BIOCLINICA INC
Form 10-K
February 22, 2013
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# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

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# FORM 10-K

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

**THE SECURITIES EXCHANGE ACT OF 1934**

**For the fiscal year ended December 31, 2012**

**Commission File No. 001-11182**

# BIOCLINICA, INC.

(Exact name of Registrant as specified in its Charter)

| **Delaware** | **11-2872047** |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification No.) |
| **826 Newtown-Yardley Road, Newtown, Pennsylvania** | **18940-1721** |
| (Address of principal executive offices) | (Zip Code) |

**(267) 757-3000**

(Registrant s telephone number,
including area code)

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

| Title of each class | Name of each exchange on which registered |
|---|---|
| Common Stock, $0.00025 par value per share | NASDAQ Global Market |
| Preferred Share Purchase Rights | |

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

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

Indicate by check mark if 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: o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website; if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes: x No:o

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

Indicate by check mark if the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See definition of large accelerated filer , accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act (check one):

| | |
|---|---|
| Large accelerated filer o | Accelerated filer o |
| Non-accelerated filer o (do not check if a smaller reporting company) | Smaller reporting company x |

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was $60.7 million on June 30, 2012, the last business day of the registrant s most recently completed second fiscal quarter, based on the close price on that date.

Indicate the number of shares outstanding of each of the registrant s classes of common equity, as of January 31, 2013:

| **Class** | **Number of Shares** |
|---|---|
| Common Stock, $.00025 par value | 15,685,671 |

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**PART I**

**Item 1. Business.**

***Overview***

BioClinica®, Inc., referred to herein as BioClinica , we , us and our , provides integrated clinical research technology solutions to pharmaceutical biotechnology, and medical device companies, and other organizations such as contract research organizations, or CROs, engaged in global clinical studies. Our products and services include: medical image management, electronic data capture, clinical data management, interactive voice and web response, clinical trial supply forecasting tools, clinical trial management systems, and electronic image transport and archive solutions. By supplying enterprise-class software and hosted solutions accompanied by expert services to fully utilize these tools, we believe that our offerings provide our clients, large and small, improved speed and efficiency in the execution of clinical studies, with reduced clinical and business risk.

Our solutions support clinical stage research and development, or R&D, functions for our clients, and specifically, the collection, cleaning, and reporting of data related to their clinical trials. For large pharmaceutical and biotechnology companies, outsourcing these services to BioClinica is a cost effective alternative to the fixed cost model associated with internal drug development. Moreover, these large companies can benefit from BioClinica s technical resource pool, broad therapeutic expertise, and global infrastructure to support simultaneous multi-country clinical trials. For smaller companies, BioClinica provides the focused expertise and the manpower that they simply may not have in-house to pursue the resource-intensive clinical stages of drug development.

Our vision is to build critical mass in the complementary disciplines of clinical research related to data collection and processing especially those which can benefit from our information technology products and support services and to integrate these offerings in ways that yield efficiency and value for our clients. Our goal is to provide demonstrable benefits to sponsor clients through this strategy, that is, more reliable, faster and less expensive drug development. We believe that the outsourcing of these services should continue to increase in the future because of continued pressure on clinical trial sponsors, including factors such as: the need to more tightly manage costs, capacity limitations, reductions in marketing exclusivity periods, the desire to reduce development time, increased globalization of clinical trials, productivity challenges, imminent patent expirations, and more stringent regulation. We believe these trends will continue to create opportunities for companies like BioClinica that are focused on improving the efficiency of drug and medical device development.

***Our Business***

We view our operations and manage our business as one operating segment. Our extensive customer base includes all of the top 20 global pharmaceutical companies measured by revenue and many small and middle-market life sciences companies, as well as CROs.

