BIOCLINICA INC Form 10-K March 30, 2010

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

#### **FORM 10-K**

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

For the fiscal year ended December 31, 2009 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

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: b

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: b

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: b 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 Regulate S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes: o No: o

<sup>\*</sup> The registrant has not yet been phased into the interactive data requirement

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. b

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 Smaller reporting (do not check if a smaller reporting company)

Indicate by check mark if the registrant is a shell company (as defined in Rule 12b-2 of the Act).

Yes: o No: b

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was \$41.3 million on June 30, 2009, the last business day of the registrant s most recently completed second fiscal quarter, based on the average bid and asked prices on that date.

Indicate the number of shares outstanding of each of the registrant s classes of common equity, as of March 15, 2010:

Class Number of Shares Common Stock, \$.00025 par value 14,524,102

The following documents are incorporated by reference into the Annual Report on Form 10-K: Portions of the Registrant s definitive Proxy Statement for its 2010 Annual Meeting of Stockholders are incorporated by reference into Part III of this Report.

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#### **PART I**

# Item 1. Business.

#### **Overview**

On July 8, 2009, our shareholders approved an amendment to our Certificate of Incorporation, as amended, to change our name from Bio-Imaging Technologies, Inc. to BioClinica, Inc.

BioClinica<sup>TM</sup>, Inc., referred to herein as we, us and our, provides integrated clinical research services including imaging core lab and eClinical technologies and services to pharmaceutical, biotechnology, and medical device companies, and other organizations such as contract research organizations (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, 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 services support clinical stage research and development (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 them 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, faster and less expensive drug development. We believe that the outsourcing of these services should continue to increase in the future because of increased pressure on clients, 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 19 of the top 20 global pharmaceutical companies measured by revenue and many small and middle-market life sciences companies, as well as CROs. Our product offerings fall into two general product and service categories: eClinical and Imaging Core Laboratory solutions.

BioClinica s eClinical 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.

Like our eClinical solutions, BioClinica s Imaging Core Laboratory services also 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 Imaging Core Laboratory services also assist clients with the 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 (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 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 eClinical product line, and we believe that their interactive voice (IVR)/interactive web (IWR) technology developments will greatly advance BioClinica s capabilities in this area.

On August 27, 2009, we acquired the CardioNow unit of Agfa HealthCare. With this addition, BioClinica now offers electronic transport solutions to facilitate the blinding, sharing, tracking, and archiving of medical images for multi-center clinical trials as part of its suite of imaging services. Imaging tracking information can also be integrated with BioClinica eClinical data to further simplify and enhance the clinical trial process for life science companies.

On January 6, 2009, we sold our CapMed division to MBI Benefits, Inc., an indirectly owned subsidiary of Metavante Technologies, Inc. This division included the Personal Health Record (PHR) software and the patent-pending Personal HealthKey technology. The sale of CapMed enables us to focus on our core Clinical Trials Services business.

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.bioimaging.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 <a href="http://www.sec.gov">http://www.sec.gov</a>. The public can also obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330.

#### **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. *eClinical Services* 

Our eClinical product line is comprised of four primary product and service offerings: BioClinica<sup>TM</sup> Express electronic data capture (EDC);

BioClinica<sup>TM</sup> Express clinical data management;

BioClinica<sup>TM</sup> Optimizer clinical supply forecasting and optimization; and

BioClinica<sup>TM</sup> interactive response technologies (IVR/IWR).

#### Electronic Data Capture

BioClinica Express is an electronic data capture (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 (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.

We also offer modules and add-on products and services for the Express Platform, which include: The Express AutoEncoder to automatically or manually code clinical drug names and indications, adverse event terms, and patient medical histories;

Direct integration with BioClinica IVR/IWR to enable randomization and drug supply tracking through either a computer or the telephone with the same clinical study;

The BioClinica Reportal, which enables clinical trial sponsors to securely publish and share relevant clinical trial-related data for use by clinical investigators through a standard Web-browser; and

Access to Clinical Data Acquisition Standards Harmonization (CDASH) and Clinical Data Interchange Standards Consortium (CDISC)-based forms libraries to assist clients with the rapid adoption and utilization of complex data formatting standards for regulatory submission.

# Data Management

BioClinica s 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 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. *Clinical Supply Forecasting and Optimization* 

BioClinica Optimizer is a product that allows biopharmaceutical companies to simulate 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. Optimization 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.

#### IVR/IWR Interactive Response Solutions

Interactive Voice Response (IVR) solutions, systems that use the telephone to interact with databases, have been used in clinical trials for many years for basic data capture. BioClinica has significantly expanded the capabilities of our IVR offering with the introduction of BioClinica IVR the first IVR created from inception as an eClinical module tightly integrated with EDC technology for improved clinical trial management. Our system is extremely useful for obtaining multi-lingual study subject randomization codes and can initiate call backs to issue reminders (such as patient visits) and integrate fully with the central database, for a full electronic data collection mechanism.

Process knowledge and expertise in IVR/IWR, simulation and forecasting, and clinical supplies combined with other innovations, has led to the development of Trident, a next-generation interactive voice/interactive web response system that will be 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.

# **Imaging Core Laboratory Services**

BioClinica provides a broad array of medical imaging management services 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 contain 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 our computer assisted masked reading system (BioRead) 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.

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 (CT), magnetic resonance imaging (MRI), radiography, dual energy x-ray absorptiometry (DXA/DEXA), positron emission tomography (PET), single photon emission computerized tomography (SPECT), quantitative coronary angiography (QCA), cardiac MRI and CT, intravascular ultrasound (IVUS), peripheral quantitative angiography (QVA), central nervous system (CNS) MRI, and ultrasound.

The acquisition of CardioNow resulted in an opportunity for two new product offerings for BioClinica. CardioNow has developed a web-based system for the secure transmission of medical cardiac images. The software was specifically developed for and marketed to the invasive cardiology departments of hospitals within the United States. BioClinica will integrate and enhance the current CardioNow software and service to offer our clients 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 will provide 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 WebView will extend 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 office or home, with the utmost possible speed in transport. Imaging information can also be integrated with BioClinica Express EDC to further simplify and enhance the clinical trial process and improve the visibility of clinical data for life science companies.

### **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, India, China, and the United Kingdom.

Application Hosting Services. Other than our internal Imaging Core Lab 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 eClinical 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 BioClinicaÔ and Intelligent ImagingÔ. We hold patents for the two DEXA phantoms, titled Spine and Variable Composition Phantoms, which we sell to trial sites. We have registered our Stylized Man Design with the U.S. Patent and Trademark Office. 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 U.S. Food and Drug Administration, or 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 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.

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 imaging services primarily compete against specialty contract research organizations, or CROs, and to a lesser extent, universities and teaching hospitals. Our eClinical Services compete with internally developed solutions, CRO s, 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 two 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. As of December 31, 2009, we had 29 employees in sales and marketing.

### **Significant Clients**

No one client represented more than 10% of our service revenues for the years ended December 31, 2009 or December 31, 2008, while for the year ended December 31, 2007, one client, Hoffmann-La Roche, which encompassed 11 projects, accounted for 13.4% of our service revenues. Contracts are terminable by our clients at any time and for any reason. The loss of a significant client, or a reduction in services provided to a significant client, would have a material adverse effect on our business, financial condition and results of operations.

#### **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. In January 2010, we incorporated BioClinica Private Limited in Bhubaneshwar, India to provide information technology support services.

#### **Employees**

As of December 31, 2009, we had 479 employees, four of whom were executive officers.

Of our employees, as of December 31, 2009, 29 were engaged in sales and marketing, 406 were engaged in client-related projects and 44 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 February 28, 2010, we have employment agreements with three of our executive officers. See Item 11. Executive Compensation . We consider relations with our employees to be good.

#### 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. Investing in our common stock involves a high degree of risk. Any of the following factors could harm our business and future results of operations and you could lose all or part of your investment.

# Risks Related to Our Company and Business

We may incur financial losses because contracts may be delayed or terminated or reduced in scope for reasons beyond our control.

