may impact the expenses related to our stock options.

The above listing is not intended to be a comprehensive list of all of our accounting policies. In many cases, the accounting treatment of a particular transaction is specifically dictated by generally accepted accounting principles. There are also areas in which management s judgment in selecting any available alternatives would not produce a materially different result. See our audited Consolidated Financial Statements and Notes thereto, which begin on page F-1 of this Form 10-K, for a description of our accounting policies and other disclosures required by generally accepted accounting principles.

Table of Contents

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

Interest Rate Risk

Long-term debt

At December 31, 2011, our long-term debt was comprised of $21.0 million drawn under our $40.0 million credit facility with Citizens Bank of Pennsylvania. We do not manage the interest rate risk on our debt through the use of derivative instruments. Our credit facility s interest rates may be reset due to fluctuations in the London Interbank Offered Rate (LIBOR). A hypothetical 100-basis-point change in the interest rate of our credit facilities would change our annual pre-tax earnings by $0.2 million based on our current borrowings under the credit facility.

Investments

We generally place our investments in highly-rated securities such as money market funds, municipal securities, bonds of government sponsored agencies, certificates of deposit with fixed rates with maturities of less than one year and A1P1 rated commercial bonds and paper. We actively manage our portfolio of cash equivalents and short-term investments, but in order to ensure liquidity, will only invest in instruments with high credit quality where a secondary market exists. We have not held and do not hold any derivatives related to our interest rate exposure. Due to the average maturity and conservative nature of our investment portfolio, a sudden change in interest rates would not have a material effect on the value of the portfolio. The impact on interest income of future changes in investment yields will depend largely on the gross amount of our cash, cash equivalents, short-term investments and long-term investments. See Liquidity and Capital Resources as part of Management s Discussion and Analysis of Financial Condition and Results of Operations.

Foreign Currency Risk

We operate on a global basis from locations in the United States (U.S.), the United Kingdom (U.K.) and Germany. All international net revenues and expenses are billed or incurred in either U.S. dollars, British pounds sterling or euros. As such, we face exposure to adverse movements in the exchange rate of the pound sterling and euro. As the currency rate changes, translation of the statement of operations of our U.K. and German subsidiaries from the local currency to U.S. dollars affects year-to-year comparability of operating results. With the RS acquisition, there has been a significant increase in activity in countries outside the U.S. As a result, we entered into foreign exchange contracts during the year ended December 31, 2011 to mitigate such foreign exchange fluctuations. Contracts totaling $35.7 million settled during the year ended December 31, 2011 at an average price of $1.42 U.S. dollars to 1 euro. There were no contracts open at December 31, 2011.

Management estimates that a 10% change in the exchange rate of the pound sterling and euro would have impacted the reported operating income for the year ended December 31, 2011 by approximately $1.5 million. In addition, management estimates the effect of a 10% change in the exchange rates at December 31, 2011, primarily on U.S. dollar denominated accounts receivable held by our foreign subsidiaries, would have impacted the reported foreign exchange (losses) gains for the year ended December 31, 2011 by approximately $1.6 million before income taxes.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The information called for by this Item is set forth on Pages F-1 through F-36.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE
Not applicable.

Table of Contents

ITEM 9A. CONTROLS AND PROCEDURES

Conclusions regarding disclosure controls and procedures

We carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures pursuant to Rule 13a-15 under the Securities Exchange Act of 1934, as amended, as of the end of the period covered by this report. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures as of the end of the period covered by this report were designed and functioning effectively to provide reasonable assurance that information required to be disclosed by the Company (including our consolidated subsidiaries) in the reports we file with or submit to the SEC is (i) recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms and (ii) accumulated and communicated to our management, including our Chief Executive Officer and our Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure. We believe that a controls system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the controls system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected.

Management s annual report on internal control over financial reporting

See Management s Report on Internal Control Over Financial Reporting on page F-2, which is incorporated herein by reference.

Report of the independent registered public accounting firm

See Report of Independent Registered Public Accounting Firm on page F-3, which is incorporated herein by reference.

Changes in internal control over financial reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of Exchange Act Rule 13a-15 that occurred during our fourth fiscal quarter of 2011 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

Table of Contents

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information with respect to this item is set forth in our definitive Proxy Statement (the Proxy Statement) to be filed with the SEC for our Annual Meeting of Stockholders to be held on April 26, 2012, under the headings Election of Directors, Section 16(a) Beneficial Ownership Reporting Compliance and Code of Ethics and Business Conduct, and is incorporated herein by reference. Information regarding our executive officers is included at the end of Part I of this Form 10-K.

ITEM 11. EXECUTIVE COMPENSATION

Information with respect to this item is incorporated by reference to the information set forth in Executive Compensation in the Proxy Statement.