BioClinica s clinical trial solutions enhance pharmaceutical and biotech companies ability to collect, clean (i.e., verify and ensure accuracy), process, and store the vast quantities of data generated in clinical trials. Through the use of our proprietary software and associated services, our

customers see the results of their clinical trials sooner and more accurately than through alternate methods. We believe our forecasting, simulation, and reporting tools improve our clients ability to manage their clinical trials and significantly reduce cost and risk inherent in clinical development. Our Medical Imaging Solutions support the collection and processing of clinical data, but specifically those related to medical images. The large size of digital image files requires rigorous processes to manage this data. We have developed proprietary expert software applications and services to make image collection both accurate and efficient. BioClinica s Medical Imaging Solutions also assist clients with the

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design and management of the medical imaging component of clinical trials and with the analysis and regulatory submission. Our systems enable us to contract with the foremost independent radiologists and other medical specialists who are involved in clinical trials to review medical image data in an entirely digital format and make highly precise measurements and biostatistical inferences to evaluate the efficacy and safety of pharmaceuticals, biologics, or medical devices. The resulting data enables our clients and regulatory reviewers, primarily the U.S. Food and Drug Administration, or the FDA, and comparable European agencies, to evaluate product efficacy and safety.

Acquisitions have been, and may continue to be, an important component of BioClinica s growth strategy.

On March 25, 2010, we acquired substantially all of the assets of privately held TranSenda International, LLC, or TranSenda. TranSenda was a provider of clinical trial management software, or CTMS, solutions. TranSenda s suite of web-based, Office-Smart CTMS solutions creates efficiencies for trial operations through interoperability with Microsoft Office tools. With this acquisition, we enhanced our ability to serve customers throughout the clinical research process with technologies that include improved efficiencies by reducing study durations and costs through integrated operational management.

On September 16, 2009, BioClinica acquired Tourtellotte Solutions, Inc., a private Massachusetts software firm. Tourtellotte Solutions supply chain simulation software added a new enterprise-class offering to our product line, and their interactive voice, or IVR, interactive web, or IWR, technology developments greatly advanced BioClinica s capabilities in this area.

We were incorporated in Delaware in 1987 under the name Wise Ventures, Inc. Our name was changed to Bio-Imaging Technologies, Inc. in 1991 and was changed to BioClinica, Inc. in 2009. We changed the company name to BioClinica, Inc. in 2009 to better reflect our expanded products and services. The address of our principal executive offices is 826 Newtown-Yardley Road, Newtown, Pennsylvania, 18940, and our telephone number is 267-757-3000. Our Internet website is www.bioclinica.com. We make available on our Internet website all of our public filings with the Securities and Exchange Commission, or SEC. However, nothing on our Internet website is intended to be incorporated by reference into this Form 10-K or any other filing made by us with the SEC. The public may read or copy any filings that BioClinica, Inc. files with the SEC at the SEC Public Reference Room at 100 F. Street, N.E., Washington, D.C. 20549. The SEC maintains an internet site that contains reports, proxy, and information statements, and other information regarding issuers that file electronically with the SEC. The website is http://www.sec.gov. The public can also obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330.

***Transaction with Affiliates of JLL Partners***

On January 30, 2013, it was announced that affiliates of JLL Partners, Inc., or JLL, including BioCore Holdings, Inc., or Parent, and BC Acquisition Corp., a wholly-owned subsidiary of Parent, or Purchaser, entered into an Agreement and Plan of Merger, or the Merger Agreement, with us whereby Parent will acquire us. The acquisition will be carried out in two steps. The first step is the tender offer by Purchaser to purchase all of our outstanding shares of common stock at a price of $7.25 per share, payable net to the seller in cash, or the Tender Offer. Unless subsequently extended, the Tender Offer will expire on March 11, 2013 at 12:00 midnight New York City time.