Our clients may terminate or delay their contracts for a variety of reasons, including, but not limited to: unexpected or undesired clinical results;

the client s decision to terminate the development of a particular product or to end a particular study;

insufficient patient enrollment in a study;

insufficient investigator recruitment;

failure to perform our obligations under the contract; or

the failure of products to satisfy safety requirements.

In addition, we believe that FDA-regulated companies may proceed with fewer clinical trials or conduct them without assistance of contract service organizations if they are trying to reduce costs as a result of cost containment pressures associated with healthcare reform, budgetary limits or changing priorities. These factors may cause such companies to cancel contracts with contract service organizations.

We cannot assure you that our clients will continue to use our services or that we will be able to replace, in a timely or effective manner, departing clients with new clients that generate comparable revenues. Further, we cannot assure you that our clients will continue to generate consistent amounts of revenues over time.

The loss, reduction in scope or delay of a large contract or the loss or delay of multiple contracts could materially adversely affect our business, although our contracts entitle us to receive all fees earned up to the time of termination. *The recent economic downturn may adversely impact our ability to raise capital.* 

The recent economic downturn and adverse conditions in the national and global markets may negatively affect our operations in the future. The fallen equity markets and adverse credit markets may make it difficult for us to raise capital or procure credit in the future to fund the growth of our business, which could have a negative impact on our business and results of operations and limit our ability to pursue acquisitions.

We depend on a small number of industries and clients for all of our business, and the loss of one such significant client could cause revenues to drop quickly and unexpectedly.

We depend on research and development expenditures by pharmaceutical, biotechnology and medical device companies to sustain our business. Our operations could be materially and adversely affected if:

our clients businesses experience financial problems or are affected by a general economic downturn;

consolidation in the pharmaceutical, biotechnology or medical device industries leads to a smaller client base for us; or

clients reduce their research and development expenditures.

No one client represented more than 10% of our service revenues for the years ended December 31, 2009 or December 31, 2008, while for the comparable period of 2007, one client, Hoffmann-La Roche, which encompassed 11 projects, represented 13.4% of our service revenues. The loss of business from a significant client or our failure to continue to obtain new business to replace completed or canceled projects would have a material adverse effect on our business and revenues.

#### Our contracted/committed backlog may not be indicative of future results.

Our reported contracted/committed backlog of \$98.7 million at December 31, 2009 is based on anticipated service revenue from uncompleted projects with clients. Backlog is the expected service revenue that remains to be earned and recognized on signed and verbally agreed to contracts. Contracts included in backlog are subject to termination by our clients at any time. In the event that a client cancels a contract, we would be entitled to receive payment for all services performed up to the cancellation date and subsequent client authorized services related to the cancellation of the project. The duration of the projects included in our backlog range from less than three months to seven years. We cannot assure that this backlog will be indicative of future results. A number of factors may affect backlog, including:

the variable size and duration of the projects (some are performed over several years);

the loss or delay of projects;

the change in the scope of work during the course of a project; and

the cancellation of such contracts by our clients.

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Also, if clients delay projects, the projects will remain in backlog, but will not generate revenue at the rate originally expected. Accordingly, the historical relationship of backlog to revenues may not be indicative of future results.

We made two acquisitions in the third quarter of 2009 and may engage in future acquisitions, which may be expensive and time consuming, and from which we may not realize anticipated benefits.

We acquired the CardioNow unit from AGFA Healthcare and substantially all of the assets of Tourtellotte Solutions, Inc. in the third quarter of 2009 and may acquire additional businesses, technologies and products if we determine that these additional businesses, technologies and products complement our existing business, or otherwise serve our strategic goals. Either as a result of the recent acquisitions or future acquisitions undertaken, the process of integrating the acquired business, technology or product may result in operating difficulties and expenditures, and may absorb significant management attention that would otherwise be available for ongoing development of our business. Moreover, we may never realize the anticipated benefits of any such acquisition. Such acquisitions could result in potentially dilutive issuances of our securities, the incurrence of debt and contingent liabilities and amortization expenses related to intangible assets, all of which could adversely affect our results of operations and financial condition.

# Loss of key personnel, or failure to attract and retain additional personnel, may cause the success and growth of our business to suffer.

Future success depends on the personal efforts and abilities of the principal members of our senior management to provide strategic direction, develop business, manage operations and maintain a cohesive and stable environment. Specifically, we are dependent upon Mark L. Weinstein, President and Chief Executive Officer, Ted I. Kaminer, Executive Vice President of Finance and Administration and Chief Financial Officer, David A. Pitler, Executive Vice President, President BioImaging Services, and Peter Benton, Executive Vice President, President eClinical. Although we have employment agreements with Mr. Weinstein, Mr. Kaminer and Mr. Benton, this does not necessarily mean that they will remain with us. Although we have executive retention agreements with our officers, we do not have employment agreements with any other key personnel. Furthermore, our performance also depends on our ability to attract and retain management and qualified professional and technical operating staff. Competition for these skilled personnel is intense. The loss of services of any key executive, or inability to continue to attract and retain qualified staff, could have a material adverse effect on our business, results of operations and financial condition. We do not maintain any key employee insurance on any of our executives.

#### Our revenues, earnings and operating costs are exposed to exchange rate fluctuations.

During fiscal 2009, a portion of our service revenues were denominated in foreign currency. Our financial statements are denominated in United States dollars. In the event a greater portion of our service revenues are denominated in a foreign currency, changes in foreign currency exchange rates could affect our results of operations and financial condition. Fluctuations in foreign currency exchange rates could materially impact the operating costs of our European facility in Leiden, the Netherlands, which are primarily Euro denominated. We hedge our foreign currency exposure when and as appropriate to mitigate the adverse impact of fluctuating exchange rates.

### We may be required to record additional significant charges to earnings if our goodwill becomes impaired.

Under accounting principles generally accepted in the United States, we review our goodwill for impairment each year as of December 31 and when events or changes in circumstances indicate the carrying value

may not be recoverable. The carrying value of our goodwill may not be recoverable due to factors such as a decline in stock price and market capitalization, reduced estimates of future cash flows and slower growth rates in our industry. Estimates of future cash flows are based on an updated long-term financial outlook of our operations. However, actual performance in the near-term or long-term could be materially different from these forecasts, which could impact future estimates. For example, a significant decline in our stock price and/or market capitalization may result in impairment of our goodwill valuation. We may be required to record a charge to earnings in our financial statements during a period in which an impairment of our goodwill is determined to exist, which may negatively impact our results of operations.

# We may be unable to adequately protect, and we may incur significant costs in defending, our intellectual property and other proprietary rights.

Our success depends on our ability to protect our intellectual property and other proprietary rights. We rely upon a combination of trademark, trade secret, copyright, patent and unfair competition laws, as well as license agreements and other contractual provisions, to protect our intellectual property and other proprietary rights. In addition, we attempt to protect our intellectual property and proprietary information by requiring certain of our employees and consultants to enter into confidentiality, non-competition and assignment of inventions agreements. To the extent that our intellectual property and other proprietary rights are not adequately protected, third parties might gain access to our proprietary information, develop and market products or services similar to ours, or use trademarks similar to ours, each of which could materially harm our business. Existing U.S. federal and state intellectual property laws offer only limited protection. Moreover, the laws of other countries in which we market our software products, services and hosted solutions may afford little or no effective protection of our intellectual property. If we resort to legal proceedings to enforce our intellectual property rights or to determine the validity and scope of the intellectual property or other proprietary rights of others, the proceedings could be burdensome and expensive, even if we were to prevail. The failure to adequately protect our intellectual property and other proprietary rights may have a material adverse effect on our business, results of operations or financial condition.

#### **Risks Related to Our Industry**

# Our failure to compete effectively in our industry could cause our revenues to decline.

Significant factors in determining whether we will be able to compete successfully include: consultative and clinical trials design capabilities;

reputation for on-time quality performance;

expertise and experience in specific therapeutic areas;

the scope of service offerings;

strength in various geographic markets;

the price of services;

ability to acquire, process, analyze and report data in a time-saving and accurate manner;

ability to manage large-scale clinical trials both domestically and internationally;

our size: and

the service and product offerings of our competitors.

