ERESEARCHTECHNOLOGY INC /DE/
Form 10-K
March 02, 2012
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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.

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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.

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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

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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

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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.

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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

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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.

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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

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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,

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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;

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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

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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.