Following the successful completion of the Tender Offer, Purchaser will be merged with the Company, and all shares of our common stock not purchased in the Tender Offer (other than shares held by Purchaser or its affiliates or the Company and dissenting shares) will be converted into

the right to receive $7.25 in cash per share of our common stock. In addition, under the terms of the Merger Agreement, Purchaser is granted an option to

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acquire up to one share more than 90% of our issued and outstanding common stock if necessary to allow a short-form merger under Delaware law, which would not require a stockholder vote. The Merger is subject to customary conditions.

***Target Markets***

Our primary target market is comprised of pharmaceutical, biotechnology, and medical device companies with products in any stage of clinical development (Phase I, Phase II, Phase III, or Phase IV). Though our experience spans a wide range of therapeutic areas, we also target the largest areas of clinical research with customized products and services to support the precise requirements of these projects. Our therapeutic areas of expertise include: oncology, musculoskeletal conditions, and cardiology, plus central nervous system, neurovascular, and metabolic diseases.

***Our Solutions and Services***

The processes and technology incorporated into our offerings are designed to provide clients with the ease of use and scalability to handle large global trials as well as the flexibility, speed, and efficiency necessary to support smaller or early phase trials. The conduct of clinical trials for new drugs, biological products, and medical devices is regulated by the FDA and other regulatory bodies. Our products and services are designed to help our clients to operate in a manner that is compliant with applicable regulations and follows applicable regulatory guidance.

*Medical Imaging Solutions*

BioClinica provides a broad array of medical imaging management solutions to support clinical development. Medical image data are received by us from clinical trial sites located throughout the world. We have developed systems and procedures for data tracking and quality control that we believe to be of significant value to our clients. Our facilities in the U.S. and Europe are equipped with specialized hardware and software for the digitization of films and translation of digital data, enabling data to be standardized, regardless of its source. We believe our ability to handle most commercially available image file formats is a valuable technical asset and an important competitive advantage in gaining new business from large, global, multi-center clinical trials.

We have also developed image analysis software to measure key indicators of drug efficacy in different organs and disease states. The results from image analysis derived in our facilities can be transmitted electronically to our clients for regulatory submission. In addition, clients can use our image analysis software to determine patient eligibility for their clinical trials. Our information management services focus on providing specialized solutions for improving the quality, speed, and flexibility of image data management for clinical trials. We believe that utilizing our BioReadTM system offers numerous advantages over conventional film-based medical image reading scenarios, including increased reading speed, greater standardization of image reading, and reduced error in the capture of reader interpretations.

Using our BioRead system, independent medical specialists can review medical image data from clinical trials in a digital format. The BioRead system displays all modalities of medical image data, regardless of source equipment. In addition, the systems display either translated digital data or digitized films. Such image reviews are often required during clinical trials to evaluate patients responses to therapy or to determine if

patients qualify for studies. By using the BioRead system to read and evaluate image data, medical specialists achieve greater reading speed than is possible with a manual film-based system and can perform evaluations in a more objective, reproducible manner.

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We have also developed remote BioRead systems that are located on the premises of the individual medical specialists who are engaged by the sponsor to perform the analysis of the medical image data. Historically, the BioRead systems have been utilized to determine efficacy of the compounds being studied.

BioClinica assists clients in the design and management of the medical imaging component of clinical trials for all modalities, which includes computerized tomography, or CT, magnetic resonance imaging, or MRI, radiography, dual energy x-ray absorptiometry, or DXA/DEXA, positron emission tomography, or PET, single photon emission computerized tomography, or SPECT, quantitative coronary angiography, or QCA, cardiac MRI and CT, intravascular ultrasound, or IVUS, peripheral quantitative angiography, or QVA, central nervous system, or CNS, MRI, and ultrasound. We offer our clients therapeutic expertise in areas including oncology, musculoskeletal conditions, and cardiology, plus central nervous system, neurovascular, and metabolic diseases.