If our services are not competitive based on these or other factors, our business, financial condition and results of operations could be materially harmed.

The biopharmaceutical services industry is highly competitive, and we face numerous competitors in our business, including hundreds of CROs. If we fail to compete effectively, we will lose clients, which would cause our business to suffer. We primarily compete against in-house departments of pharmaceutical companies, full service CROs, small specialty CROs, and to a lesser extent, universities and teaching hospitals. Some of these competitors have substantially greater capital, technical and other resources than we do. In addition, certain of our competitors that are smaller specialized companies may compete effectively against us because of their concentrated size and focus. Changes in outsourcing trends in the pharmaceutical and biotechnology industries could adversely affect our operating results and growth rate.

Service revenues depend greatly on the expenditures made by the pharmaceutical and biotechnology industries in research and development. Accordingly, economic factors and industry trends that affect our clients in these industries also affect our business. For example, the practice of many companies in these industries has been to hire outside organizations like us to conduct clinical research projects. This practice has grown significantly in the last decade, and we have benefited from this trend. However, if this trend were to change and companies in these industries were to reduce the number of research and development projects they outsource, our business could be materially adversely affected.

Additionally, numerous governments have undertaken efforts to control growing healthcare costs through legislation, regulation and voluntary agreements with medical care providers and pharmaceutical companies. If future regulatory cost containment efforts limit the profits that can be derived from new drug sales, our clients might reduce their research and development spending, which could reduce our business.

# Consolidation among our customers could cause us to lose customers, decrease the market for our products and result in a reduction of our revenues.

Our customer base could decline because of industry consolidation, and we may not be able to expand sales of our products and services to new customers. Consolidation in the pharmaceutical, biotechnology and medical device industries has accelerated in recent years, and we expect this trend to continue. As these industries consolidate, competition to provide products and services to industry participants will become more intense and the importance of establishing relationships with large industry participants will become greater. These industry participants may try to use their market power to negotiate price reductions for our products and services. Also, if consolidation of larger current customers occurs, the combined organization may represent a larger percentage of business for us and, as a result, we are likely to rely more significantly on the combined organization s revenues to continue to achieve growth. The recent economic downturn coupled with the current regulatory environment could have a negative impact on the pharmaceutical, biotechnology and medical device industries.

The recent economic downturn and adverse conditions in the national and global markets may negatively affect our operations in the future. Our revenues are contingent upon the research and development expenditures by pharmaceutical, biotechnology and medical device companies. Some companies in these industries have found it difficult to raise capital in the equity and debt markets or through traditional credit markets to fund research and development. In addition, increased regulatory scrutiny from the FDA may have increased the costs of research and development for these companies. These companies have responded to the recent economic downturn and regulatory environment, by postponing, attenuating or cancelling clinical trials projects, or portions thereof, which may reduce the need for our services. As a result, our revenues may be similarly decreased. Furthermore, while our revenues may decrease, our costs may remain relatively fixed, resulting in decreased earnings.

#### Failure to comply with existing regulations could result in increased costs to complete clinical trials.

Our business is subject to numerous governmental regulations, primarily relating to pharmaceutical product development and the conduct of clinical trials. In particular, we are subject to 21 CFR Part 11 of the Code of Federal Regulations that provides the criteria for acceptance by the FDA of electronic records. If we fail to comply with these governmental regulations, it could result in the termination of ongoing clinical research or the disqualification of data for submission to regulatory authorities. We also could be barred from providing clinical trial services in the future or be subjected to fines. Any of these consequences would harm our reputation, our prospects for future work and our operating results.

# Changes in governmental regulation could decrease the need for the services we provide, which would negatively affect our future business opportunities.

In recent years, the United States Congress and state legislatures have considered various types of healthcare reform in order to control growing healthcare costs. The United States Congress and state legislatures may again address healthcare reform in the future. We are unable to predict what legislative proposals will be adopted in the future, if any. Similar reform movements have occurred in Europe and Asia.

Implementation of healthcare reform legislation that results in additional costs could limit the profits that can be made by clients from the development of new products. This could adversely affect our clients—research and development expenditures, which could, in turn, decrease the business opportunities available to us both in the United States and abroad. In addition, new laws or regulations may create a risk of liability, increase costs or limit service offerings. We cannot predict the likelihood of any of these events.

In addition to healthcare reform proposals, the expansion of managed care organizations in the healthcare market may result in reduced spending on research and development. Managed care organizations efforts to cut costs by limiting expenditures on pharmaceuticals and medical devices could result in pharmaceutical, biotechnology and medical device companies spending less on research and development. If this were to occur, we would have fewer business opportunities and our revenues could decrease, possibly materially.

Governmental agencies throughout the world, but particularly in the United States, strictly regulate the drug development/approval process. Our business involves helping pharmaceutical and biotechnology companies navigate the regulatory drug approval process. Changes in regulation, such as relaxation in regulatory requirements or the introduction of simplified drug approval procedures or an increase in regulatory requirements that we may have difficulty satisfying could eliminate or substantially reduce the need for our services. If these changes in regulations were to occur, our business, results of operations and financial condition could be materially adversely affected. These and other changes in regulation could have a material adverse impact on our available business opportunities.

# If governmental agencies do not accept the data and analyses generated by our services, the need for our services would be eliminated or substantially reduced.

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, the FDA or other regulatory authorities may not

require the application of imaging techniques to the number of patients and over time periods substantially similar to those required of traditional safety and efficacy techniques. If the governmental agencies do not accept data and analyses generated by our services in connection with the evaluation of new drugs and devices, the need for our services would be eliminated or substantially reduced, and, as a result, our business, results of operations and financial condition could be materially adversely affected.

Our software products and hosted solutions are at varying stages of market acceptance and the failure of any of our products to achieve or maintain wide acceptance would harm our operating results.

We began offering our electronic data capture software solution for clinical trials in March 2008. Continued use of our current electronic data capture software products, and broad and timely acceptance of newly-introduced electronic data capture software products, as well as integrated solutions combining one or more of our software products, is critical to our future success and is subject to a number of significant risks, some of which are outside our control. These risks include:

our customers and prospective customers desire for and acceptance of our electronic data capture, clinical data management, drug safety and interactive response technology solutions;

our ability to meet product development and release schedules;

our software products and hosted solutions ability to support large numbers of users and manage vast amounts of data;

our ability to significantly expand our internal resources and increase our capital and operating expenses to support the anticipated growth and continued integration of our software products, services and hosted solutions; and

our customers ability to use our software products and hosted solutions, train their employees and successfully deploy our technology in their clinical trial and safety evaluation and monitoring activities.

Our failure to address, mitigate or manage these risks would seriously harm our business, particularly if the failure of any or all of our software products or hosted solutions to achieve market acceptance negatively affects our sales of our other products and services.

#### We may be exposed to liability claims as a result of our involvement in clinical trials.

We may be exposed to liability claims as a result of our involvement in clinical trials. We cannot assure you that liability claims will not be asserted against us as a result of work performed for our clients. We maintain liability insurance coverage in amounts that we believe are sufficient for the pharmaceutical services industry. Furthermore, we cannot assure you that our clients will agree to indemnify us, or that we will have sufficient insurance to satisfy any such liability claims. If a claim is brought against us and the outcome is unfavorable to us, such outcome could have a material adverse impact on us.

#### Risks Related to Our Common Stock

Your percentage ownership and voting power and the price of our common stock may decrease as a result of events that increase the number of our outstanding shares.

As of December 31, 2009, we had the following capital structure (in thousands):

Common stock outstanding	14,394

Common stock issuable upon:

Exercise of options which are outstanding	1,865
Available shares in the stock incentive plan which have not yet been granted	753
Restricted stock units outstanding	173

Total common stock outstanding assuming exercise or conversion of all of the above

17,185

As of December 31, 2009, we had outstanding options to purchase 1,865,235 shares of common stock at exercise prices ranging from \$0.66 to \$8.06 per share (exercisable at a weighted average of \$4.29 per share), of which 1,303,432 options were then exercisable. Exercise of our outstanding options into shares of our common stock may significantly and negatively affect the market price for our common stock as well as decrease your percentage ownership and voting power. In addition, we may conduct future offerings of our common stock or other securities with rights to convert the securities into shares of our common stock. As a result of these and other events, such as future acquisitions, that increase the number of our outstanding shares, your percentage ownership and voting power and the price of our common stock may decrease.