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

Information with respect to this item is incorporated by reference to the information set forth in Stock Ownership The Stock Ownership of Our Principal Stockholders, Directors and Executive Officers and Executive Compensation Compensation Discussion and Analysis Elements of Our Compensation Program Existing Equity Compensation Plans in the Proxy Statement.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Information with respect to this item is incorporated by reference to the information set forth in Related Party Transactions and Corporate Governance Matters Director Independence in the Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Information with respect to this item is incorporated by reference to the information set forth in Ratification of Independent Registered Public Accountants and Audit and Non-Audit Fees in the Proxy Statement.

Table of Contents

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

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

1. The consolidated financial statements of eResearchTechnology, Inc. (the Company) filed as a part of this Form 10-K are listed on the attached Index to Consolidated Financial Statements and Financial Statement Schedule at F-1.

2. The financial statement schedule of the Company filed as a part of this Form 10-K is listed in the attached Index to Consolidated Financial Statements and Financial Statement Schedule at F-1. All other schedules have been omitted because they are not required, not applicable, or the required information is otherwise included.

3. Exhibits.

2.1	Definitive Purchase Agreement between Blitz F10-acht-drei-fünf GmbH & Co. KG, an indirect wholly-owned subsidiary of eResearchTechnology, Inc., and CareFusion Germany 234 GmbH, an indirect wholly-owned subsidiary of CareFusion Corporation, dated April 29, 2010.(1)
2.2	First Amendment dated May 28, 2010 to the Agreement Relating to the Sale, Purchase and Transfer of All Shares of Research Services Germany 234 GmbH between CareFusion Germany 234 GmbH and Blitz F10-acht-drei-fünf GmbH & Co. KG.(1)
3.1	Restated Certificate of Incorporation, as amended.(2)
3.2	Amended and Restated Bylaws.(3)
3.4	Certificate of Merger between the Company and ERT Operating Company.(4)
4.1	Form of Stock Certificate.(4)
10.1	Registration Rights Agreement dated August 27, 1999.(5)
10.2	Share Purchase Agreement dated November 27, 2007 by and among the Company, Covance Central Laboratory Services Limited Partnership, Covance Cardiac Safety Services Inc. and Covance Inc.(6)
10.4	Exclusive Marketing Agreement dated November 27, 2007 by and between the Company and Covance Inc.(7)
10.7	1996 Stock Option Plan, as amended.(4)*
10.10	Reciprocal Guaranty between CareFusion Corporation, in favor of Blitz F10-acht-drei-fünf GmbH & Co. KG, and eResearchTechnology, Inc., in favor of CareFusion Germany 234 GmbH.(8)
10.13	2010 Bonus Plan.(8)*
10.14	2011 Bonus Plan.*
10.15	Credit Agreement dated May 27, 2010 between eResearchTechnology, Inc. and Citizens Bank of Pennsylvania.(1)
10.16	Revolver Note dated May 27, 2010 made by eResearchTechnology, Inc. payable to the order of Citizens Bank of Pennsylvania.(1)
10.17	Guaranty dated May 27, 2010 by ERT Tech Corporation, ERT Investment Corporation, Covance Cardiac Safety Services Inc. and eResearchTechnology, Inc. in favor of Citizens Bank of Pennsylvania.(1)

Table of Contents

10.18	Charge Over Shares and Securities dated May 27, 2010 between eResearchTechnology, Inc. and Citizens Bank of Pennsylvania.(9)
10.20	1818 Market Street Office Lease between the Company and NNN 1818 Market Street, LLC and Affiliates.(10)
10.31	Amended and Restated 2003 Equity Incentive Plan, as amended.(11)*
10.42	Management Employment Agreement effective March 1, 2010 between Dr. Joel Morganroth and the Company.(8)*
10.44	Management Employment Agreement effective May 1, 2011 between Dr. Jeffrey Litwin and the Company.(11)*
10.45	Management Employment Agreement effective August 31, 2004 between Amy Furlong and the Company.(12)*
10.46	Consultant Agreement effective March 1, 2010 between Joel Morganroth, M.D., P.C. and the Company.(8)*
10.48	Management Employment Agreement effective September 7, 2004 between Thomas P. Devine and the Company.(13)*
10.49	Amendment to Management Employment Agreement effective March 17, 2010 between Thomas P. Devine and the Company.(13)*
10.51	Amendment to Management Employment Agreement effective March 17, 2010 between Amy Furlong and the Company.(8)*
10.53	Management Employment Agreement effective July 28, 2008 between Keith D. Schneck and the Company.(14)*
10.54	Lease Agreement dated September 28, 2004 between Royal and Sun Alliance Insurance PLC and the Company s subsidiary, eResearchTechnology Limited.(15)
10.56	Amendment to Management Employment Agreement effective March 17, 2010 between Keith D. Schneck and the Company.(8)*
10.59	Retirement Agreement effective December 21, 2010 between Michael J. McKelvey.* and the Company.(16)*
12.1	Statement of Computation of Ratio of Earnings to Fixed Charges.
21.1	Subsidiaries of the Registrant.(16)
23.1	Consent of KPMG LLP.
31.1	