BioClinica WebSend provides our clients with a streamlined electronic transport solution to facilitate the blinding, sharing, tracking, and archiving of medical images for multi-center clinical trials as part of our suite of imaging services. Most clinical studies use courier services to transport large medical image files a process that can be slow, cumbersome, and prone to error. BioClinica WebSend provides investigator sites with a simple tool to complete transmittal forms with full validation of protocol-specific requirements and send large image studies directly to BioClinica in minutes via an Internet connection. BioClinica extends WebSend functionality to facilitate electronic sharing, tracking, analysis, and archiving of medical images for single or multi-center clinical trials with imaging endpoints.

Clients are increasingly using imaging criteria for inclusion/exclusion criteria. This use requires extremely rapid turn-around reads. We believe that the combination of WebSend and BioRead offers the optimal tool for this work because it allows us, at our client s discretion, to provide the images to an expert in the field to facilitate the review of the images from the expert s remote location, with the utmost possible speed in transport. Imaging information can also be integrated with BioClinica Express electronic data capture, or EDC, to further simplify and enhance the clinical trial process and improve the visibility of clinical data for life science companies.

*Electronic Data Capture (EDC)*

BioClinica Express™ EDC is an EDC technology platform that automates expensive, time-consuming, paper-based clinical trial processes and scales securely, reliably, and cost-effectively for global clinical trials involving large numbers of clinical sites and patients. The Express system integrates EDC functionality with clinical data management system features into a single solution that replaces traditional paper-based methods. Using our proprietary software, clients collect, clean, and manage their clinical data completely in electronic format. This technology-enabled process improves data quality and allows our sponsors to see the results of their clinical trials faster than conventional paper-based methods. Electronic versions of case report forms, or eCRFs, are made available to each research site participating in the clinical trial via the Internet. The Express system also allows the import and integration of clinical data from other sources during the course of the trial to help to reduce the imprecision and inefficiencies of waiting until the end of the trial to get a full and accurate analysis of the efficacy and safety of the investigational compound.

*IVR/IWR Interactive Response Solutions*

BioClinica Trident IWR is a next-generation interactive voice response IVR/IWR system that was released in 2010. It is parameter-driven, built specifically for the web, and is able to support rapid, flexible customization that supplies greater control over cost and data than legacy clinical IVR systems. Process knowledge and expertise in IVR/IWR, simulation and forecasting, and clinical supplies combined with other

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innovations, has led to the development of Trident IWR.

Trident IWR s unique interface provides clinical operations personnel with an intuitive way to directly set up, monitor, and maintain randomization and supplies for their clinical trials, in a fraction of the time

previously required. Trident IWR delivers rapid study setup with no programming, while supporting multiple concurrent studies. Trident IWR eliminates the need to design and create a new database for each new trial, and it provides custom data reporting and metrics. Trident IWR also offers an innovative integration with BioClinica Optimizer that unifies planning and execution systematically, extending clients precision and control over these complex processes.

*Clinical Supply Forecasting and Optimization*

BioClinica Optimizer clinical supply forecasting and optimization is a product that allows biopharmaceutical companies to simulate, forecast, and optimize their clinical supply chain. Optimizer allows clients to design unlimited supply chain scenarios and vary relevant study parameters from a global level down to a site level. Simulated results can be analyzed and modified to create the ideal clinical supply chain. Simulation is a process that replicates a real-world system or environment in order to predict actual behavior. Simulating study scenarios can help identify and mitigate supply crisis, study delays, and unnecessary overages. Optimizer helps define the minimum thresholds for site stock and local country depots using specific shipping lead times. Finding the maximum unpredictable demand over time allows users to change their minimum stock levels as the study progresses, e.g. dropping off as enrollment or other unpredictable events become complete. BioClinica offers Optimizer both through software licensing and as an outsourced service to make these benefits accessible to organizations of any size.