#### Shares of our common stock eligible for public sale may have a negative impact on its market price.

Future sales of shares of our common stock by existing holders of our common stock or by holders of outstanding options, upon the exercise thereof, could have a negative impact on the market price of our common stock. As of December 31, 2009, we had 14.4 million shares of our common stock issued and outstanding, all of which are currently freely tradable. As part of the acquisition of substantially all of the assets of Tourtellotte Solutions, we also agreed to issue 350,000 shares of our common stock to Tourtellotte Solutions based upon achieving certain milestones, which include certain product development and revenue targets. At December 31, 2009, we believe these milestones will be achieved in 2010, see Note 2 to our Consolidated Financial Statements for additional information.

We are unable to estimate the number of shares that may be sold because this will depend on the market price for our common stock, the personal circumstances of the sellers and other factors. Any sale of substantial amounts of our common stock or other securities in the open market may adversely affect the market price of our securities and may adversely affect our ability to obtain future financing in the capital markets as well as create a potential market overhang.

There are a limited number of stockholders who have significant control over our common stock, allowing them to have significant influence over the outcome of all matters submitted to our stockholders for approval, which may conflict with our interests and the interests of our other stockholders.

Our directors, officers and principal stockholders (stockholders owning 10% or more of our common

stock), including Covance Inc., beneficially owned 25% of the outstanding shares of common stock, restricted stock units and stock options that could have been converted to common stock at December 31, 2009, and such stockholders will have significant influence over the outcome of all matters submitted to our stockholders for approval, including the election of our directors and other corporate actions. In addition, such influence by these affiliates could have the effect of discouraging others from attempting to take us over, thereby increasing the likelihood that the market price of the common stock will not reflect a premium for control.

Because we do not intend to pay dividends, stockholders will benefit from an investment in our common stock only if it appreciates in value.

We have never declared or paid any cash dividends on our common stock. We currently intend to retain our future earnings, if any, to finance further research and development and do not expect to pay any cash dividends in the foreseeable future. As a result, the success of an investment in our common stock will depend upon any future appreciation in its value. There is no guarantee that our common stock will appreciate in value or even maintain the price at which stockholders have purchased their shares.

Trading in our common stock may be volatile, which may result in substantial declines in its market price.

The market price of our common stock has experienced historical volatility and might continue to experience volatility in the future in response to quarter-to-quarter variations in:

operating results;

analysts reports;

market conditions in the industry;

changes in governmental regulations; and

changes in general conditions in the economy or the financial markets.

The overall market (including the market for our common stock) has also experienced significant decreases in value in the past. This volatility and potential market decline could affect the market prices of securities issued by many companies, often for reasons unrelated to their operating performance, and may adversely affect the price of our common stock. Between January 1, 2009 and December 31, 2009, our common stock has traded at a low of \$2.75 per share and a high of \$4.75 per share. Between January 1, 2010 and February 28, 2010, our common stock has traded at a low of \$4.15 per share and a high of \$5.93 per share.

Our common stock began trading on the NASDAQ Global Market, formerly called the NASDAQ National Market, on December 18, 2003 and has a limited trading market. We cannot assure you that an active trading market will develop or, if developed, will be maintained. As a result, our stockholders may find it difficult to dispose of shares of our common stock and, as a result, may suffer a loss of all or a substantial portion of their investment.

Certain provisions of our charter and Delaware law could make a takeover difficult and may prevent or frustrate attempts by our stockholders to replace or remove our management team.

We have an authorized class of 3,000,000 shares of undesignated preferred stock, of which 1,250,000 shares were previously issued and converted to common stock. The remaining 1,750,000 shares may be issued by our board of directors, on such terms and with such rights, preferences and designation as the board of directors may determine. Issuance of such preferred stock, depending upon the rights, preferences and designations thereof, may have the effect of delaying, deterring or preventing a change in control of our company. In addition, we are subject to provisions of Delaware corporate law which, subject to certain exceptions, will prohibit us from

engaging in any business combination with a person who, together with affiliates and associates, owns 15% or more of our common stock for a period of three years following the date that the person came to own 15% or more of our common stock, unless the business combination is approved in a prescribed manner. In July 2009, our board of directors also adopted a stockholder rights plan, similar to plans adopted by many other publicly-traded companies. The stockholder rights plan is intended to protect stockholders against unsolicited attempts to acquire control of us that do not offer a fair price to our stockholders as determined by our board of directors.

These provisions of our certificate of incorporation, stockholder rights plan and of Delaware law, may have the effect of delaying, deterring or preventing a change in control of our company, may discourage bids for our common stock at a premium over market price and may adversely affect the market price, and the voting and other rights of the holders, of our common stock. In addition, these provisions make it more difficult to replace or remove our current management team in the event our stockholders believe this would be in the best interest of our company and our stockholders.

#### Item 1B. Unresolved Staff Comments.

None.

# Item 2. Properties.

We lease 58,700 square feet of office space located in Newtown, Pennsylvania. This lease expires December 2018 and provides for a fixed base rent of \$95,350 per month with an annual inflation increase. We lease 9,300 square feet of additional office space located in Newtown, Pennsylvania for \$8,500 per month in base rent, which expires May 2014. We also lease 36,143 square feet of office space in Audubon, Pennsylvania for \$59,444 per month in base rent, which expires January 18, 2019. In addition, we lease 23,750 square feet of office space in Leiden, the Netherlands and another 6,265 square feet in Lyon, France. These leases are denominated in the Euro and expire in April 2013 and May 2017, respectively. The base rent for the Netherlands is \$46,200 per month and the base rent for Lyon is \$12,900, based upon the conversion rate as of December 31, 2009, with an annual inflation increase. We periodically review our office space requirements and may increase the amount of office space we lease as needed.

# Item 3. Legal Proceedings.

In the normal course of business, we may be a party to legal proceedings. We are not currently a party to any material legal proceedings.

**Item 4. RESERVED** 

#### **PART II**

# Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

On July 8, 2009, our shareholders approved an amendment to our Certificate of Incorporation, as amended, to change our name from Bio-Imaging Technologies, Inc. to BioClinica, Inc. and to change our stock symbol from BITI to BIOC. Our common stock began trading on the NASDAQ Global Market, formerly called the NASDAQ National Market, on December 18, 2003 under the symbol BITI and now trades under the symbol BIOC. Prior to listing on the NASDAQ Global Market, our common stock was traded on the American Stock Exchange under the symbol BIT from February 25, 2003 until December 18, 2003. Our common stock was quoted on the NASD OTC Bulletin Board under the symbol BITI prior to being listed on the American Stock Exchange.

The following table sets forth the high and low bid quotations for our common stock as reported on the NASDAQ Global Market for each full quarterly period within the two most recent fiscal years. Such quotations reflect interdealer prices, without retail mark-up, mark-down or commission and may not represent actual transactions.

	Common			
Quarter	Sto	ck		
Ended	High	Low		
March 31, 2008	8.95	6.57		
June 30, 2008	8.15	6.18		
September 30, 2008	7.99	6.48		
December 31, 2008	7.53	2.15		
March 31, 2009	3.71	2.63		
June 30, 2009	4.24	3.02		
September 30, 2009	4.07	3.20		
December 31, 2009	4.75	3.25		

As of February 28, 2010, the number of holders of record of our common stock was 77 and the approximate number of beneficial holders, investors who hold our shares through brokers, of our common stock was 1,600.

On September 15, 2009, BioClinica acquired substantially all of the assets of Tourtellotte Solutions, Inc., or Tourtellotte. Tourtellotte provided software applications and consulting services which support clinical trials in the pharmaceutical industry. The purchase price for Tourtellotte was \$2.1 million in cash. Pursuant to the acquisition agreement, we agreed to pay up to an additional \$3.2 million in cash and 350,000 shares of our common stock based upon achieving certain milestones, which include certain product development and revenue targets. At the acquisition date, the stock was recorded at an average price of \$3.67 per share.

