BIO IMAGING TECHNOLOGIES INC
Form 10KSB
March 29, 2004
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-KSB

ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF

THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2003

Commission File No. 1-11182

BIO-IMAGING TECHNOLOGIES, INC.

(Name of Small Business Issuer in Its Charter)

Delaware	**11-2872047**
(State or Other Jurisdiction of	**(I.R.S. Employer**
Incorporation or Organization)	**Identification No.)**
826 Newtown-Yardley Road,	
Newtown, Pennsylvania	**18940-1721**

(Address of Principal Executive Offices) **(Zip Code)**

(267) 757-3000

(Issuer s Telephone Number, Including Area Code)

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

Title of each class	**Name of each exchange on which registered**
None	**None**

Securities registered under Section 12(g) of the Exchange Act:

Common Stock, $.00025 par value per share

NASDAQ National Market

Check whether the issuer: (1) filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act during the past 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes: x No: ¨

Check if there is no disclosure of delinquent filers in response to Item 405 of Regulation S-B contained in this form, and no disclosure will 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-KSB or any amendment to this Form 10-KSB. x

State issuer s revenues for fiscal year ended December 31, 2003: $24,971,184

State the aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant: $52,549,765 at February 29, 2004 based on the average bid and asked prices on that date.

Indicate the number of shares outstanding of each of the issuer s classes of common equity, as of February 27, 2004:

Class	**Number of Shares**

Common Stock, $.00025 par value	10,754,864

Transitional Small Business Disclosure Format Yes: ¨ No: x

The following documents are incorporated by reference into the Annual Report on Form 10-KSB: Portions of the Registrant s definitive Proxy Statement for its 2004 Annual Meeting of Stockholders are incorporated by reference into Part III of this Report.

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PART I

Item 1. Business.

Overview

Bio-Imaging is a global pharmaceutical contract service organization, providing services that support the product development process of the pharmaceutical, biotechnology and medical device industries. We specialize in assisting our clients in the design and management of the medical imaging component of clinical trials for all modalities, which consist of computerized tomography, magnetic resonance imaging, x-rays, dual energy x-ray absorptiometry, or DEXA, position emission tomography, single photon emission computerized tomography and ultrasound.

We utilize proprietary processes and software applications in providing our services to pharmaceutical companies conducting clinical studies in which medical imaging modalities are used to evaluate the efficacy and safety of pharmaceuticals, biologics or medical devices. Our digital image processing and computer analysis techniques enable technologists or radiologists to make highly precise measurements and biostatistical inferences about drug or device effects. The resulting data enables our clients and regulatory reviewers, primarily the U.S. Food and Drug Administration and comparable European agencies, to evaluate product efficacy and safety. In addition, we have developed specialized computer services and software applications that enable independent radiologists and other medical specialists involved in clinical trials to review medical image data in an entirely digital format. Our services also include the following:

- Regulatory submission of medical images, quantitative data and text;
- DEXA quality assurance and quality control to the pharmaceutical and medical device industry for studies requiring bone densitometry and body composition measurements; and
- Bio-Imaging ET&C^{SM} services, which focus on education, training and certification for medical imaging equipment, facilities and staff.

We are directing our marketing and sales efforts towards those clinical development areas that heavily depend upon medical imaging. These areas include oncology, musculoskeletal, central nervous system and cardiovascular.

We have a European facility in Leiden, the Netherlands that provides centralized image processing services for our European clients. We manage our services for European-based clinical trials from this facility. Our European facility has the same processing and analysis capabilities as our United States headquarters.

In November 2003, we acquired the intellectual property of CapMed Corporation, located in Wilmington, Delaware, referred to as CapMed, including the Personal Health Record software, referred to as PHR, and the patent-pending Personal HealthKey technology. The PHR is a software application that enables users to manage and store personal health information, including their medical images, on the privacy of their desktop computer, while linking directly to sponsor-directed resources such as drug information, patient education, or disease guidelines. The Personal HealthKey plugs into a computer s USB port, allowing doctors and patients easy access to the patient s medical record without the need

for additional hardware or software, and it is password protected.