*Clinical Trial Management Systems, or CTMS*

BioClinica OnPoint CTMS is an application that helps sponsors and CROs better manage business and operational processes for clinical trials by capturing and manipulating the trial data electronically. BioClinica OnPoint includes: applications to manage data related to clinical sites, personnel, subjects, and clinical supplies; scheduling, tracking, and monitoring performance; site payments; study document management; vendors; and more.

BioClinica OnPoint leverages Microsoft® SharePoint, Microsoft® Office, and BioClinica technologies to provide superior team collaboration, connectivity, and efficiency in a multi-site environment; it is the only CTMS capable of fully utilizing the Microsoft Office environment. OnPoint also interfaces with a variety of systems, such as EDC and IVR/IWR systems, to fully integrate all clinical operational data. The CTMS product line also includes the BioClinica Clinical Payment Manager. Most financial systems do not have the functions or the flexibility needed to efficiently track payments specific to clinical trials; and manual payment calculation can involve extensive sorting through trial activity and contracts a process that takes time, limits visibility and is often prone to error. This results in one of the leading complaints of investigators a lack of timely and accurate payments. Offered as both a stand-alone system or fully integrated with BioClinica CTMS, Clinical Payment Manager also works with Microsoft Office software to further maximize efficiency.

*Data Management*

BioClinica Express clinical data management services support the accurate collection, verification, and analysis of clinical data. The data management team designs eCRFs and data management plans to ensure that data are collected in compliance with both the study protocol and applicable regulatory requirements. Prior to data lock, BioClinica personnel screen the data to detect errors, omissions, and other deficiencies in completed eCRFs. Data management personnel review, code, reconcile serious adverse events, and assist with the resolution

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of any data-related problems. Clients can utilize these services to augment their organization for an entire trial or to manage unexpected resource situations. Other clients choose to completely outsource the data management function in lieu of direct staff.

*Additional Services*

Our products are supported by comprehensive consulting, training services, and application hosting and support capabilities to support clinical trials on a global scale. In addition to our U.S. headquarters, we have offices with service personnel in the Netherlands, France and India.

*Application Hosting Services.* Other than our internal medical imaging systems, our software products are available to customers through software licensing arrangements and as hosted application solutions with technical and training support services.

*Consulting Services.* We provide technical consulting in the evaluation of the sites that may participate in clinical trials. We also provide consulting services to our clients regarding regulatory issues involved in the design, execution, analysis, and submission of medical image data in clinical trials. BioClinica provides expertise through our deep roster of collaborative consultants, which includes board-certified radiologists, oncologists, rheumatologists, cardiologists, and other therapeutic specialists to ensure the highest quality independent review, as well as clinical trial design and deployment expertise.

*Customer Support.* Our multi-lingual customer and site technical support is available 24 hours per day, seven days per week, via our call center. Customer support also includes training and software maintenance. Support services are bundled within our software licenses and outsourced service offerings.

**Intellectual Property**

Proprietary intellectual property protection for our computer-imaging programs, processes and expertise is important to our business. We have developed certain technically-derived procedures and computer software applications that are intended to increase the effectiveness and quality of our services. We rely upon patents, trademarks, copyrights, trade secrets, know-how and continuing technological innovation to develop and maintain our competitive position. We have claimed trademark protection for BioClinica. We hold patents for the two DEXA phantoms, titled Spine and Variable Composition Phantoms , which we sell to trial sites. We cannot assure you that we can limit unauthorized or wrongful disclosures of trade secrets or otherwise confidential information. In addition, to the extent we rely on trade secrets and know-how to maintain our competitive technological position, we cannot assure you that others may not develop independently the same, similar or superior techniques. Although our intellectual property rights are important to the results of our operations, we believe that other factors, such as our independence, process knowledge, technical expertise and experience are more important, and that, overall, these technological capabilities offer significant benefits to our clients.