We believe that the issuances of the foregoing securities was exempt from registration under Section 4(2) of the Securities Act of 1933, as amended, as transactions not involving a public offering. Each of the recipients were sophisticated or accredited investors, acquired the securities for investment purposes only and not with a view to distribution and had adequate information about our company.

We have neither paid nor declared dividends on our common stock since our inception and do not plan to pay dividends on our common stock in the foreseeable future. We expect that any earnings which we may realize will be retained to finance our growth.

The following table provides information as of December 31, 2009 with respect to the shares of our Common Stock that may be issued under our existing equity compensation plans.

	Number of		eighted verage		
Plan Category Equity compensation plans that have been approved by security holders Equity compensation plans not approved by security holders	Securities to be	es to be Exercise		Number of Securities Available for Future	
	Issued Upon			Issuance Under Equity	
	Exercise of Outstanding	Outs	standing	Compensation	
	Options	Options Options		Plans	
	1,865,000	\$	4.29	1,303,000	
Total	1,865,000	\$	4.29	1,303,000	
	20				

#### STOCK PRICE PERFORMANCE GRAPH

Our common stock is listed for trading on the NASDAQ Global Market under the symbol BIOC. The Stock Price Performance Graph set forth below compares the cumulative total stockholder return on the common stock for the period from December 31, 2004 through December 31, 2009, with the cumulative total return of the NASDAQ U.S. Stock Index and the NASDAQ Health Services Index over the same period. The comparison assumes \$100 was invested on December 31, 2004 in our common stock, in the NASDAQ U.S. Stock Index and in the NASDAQ Health Services Index and assumes reinvestment of dividends, if any.

	Dec. 31,					
	2004	2005	2006	2007	2008	2009
BioClinica, Inc.	100.00	58.94	147.08	147.45	66.79	77.19
NASDAQ U.S. Stock						
Index	100.00	102.13	112.21	121.69	58.69	84.30
Nasdaq Health						
Services Index	100.00	137.44	137.24	179.38	131.01	173.20

Source: CRSP NASDAQ Monthly Historical Industry Indexes. Copyright<sup>©</sup> NASDAQ. All rights reserved

The foregoing Stock Price Performance Graph and related information shall not be deemed soliciting material or to be filed with the SEC, nor shall such information be incorporated by reference into any future filing under the Securities Act of 1933 or Securities Exchange Act of 1934, each as amended, except to the extent that we specifically incorporate it by reference into such filing.

Item 6. Selected Financial Data.

The following table presents selected consolidated financial data. This data is derived from historical financial information and should be read in conjunction with Management's Discussion and Analysis of Financial Condition and Results of Operations and the consolidated financial statements and related footnotes included in this Form 10-K.

For the years ended,

(in thousands, except per share data and number of employees)

	Dec. 31, 2009	Dec. 31, 2008	Dec. 31, 2007	Dec. 31, 2006	Dec. 31, 2005
CONTINUING OPERATIONS					
Service revenue	\$57,393	\$56,181	\$37,543	\$31,853	\$23,734
Total revenue	72,723	69,116	47,254	40,257	30,126
Income (loss) from continuing					
operations before interest and taxes	4,688	8,480	4,848	2,670	(3,226)
Income (loss) from continuing					
operations, net of taxes	2,959	5,791	3,343	1,968	(1,881)
Basic earnings (loss) per share:					
Income (loss) from continuing					
operations	0.21	0.42	0.29	0.18	(0.17)
operations	0.21	0.42	0.27	0.10	(0.17)
Diluted earnings (loss) per share:					
Income (loss) from continuing					
operations	0.20	0.40	0.26	0.16	(0.17)
Weighted evenes above yeard to					
Weighted average shares used to calculate earnings (loss) per share:					
Basic	14,354	13,752	11,616	11,219	11,114
Diluted	15,100	14,469	12,745	12,364	11,114
Dilucci	15,100	14,409	12,743	12,304	11,114
FINANCIAL POSITION					
Cash, cash equivalents	\$14,570	\$14,265	\$17,915	\$16,166	\$10,554
Working capital	7,302	7,918	9,721	10,219	8,055
Total assets	75,337	69,208	43,057	34,108	28,791
Other liabilities	2,162	641	597	305	757
Stockholders equity	48,535	43,412	23,529	18,842	17,197
OTHER DATA					
Purchases of property and					
equipment	\$ 4,258	\$ 2,916	\$ 3,928	\$ 2,232	\$ 1,871
equipment	Ψ ¬,∠36	ψ 2,910	ψ 5,920	Ψ 2,232	ψ 1,0/1
Depreciation and amortization	2,713	2,266	2,335	2,035	2,312
Number of employees	479	474	337	283	264
		22			

# Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations. Overview

On July 8, 2009, our shareholders approved an amendment to our Certificate of Incorporation, as amended, to change our name from Bio-Imaging Technologies, Inc. to BioClinica, Inc.

BioClinica, provides integrated clinical research services including imaging core lab and eClinical technologies and services to pharmaceutical, biotechnology, and medical device companies, and other organizations such as contract research organizations (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, 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.

#### **Market For Our Services**

We believe that the short-term market for our services has been adversely impacted by pharmaceutical companies response to overall economic conditions, resulting in some contract decisions being delayed and major projects being split into smaller components as part of a revised budgetary approval process. On a long term basis, we believe that the recognition within the bio-pharmaceutical industry of the operational efficiency and scalable reliability of using an independent centralized core laboratory for analysis of medical-imaging data and compliance with the regulatory demands for the submission of such data will continue to drive demand for our services. We also believe that rapidly growing recognition of the inherent advantages of eClinical technology to standardize and accelerate reliable data flow from the clinical trial sites to the clinical trial sponsor will further drive the adoption and growth of our eClinical service offerings. We believe our eClinical services favorably compare to the traditional process of manual data collection on paper case report forms that are more susceptible to transcription and other data entry errors. Our rebranding to BioClinica continues to be well received, re-energizing our marketplace reputation for offering what we believe to be best in class solutions for imaging and eClinical services for clinical trials.

# Sales and Backlog

Our sales cycle, referring to the period from the presentation by us to a potential client to the engagement of us by such client, has historically ranged from three to 12 months. In addition, the contracts under which we perform services typically cover a period of 3 to 60 months and the volume and type of services performed by us generally vary during the course of a project. We cannot assure you that our project revenues will be at levels sufficient to maintain profitability.

Our contracted/committed backlog, referred to as backlog, is the expected service revenue that remains to be earned and recognized on both signed and verbally agreed to contracts. Our backlog as of December 31, 2009, which includes our medical image management and eClinical services, was \$98.7 million compared to \$92.7 million at December 31, 2008 and \$92.5 million at December 31, 2007. Changes in backlog for the period reflect the net effect of new contract signings, addendums, cancellations expansions, and reductions in scope of existing projects, all of which impacted our backlog at December 31, 2009.

Contracts included in backlog are subject to termination by our clients at any time. In the event that a contract is cancelled by the client, we would be entitled to receive payment for all services performed up to the cancellation date. The duration of the projects included in our backlog range from less than three months to seven years. We do not believe that backlog is a reliable predictor of future results because service revenues may be incurred in a given period on contracts that were not included in the previous reporting period s backlog and/or contract cancellations or project delays may occur in a given period on contracts that were included in the previous reporting period s backlog.

Acquisitions and Dispositions

During the third quarter of 2009, the Company acquired two companies that expand the range of products and services the Company offers in the clinical trials services sector.

On September 15, 2009, BioClinica acquired substantially all of the assets of Tourtellotte Solutions, Inc., or Tourtellotte. Tourtellotte provided software applications and consulting services which support clinical trials in the pharmaceutical industry. The purchase price for Tourtellotte was \$2.1 million in cash. Pursuant to the acquisition agreement, we agreed to pay up to an additional \$3.2 million in cash and 350,000 shares of our common stock based upon achieving certain milestones, which include certain product development and revenue targets, hereinafter referred to as the earn-out. The fair value of the cash earn-out of \$2.8 million has been recorded as a liability and the fair value of the 350,000 shares of \$1.3 million has been classified separately within stockholders equity as contingent consideration for a total purchase price of \$6.2 million as of December 31, 2009. We used cash from operations to fund the cash purchase price for Tourtellotte. The financial results of Tourtellotte for the fiscal year are included in the consolidated statement of income for the period ended December 31, 2009.