**Government Regulation**

It is our view that demand for our software products, services and hosted solutions is largely a function of the regulatory requirements associated with the investigation and approval of drugs, biologics and medical devices, as well as the monitoring of and reporting on the safety of these products. The clinical testing of drugs, biologics and medical devices is subject to regulation by the FDA and other governmental authorities worldwide. The use of software and services during the clinical trial process must adhere to the regulations known as Good Clinical Practices and other various codified FDA regulations, and should adhere to regulatory guidance such as

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the Consolidated Guidance for Industry from the International Conference on Harmonization regarding Good Clinical Practice for Europe, Japan and the United States and other guidance documents. Our products, services and hosted solutions are developed using our domain expertise and are designed to allow compliance with applicable rules and regulations and conformance with applicable guidance. The foregoing regulations and regulatory guidance are subject to change at any time. Changes in regulations and regulatory guidance to either more or less stringent conditions could adversely affect our business and the software products, services and hosted solutions we make available to our customers. Further, a material violation by us or our customers of Good Clinical Practices could result in a warning letter from the FDA, the suspension or termination of clinical trials, investigator disqualification, debarment, the rejection or withdrawal of a product marketing application, criminal prosecution or civil penalties, any of which could have a material adverse effect on our business, results of operations or financial condition.

In addition to the aforementioned regulations and regulatory guidance, the FDA has developed regulations and regulatory guidance concerning electronic records and electronic signatures. The regulations, codified as 21 CFR Part 11, are interpreted for clinical trials in a guidance document titled Computerized Systems Used in Clinical Trials . This regulatory guidance stipulates that computerized systems used to capture or manage clinical trial data must meet certain standards for attributability, accuracy, retrievability, traceability, inspectability, validity, security and dependability. Other guidance documents have been issued that also help in the interpretation of 21 CFR Part 11. We cannot assure you that the design of our software solutions, will continue to allow customers to maintain conformance with these guidelines as they develop. Any changes in applicable regulations that are inconsistent with the design of any of our software solutions or which reduce the overall level of record-keeping or other controls or performances of clinical trials, may have a material adverse effect on our business and operations. If we fail to offer solutions that allow our customers to comply with applicable regulations, it could result in the suspension or termination of on-going clinical trials, the disqualification of data for submission to regulatory authorities, or the withdrawal of approved marketing applications.

The FDA has established mandatory procedures and safety standards that apply to the clinical testing, manufacturing and marketing of drugs and medical devices. These procedures and safety standards include, among other things, the completion of adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug or device for its recommended conditions or use. We advise our clients in the execution of clinical trials and other drug and device development tasks. We do not administer drugs to or utilize medical devices on patients.

The success of our business is dependent upon continued acceptance by the FDA and other regulatory authorities of the data and analyses generated by our services in connection with the evaluation of the safety and efficacy of new drugs and devices. The FDA has formal guidelines that encourage the use of surrogate measures, through submission of digital image data, for evaluation of drugs to treat life-threatening or debilitating conditions. We cannot assure you that the FDA or other regulatory authorities will accept the data or analyses generated by us in the future and, even assuming acceptance, we cannot assure you that the FDA or other regulatory authorities will require the application of imaging techniques to numbers of patients and over time periods substantially similar to those required of traditional safety and efficacy techniques.

Changes in the FDA s policy for the evaluation of therapeutic oncology agents may have a positive impact on the time to market of such therapeutics. According to FDA guidelines, approval times for new cancer therapies can be shortened if evidence of tumor shrinkage is verifiable and demonstrable through the use of objective measurement techniques. These guidelines place greater reliance on the use of medical image data to demonstrate objective tumor shrinkage. In addition, the FDA has implemented guidelines aimed at accelerating other therapeutic categories through the use of imaging markers as surrogate endpoints for measuring therapeutic effectiveness. We believe the FDA s initiatives to streamline and accelerate the submission and review process of therapeutic agents has had a favorable impact on our business.

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We believe that our ability to achieve continued and sustainable growth will be materially dependent upon, among other factors, the continued stringent enforcement of the comprehensive regulatory framework by various government agencies. Any significant change in these regulatory requirements or the enforcement thereof, especially relaxation of standards, could adversely affect our business.

The current European market regulation is more fragmented than in the United States. However, we believe that our expertise in working with the standards of the FDA provides us with experience when working with the various European regulatory agencies.

**Competition**

The market for medical image management, electronic data collection, data management and other clinical trial services is highly competitive and rapidly evolving. Our clinical research technology solutions compete against specialty CROs, and to a lesser extent, universities and teaching hospitals. Certain of our technology solutions compete with internally developed solutions, general CROs, and independent providers of such services. Certain of these competitors are owned by or are divisions of larger organizations, some of which have substantially greater resources than we do. As competition increases, we will look to provide value-added services and undertake marketing and sales programs to differentiate our services based on our expertise and experience in specific therapeutic and diagnostic areas, our technical expertise, our regulatory and clinical development experience, our quality performance and our international capabilities. Our competitive position also depends upon our ability to attract and retain qualified personnel and develop and preserve proprietary technology, processes and know-how. Competition in our industry has resulted in additional pressure being placed on price, service and quality. Although we believe that we are well positioned against our competitors due to our experience in clinical trials and regulatory compliance along with our international presence, we cannot assure you that our competitors or clients will not provide or develop services similar or superior to those provided by us. This competition could have a material adverse impact on us.

**Marketing and Sales**

We provide and market our services on an international basis primarily to pharmaceutical, biotechnology and medical device companies. We sell our products through a direct sales force and through relationships with CROs. Our direct sales force is operated out of three U.S. field offices and two European field offices, as well as our operational facilities in Pennsylvania and Leiden, The Netherlands. In addition, follow-on sales are accomplished by the efforts of sales professionals, project managers and other consulting services professionals.

Our selling efforts are primarily focused on North America and Western Europe. Our marketing activities include exhibiting at major trade shows, advertising in trade journals and the sponsoring of industry associations.

**Significant Clients**

Contracts with one client, Pfizer Inc., which encompassed 24 projects, represented 18.7% of our service revenues for the year ended December 31, 2012. Contracts with Pfizer, Inc., which encompassed 21 projects, represented 19.8% of our service revenues for the year ended December 31, 2011. Contracts with Pfizer, Inc., which encompassed 22 projects, represented 19.9% of our service revenues for the year ended

December 31, 2010. Contracts are terminable by our clients at any time and for any reason. The loss of business from a significant client or our failure to continue to obtain new business to replace completed or cancelled projects would have a material adverse effect on our business and revenues.

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**Business Segments and Geographic Information**

We view our operations and manage our business as one operating segment, clinical trials services.

Our corporate headquarters and operational facilities are in Pennsylvania, in the United States. We also have a European facility in Leiden, the Netherlands. We manage our services for European-based clinical trials from the Leiden facility. Our European facility has similar processing and analysis capabilities as our United States headquarters. We also have a facility in Lyon, France that provides product development and research activities. We have an office in Bhubaneshwar, India to provide information technology support services.

**Employees**

As of December 31, 2012, we had 585 full-time employees, four of whom were executive officers.

Of our employees, as of December 31, 2012, 40 were engaged in sales and marketing, 483 were engaged in client-related projects, and 62 were engaged in administration and management. A significant number of our management and professional employees have prior industry experience. We believe that we have been successful in attracting skilled and experienced personnel; however, it remains a competitive market for recruiting such personnel. As of January 31, 2013, we have employment agreements with three of our executive officers. See Item 11. Executive Compensation . We consider relations with our employees to be good.

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**Item 1A. Risk Factors.**

The more prominent risks and uncertainties inherent in our business are described below. However, additional risks and uncertainties may also impair our business operations. If any of the following risks actually occur, our business, financial condition or results of operations may suffer. Any of the following factors could harm our business and future results of operations, and you could lose all or part of your investment.