On August 27, 2009, BioClinica acquired the CardioNow unit of Agfa Healthcare, or CardioNow. CardioNow has developed a web-based system for the secure transmission of medical cardiac images. The software was specifically developed for and marketed to the invasive cardiology departments of hospitals within the United States. BioClinica will integrate and enhance the current CardioNow software and service to offer our clients 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. The purchase price for CardioNow consisted of cash consideration paid to Agfa Healthcare of \$1 million. We paid the purchase price for CardioNow with cash from operations. The financial results of CardioNow for the fiscal year are included in the consolidated statement of income for the period ended December 31, 2009.

On January 6, 2009, pursuant to the asset aurchase agreement by and among BioClinica and MBI Benefits, Inc., or MBI, an indirectly owned subsidiary of Metavante Technologies, Inc., or Metavante, dated as of January 6, 2009, we sold our CapMed Division, including the division s Personal Health Record (PHR) software and the patent-pending Personal HealthKey technology, to Metavante. Under the terms of the agreement, Metavante paid us an upfront payment of Five Hundred Thousand Dollars (\$500,000) in cash and will make an earn-out payment to us based upon a percentage of the gross revenues recognized by Metavante for contracts entered into with certain prospects set forth on a schedule during certain time periods in 2009 and 2010. We will receive 25% of the gross revenues recognized by Metavante during any period ending on or prior to December 31, 2010 from the sale pursuant to any contract MBI enters into with certain prospects during the first six months of 2009. Additionally, we will receive 15% of the gross revenues recognized by Metavante during any period ending on or prior to December 31, 2010 from the sale pursuant to any contract MBI enters into with certain prospects during the period commencing on July 1, 2009 and ending on December 31, 2010. At December 31, 2009, we have not received any earn-out payments from Metavante.

#### **Forward Looking Statements**

Certain matters discussed in this Form 10-K are forward-looking statements intended to qualify for the safe harbors from liability established by the Private Securities Litigation Reform Act of 1995. Such forward-looking statements may be identified by, among other things, the use of forward-looking terminology such as believes, expects, may, should or anticipates or the negative thereof or other variations thereon or comparable terminology, or by discussions of strategy that involve risks and uncertainties. In particular, our statements regarding: our projected financial results; the demand for our services and technologies; growing recognition for the use of independent centralized core laboratories; trends toward the outsourcing of imaging services in clinical trials; realized return from our marketing efforts; increased use of digital medical images in clinical trials; integration of our acquired companies and businesses; expansion into new business segments; the success of any potential acquisitions and the integration of current acquisitions; and the level of our backlog are examples of such forward-looking statements. The forward-looking statements include risks and uncertainties, including, but not limited to, the timing of revenues due to the variability in size, scope and duration of projects, estimates made by management with respect to our critical accounting policies, regulatory delays, clinical study results which lead to reductions or cancellations of projects, and other factors, including general economic conditions and regulatory developments, not within our control. The factors discussed in this Form 10-K and expressed from time to time in our filings with the SEC, as well as the risk factors set forth in this Form 10-K, could cause actual results and developments to be materially different from those expressed in or implied by such statements. The forward-looking statements are made only as of the date of this filing, and we undertake no obligation to publicly update such forward-looking statements to reflect subsequent events or circumstances.

#### Critical Accounting Policies, Estimates and Risks

Our discussion and analysis of our financial condition and results of operations are based upon our Consolidated Financial Statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of financial statements in accordance with generally accepted accounting principles in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, including the recoverability of tangible and intangible assets, disclosure of contingent assets and liabilities as of the date of the financial statements and the reported amounts of revenues and expenses during the reported period.

On an on-going basis, we evaluate our estimates. The most significant estimates relate to the recognition of revenue and profits based on the proportional performance method of accounting for fixed service contracts, accounting for acquisitions, capitalization of software development costs, income taxes and fair value accounting for stock based compensation.

We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our Consolidated Financial Statements:

*Revenue*. Service revenues are recognized over the contractual term of our customer contracts using the proportional performance method. Service revenues are first recognized when we have a signed contract from a customer which: (i) contain fixed or determinable fees; (ii) collectability of such fees is reasonably assured; and (iii) services are performed. Any change to recognized service revenue as a result of revisions to estimated total hours are recognized in the period the estimate changes.

We enter into contracts that contain fixed or determinable fees. The fees in the contracts are based on the scope of work we are contracted to perform; there are unitized fees per service and fixed fees with a total

estimated for the contract based upon the estimated unitized service expected to be performed, as well as the service to be delivered under the fixed fee component of the contract. The units are estimated based on the information provided by the customer, and we bill the customer for actual units completed in accordance with the terms of the contract. In the event that a contract is cancelled by the client, we would be entitled to receive payment for all services performed up to the cancellation date.

We, at the request of our clients, directly contract with and pay independent radiologists, referred to as Readers, who review the client s imaging data as part of the clinical trial. The costs of the Readers and other out-of-pocket expenses are reimbursed to us and recognized gross as reimbursement revenues

Goodwill and Other Intangible Assets, Net. Goodwill is not amortized; instead, it is tested for impairment annually (at December 31<sup>st</sup>) or more frequently if indicators of impairment exist or if a decision is made to sell a business. A significant amount of judgment is involved in determining if an indicator of impairment has occurred. Such indicators may include a decline in expected cash flows, a significant adverse change in legal factors or in the business climate, unanticipated competition, or slower growth rates, among others. It is important to note that fair values that could be realized in an actual transaction may differ from those used to evaluate the impairment of goodwill.

Goodwill is allocated among and evaluated for impairment at the reporting level unit, which is defined as an operating segment or one level below an operating segment. BioClinica has one operating segment, clinical trial services, which is a single reporting unit.

We use a discounted cash flow model to estimate the current fair value of the reporting unit when testing for impairment, as management believes forecasted cash flows are the best indicator of such fair value. A number of significant assumptions and estimates are involved in the application of the discounted cash flow model to forecast operating cash flows, including revenue growth rate, operating profit margins, discount rate, tax rates, capital spending, and working capital changes. We consider market participant assumptions in estimating fair value of the reporting unit. Revenue growth rate and operating profit assumptions are consistent with those utilized in our operating plan and long-term financial planning process. Management judgment is required in the determination of each assumption utilized in the valuation model, and actual results could differ from the estimates. At December 31, 2009, we conducted the required annual test of impairment. In 2009, the estimated fair values of the clinical trial services reporting unit was in excess of its carrying values, resulting in no impairment.

Capitalized Software Development. We capitalize development costs for a software project once the preliminary project stage is completed, we have committed to fund the project and it is probable that the project will be completed and the software will be used to perform the function intended. We cease capitalization at such time as the computer software project is substantially complete and ready for its intended use. The determination that a software project is eligible for capitalization and the ongoing assessment of recoverability of capitalized software development costs require considerable judgment by us with respect to certain external factors including, but not limited to, anticipated future revenue, estimated economic life and changes in software and hardware technologies.

Income Taxes. We evaluate the need to record a valuation allowance to reduce our deferred tax assets to an amount that is more likely than not to be realized. In assessing the need for the valuation allowance, we consider our future taxable income and on-going prudent and feasible tax planning strategies. In the event that we were to determine that, in the future, we would be able to realize our deferred tax assets in excess of its net recorded amount, an adjustment to the deferred tax asset would be made, thereby increasing net income in the period such determination was made. Likewise, should we determine that it is more likely than not that we will

be unable to realize all or part of our net deferred tax asset in the future, an adjustment to the deferred tax asset would be charged, thereby decreasing net income in the period such determination was made. We recognize contingent liabilities for any tax related exposures when those exposures are more likely than not to occur.

Stock-based compensation costs. We account for stock-based compensation costs in accordance with FASB ASC 718 Compensation Stock Compensation, which requires the measurement and recognition of compensation expense for all stock-based payment awards made to our employees and directors. Under the fair value recognition of this guidance, stock-based compensation cost is measured at the grant date based on the value of the award and is recognized as expense over the vesting period. Determining the fair value of the stock-based awards at the grant date requires considerable judgment. In addition, judgment is also required in estimating the amount of stock-based awards that are expected to be forfeited. If the actual experience differs significantly from the assumptions used to compute our stock-based compensation cost, or if different assumptions had been used, we may have recorded too much or too little stock-based compensation cost.

### **Foreign Currency Risks**

Our financial statements are denominated in U.S. dollars. Fluctuations in foreign currency exchange rates could materially increase the operating costs of our facilities in the Netherlands and France, which are Euro denominated. A ten percent increase or decrease in the Euro to U.S. dollar spot exchange rate would result in a change of \$215,000 and \$279,000 to our net asset position, at December 31, 2009 and December 31, 2008, respectively. In addition, certain of our contracts are denominated in foreign currency. We believe that any adverse fluctuation in the foreign currency markets relating to these costs will not result in any material adverse effect on our financial condition or results of operations. In the event we derive a greater portion of our service revenues from international operations, factors associated with international operations, including changes in foreign currency exchange rates, could affect our results of operations and financial condition.

Our foreign currency financial assets and liabilities primarily consist of cash, trade receivables, prepaid expenses, fixed assets, trade payables and accrued expenses. We were in a net asset position at December 31, 2009 and December 31, 2008. An increase in the exchange rate would result in less net assets when converted to U.S. dollars. Conversely, if we were in a net liability position, a decrease in the exchange rate would result in more net liabilities when converted to U.S. dollars.

We hedge our foreign currency exposure when and as appropriate to mitigate the adverse impact of fluctuating exchange rates. As of December 31, 2009, there are no outstanding derivative positions.

Results of Operations

Year Ended December 31, 2009 Compared with Year Ended December 31, 2008.

		% of		% of		
		_ Total		_ Total	\$	%
(in thousands)	2009	Revenue	2008	Revenue	Change	Change
Service revenues	\$ 57,393	78.9%	\$ 56,181	81.3%	\$ 1,212	2.2%
Reimbursement revenues	15,330	21.1%	12,935	18.7%	2,395	18.5%
<b>Total revenues</b>	72,723	100.0%	69,116	100.0%	3,607	5.2%
Cost and expenses:						
Cost of service revenues Cost of reimbursement	35,630	49.0%	32,446	46.9%	3,184	9.8%
revenues Sales and marketing	15,330	21.1%	12,935	18.7%	2,395	18.5%
expenses General and administrative	8,052	11.1%	7,860	11.4%	192	2.4%
expenses Amortization of intangible	7,414	10.2%	7,015	10.1%	399	5.7%
assets related to		0 = 4	• • • •			
acquisitions	489	0.7%	380	0.6%	109	28.7%
Restructuring charges Merger and acquisition	466	0.6%		0.0%	466	
related costs	654	0.9%		0.0%	654	
<b>Total cost and expenses</b>	68,035	93.6%	60,636	87.7%	7,399	12.2%
Income from continuing operations before interest						
and taxes	4,688	6.4%	8,480	12.3%	(3,792)	(44.7%)
Interest income	41	0.1%	429	0.6%	(388)	(90.4%)
Interest expense	(13)	0.0%	(7)	0.0%	(6)	85.7%
Income tax provision	(1,757)	(2.4%)	(3,111)	(4.5)%	1,354	(43.5%)
Income from continuing						
operations, net of taxes	\$ 2,959	4.1%	\$ 5,791	8.4%	\$ (2,832)	(48.9%)
Loss from discontinued						
operations, net of taxes		0.0%	(3,001)	(4.3)%	3,001	(100%)
Net income	\$ 2,959	4.1%	\$ 2,790	4.1%	\$ 169	6.1%

The Consolidated Statements of Income for all periods presented reflect the CapMed division in discontinued operations.

The results of operations of CardioNow and Tourtellotte are included in the Consolidated Statements of Income for the period ended December 31, 2009 from the respective acquisition dates. The results of operations for the year ended December 31, 2008 excludes the results of PDS from January 1, 2008 through March 31, 2008 (PDS was acquired on March 24, 2008 and we did not include the eight days from March 24, 2008 through March 31, 2008 due to immateriality).

Service revenues were \$57.4 million for fiscal 2009 and \$56.2 million for fiscal 2008, an increase of \$1.2

million, or 2.2%. The increase in our service revenues was due to a full year of PDS service revenue for fiscal 2009 versus only nine months of PDS service revenue for fiscal 2008 offset by an overall decrease in service revenues for fiscal 2009. Our service revenues have been impacted due to the pharmaceutical companies—response to overall economic conditions, resulting in re-evaluation of drug programs and some contract decisions being delayed. We believe as worldwide demand for new drugs grow, our customers will continue to conduct more clinical trials in pursuit of regulatory approval in countries around the world and clinical trials service organizations, such as ours, with an established global presence, depth of services and expertise, will continue to benefit.

Reimbursement revenues and cost of reimbursement revenues was \$15.3 million for fiscal 2009 and \$12.9 million for fiscal 2008, an increase of \$2.4 million, or 18.5%. Reimbursement revenues and cost of reimbursement revenues consist of payments received from the customer for reimbursable costs. Reimbursement revenues and cost of reimbursement revenues fluctuate significantly over the course of any given project and quarter to quarter variations are a reflection of this project timing. Therefore, our management believes that reimbursement revenues and cost of reimbursement revenues are not a significant indicator of our overall performance trends. At the request of our clients, we may directly pay the independent radiologists who review our client s imaging data. In such cases, per contractual arrangement, these costs are billed to our clients and are included in reimbursement revenues and cost of reimbursement revenues.

Cost of service revenues was \$35.6 million for fiscal 2009 and \$32.4 million for fiscal 2008, an increase of \$3.2 million, or 9.8%. The increase in cost of service revenues is primarily due to a full year of PDS costs in 2009 versus nine months of PDS costs in 2008 and the addition of personnel from the Tourtellotte acquisition in the third quarter of 2009. The cost of service revenues as a percentage of total revenues also fluctuates due to work-flow variations in the utilization of staff and the mix of services provided by us in any given period. We expect that our cost of service revenues will increase in 2010 due to the addition of personnel from Tourtellotte from the acquisition on September 15, 2009 offset by the savings of \$1.6 million from the restructuring in Q2 2009.

Sales and marketing expenses were \$8.1 million for fiscal 2009 and \$7.9 million for fiscal 2008, an increase of \$192,000 or 2.4%. The increase is primarily due to a full year of sales personnel from the PDS acquisition offset by less marketing costs and tradeshow attendance. We expect that sales and marketing expenses will remain relatively flat in fiscal 2010.

General and administrative expenses were \$7.4 million for fiscal 2009 and \$7.0 million for fiscal 2008, an increase of \$400,000, or 5.7%. General and administrative expenses in fiscal 2009 and 2008 consisted primarily of salaries and benefits, allocated overhead, professional and consulting services and corporate insurance. This increase is primarily due to a full year of finance and administrative personnel from the PDS acquisition offset by less professional and consulting service fees. In the second quarter of 2009, as a result of a potential acquisition which was terminated, we incurred \$734,000 of acquisition related costs and received \$750,000, comprised of a \$500,000 break-up fee and \$250,000 expense reimbursement, from the target company, resulting in a \$16,000 gain on the transaction. We expect that our general and administrative expenses will remain relatively flat for fiscal 2010.

Amortization of intangible assets related to acquisitions for fiscal 2009 and 2008 were \$489,000 and \$380,000, respectively, an increase of \$109,000, or 28.7%. Amortization of intangible assets related to acquisitions consisted primarily of amortization of customer backlog, customer relationships, software and non-compete intangibles acquired from the acquisitions of PDS, Tourtellotte and Theralys. The increase is primarily

due to the addition of Tourtellotte. We expect that the amortization of intangible assets related to acquisitions may increase as we look to continue to expand our pharmaceutical contract services through potential acquisitions.

In the second quarter of 2009, in order to streamline the operations and reduce costs, management decided to eliminate certain positions and consolidate redundant departments. This resulted in restructuring charges of \$466,000 consisting of \$439,000 in employee severance and \$27,000 in other close down costs. We have paid the \$466,000 in the third and fourth quarters of 2009 and nothing is left to be paid from the restructuring at December 31, 2009. We expect to realize annual savings of \$1.6 million from the restructuring.

Merger and acquisition related costs of \$654,000 for fiscal 2009 include expenses of \$560,000 consisting of costs resulting directly from merger and acquisition activities for the Tourtellotte and CardioNow acquisitions such as legal, accounting and investment banking fees and other due diligence and integration costs. Also included in this cost is \$94,000 of earn-out accretion from the Tourtellotte acquisition due to the difference in the fair value from the purchase price recorded at the date of acquisition to December 31, 2009. On January 1, 2009, we adopted FASB ASC 805 which requires acquisition-related costs to be expensed in the period in which the costs are incurred and the services are received instead of including such costs as part of the acquisition price.

Net interest income was \$28,000 for fiscal 2009 and net interest income was \$422,000 for fiscal 2008, a decrease of \$394,000, or 93.4%. Net interest income and expense for fiscal 2009 and 2008 is comprised of interest income earned on our cash balance and interest expense incurred on equipment lease obligations. The decrease was due to a decline in market interest rates for short-term cash investments; we expect this trend to continue throughout 2010.

Our income tax provision for fiscal 2009 was \$1.8 million and \$3.1 million for fiscal 2008. Our effective tax rate from continuing operations was 37% for fiscal 2009 and 35% for fiscal 2008. The lower effective tax rate in fiscal 2008 was due to the mix of pre-tax income in the U.S. and in the Netherlands, which has a lower corporate income tax rate than the U.S., and the changes affecting state tax rates.

Results of Operations

Year Ended December 31, 2008 Compared with Year Ended December 31, 2007.

(in thousands) Service revenues Reimbursement revenues	<b>2008</b> \$ 56,181 12,935	% of Total Revenue 81.3% 18.7%	<b>2007</b> \$ 37,543 9,711	% of Total Revenue 79.4% 20.6%	\$ Change \$ 18,638 3,224	% Change 49.6% 33.2%
Total revenues	69,116	100.0%	47,254	100.0%	21,862	46.3%
Cost and expenses: Cost of service revenues	32,446	46.9%	21,900	46.3%	10,546	48.2%
Cost of reimbursement revenues	12,935	18.7%	9,711	20.6%	3,224	33.2%
Sales and marketing expenses	7,860	11.4%	5,005	10.6%	2,855	57.0%
General and administrative expenses Amortization of intangible	7,015	10.1%	5,734	12.1%	1,281	22.3%
assets related to acquisitions	380	0.6%	56	0.1%	324	578.6%
<b>Total cost and expenses</b>	60,636	87.7%	42,406	89.7%	18,230	43.0%
Income from continuing operations before interest						
and taxes	8,480	12.3%	4,848	10.3%	3,632	74.9%
Interest income	429 (7)	$0.6\% \\ 0.0\%$	654 (11)	$1.4\% \\ 0.0\%$	(225)	(34.4)% (36.4)%
Interest expense Income tax provision	(3,111)	(4.5)%	(2,148)	(4.6)%	(963)	44.8%
Income from continuing operations, net of taxes	\$ 5,791	8.4%	\$ 3,343	7.1%	\$ 2,448	73.2%
Loss from discontinued operations, net of taxes	(3,001)	(4.3)%	(1,011)	(2.1)%	(1,990)	196.8%
Net income	\$ 2,790	4.1%	\$ 2,332	5.0%	\$ 458	19.6%

The Consolidated Statements of Income for all periods presented reflect the CapMed division in discontinued operations.

The Consolidated Statement of Income for fiscal 2008 excludes the financial results of PDS from the acquisition date of March 24, 2008 through March 31, 2008 due to immateriality of PDS s results of operations for that period. Service revenues were \$56.2 million for fiscal 2008 and \$37.5 million for fiscal 2007, an increase of \$18.6 million, or 49.6%. The increase in fiscal 2008 service revenues of \$18.6 million, included \$12.5 million in service revenue from PDS from the date of acquisition through December 31, 2008. The additional increase in service revenues of \$6.1 million, a 16.3% increase in non-PDS revenues, resulted from an increase in work

performed from our backlog. In fiscal 2008, no one client accounted for more than 10% of our service revenues, while in fiscal 2007 one client, Hoffmann-La Roche, with 11 projects, represented 13.4% of our service revenues.

Reimbursement revenues and cost of reimbursement revenues was \$12.9 million for fiscal 2008 and \$9.7 million for fiscal 2007, an increase of \$3.2 million, or 33.2%. Reimbursement revenues and cost of reimbursement revenues consist of payments received from the customer for reimbursable costs. Reimbursement revenues and cost of reimbursement revenues fluctuate significantly over the course of any given project and quarter to quarter variations are a reflection of this project timing. Therefore, our management believes that reimbursement revenues and cost of reimbursement revenues are not a significant indicator of our overall performance trends. At the request of our clients, we may directly pay the independent radiologists who review our client s imaging data. In such cases, per contractual arrangement, these costs are billed to our clients and are included in reimbursement revenues and cost of reimbursement revenues.

Cost of service revenues was \$32.4 million for fiscal 2008 and \$21.9 million for fiscal 2007, an increase of \$10.5 million, or 48.2%. Cost of service revenues for fiscal 2008 and 2007 were comprised of professional salaries and benefits and allocated overhead. The increase in cost of service revenues was primarily due to the addition of salaries and other labor related costs of \$7.8 million, a 35.6% increase related to the operations of PDS. The remaining increase of \$2.7 million was attributable to the increase in costs of our European facilities, and an increase in operational personnel to support the increased service revenue. The cost of revenues as a percentage of total revenues also fluctuates due to work-flow variations in the utilization of staff and the mix of services provided by us in any given period.

Sales and marketing expenses were \$7.9 million for fiscal 2008 and \$5.0 million for fiscal 2007, an increase of \$2.9 million, or 57.0%. Sales and marketing expenses in fiscal 2008 and 2007 were comprised of direct sales and marketing costs, salaries and benefits and allocated overhead. The increase was primarily due to the addition of sales personnel from the PDS acquisition along with increased marketing and tradeshow attendance.

General and administrative expenses were \$7.0 million for fiscal 2008 and \$5.7 million for fiscal 2007, an increase of \$1.3 million, or 22.3%. General and administrative expenses in fiscal 2008 and 2007 consisted primarily of salaries and benefits, allocated overhead, professional and consulting services and corporate insurance. The increase was primarily due to the addition of personnel and other professional services related to the administration of PDS.

Net interest income was \$422,000 for fiscal 2008 and net interest income was \$643,000 for fiscal 2007, a decrease of \$221,000, or 34.4%. This decrease is primarily due to a lower investable cash balances and lower interest rates on short term investments. Net interest income and expense for 2008 and 2007 is comprised of interest income earned on our cash balance and interest expense incurred on equipment lease obligations.

Our income tax provision for fiscal 2008 was \$3.1 million and \$2.1 million for fiscal 2007. Our effective tax rate from continuing operations was 34.9% for fiscal 2008 and 39.1% for fiscal 2007. The lower effective tax rate in fiscal 2008 was due to the mix of pre-tax income in the U.S. and in the Netherlands, which has a lower corporate income tax rate than the U.S., and the changes affecting state tax rates.

# Quarterly Results

The following is a summary of unaudited quarterly results of operations for the years ended December 31, 2009 and 2008. This quarterly financial data should be read in conjunction with the audited consolidated financial statements included herein.

# Quarter Ended

	Dec.	Sept.	June	Mar.	Dec.	Sept.	June	Mar.
	31,	30,	30,	31,	31,	30,	30,	31,
(in thousands except per share data)	2009	2009	2009	2009	2008	2008	2008	2008
Service revenues	14,851	14,146	13,921	14,475	14,956	15,093		