We were incorporated in Delaware in 1987 under the name Wise Ventures, Inc. Our name was changed to Bio-Imaging Technologies, Inc. in 1991. 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 also utilize the Internet website www.capmed.com for the CapMed division of our business. We make available on our Internet website all of our public filings with the Securities and Exchange Commission. However, nothing on our Internet website is intended to be incorporated by reference into this Form 10-KSB or any other filing made by us with the Securities and Exchange Commission.

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Business Services

Core Laboratory Services

We are a leading provider of medical imaging management services for clinical development purposes. Our imaging core laboratory facilities in the United States and Europe provide centralized image data collection, processing, analysis and archival services for clinical trials conducted worldwide. The facilities are designed for high-volume efficient processing of film and digital image data in a secure environment that complies with regulatory guidelines for clinical data management.

Medical image data are received by us from clinical trial sites, located throughout the world. We have developed procedures for data tracking and quality control that we believe to be of significant value to our clients. Our facilities 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 for large global multi-center clinical trials.

We perform image analyses on client data using internally developed or specially configured software. We measure key indicators of drug efficacy in different organs and disease states. The results from image analysis derived in our facilities are transferred to databases that can be transmitted electronically to our clients or integrated directly into our Bio/ImageBase package for regulatory submission on our client s behalf.

Information Management Services

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 systems, or CAMR systems, offer 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 CAMR systems, independent medical specialists can review medical image data from clinical trials in a digital format. The CAMR systems can display all modalities of medical image data, regardless of source equipment. In addition, the systems can 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 CAMR systems to read and evaluate image data, medical specialists can achieve greater reading speed than is possible with film and can perform evaluations in a more objective, reproducible manner.

We have also developed remote CAMR systems, or rCAMR systems, that are located on the premises, either home or office, of the individual medical specialists who are engaged by the sponsor to perform the analysis of the medical image data. Historically, the CAMR systems have been utilized to determine efficacy of the compounds being studied. More recently, clients are requesting us to provide rapid turn-around reads for inclusion/exclusion criteria. We believe that the rCAMR system is the optimal tool for this type of 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.

We have developed an image database software application, Bio/ImageBase, that enables our clients to submit their medical images and related clinical data to the FDA in a digital format. Using data stored on CD-ROM or DVD disks, Bio/ImageBase allows clients and FDA medical reviewers to review medical images and related clinical data. We believe that Bio/ImageBase offers the potential to decrease review time, resulting in faster regulatory approvals and reduced time-to-market for new drugs, biologics and medical devices.

Our Bio/ImageBase software has been installed at client sites and on two off-the-shelf image reading and review computer systems at the FDA. We have been using our Bio/ImageBase software to submit medical

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images and related data to the FDA since mid-1993. In March 1996, Bio/ImageBase was cited in the FDA s 1996 Computer-Assisted Product License Application Guidance Manual as an acceptable database for submission of imaging data.

Education, Training and Certification

Bio-Imaging ET&C[SM] focuses on education, training and certification for medical imaging equipment, facilities and staff. A program of Instrument Quality Control will provide physicians with a method of ensuring that systems operate to specifications on a continual basis. This program is designed to protect the accuracy of diagnostic interpretation of bone density data and give the physicians current and in-depth feedback on the status of their instruments. In addition, Bio-Imaging ET&C[SM] will train entry-level physicians and allied health professionals in routine clinical practice.

CapMed Division

Our CapMed division includes the PHR, which is a software application that enables users to manage and store personal health information, including their medical images, on the privacy of their desktop computer, while linking directly to sponsor-directed resources such as drug information, patient education or disease guidelines. CapMed also includes the Personal HealthKey that plugs into a computer s USB port, allowing doctors and patients easy access to the patient s medical record without the need for additional hardware or software, and it is password protected.

Other Services

We provide technical consulting in the evaluation of the sites that may participate in clinical trials. We also consult with clients regarding regulatory issues involved in the design, execution, analysis and submission of medical image data in clinical trials.

Target Markets

Our primary target market is comprised of pharmaceutical, biotechnology and medical device companies whose clinical development pipelines include drugs, biologics or devices that are typically evaluated by medical imaging methods. This target market includes leading international pharmaceutical companies and biotechnology companies with products currently in the clinical development pipeline.

We focus our marketing on the following stages of clinical development:

Phase II - Clinical Trials

Phase II clinical trials are generally conducted over six months to two years and involve basic efficacy, safety and dose-range testing in approximately 50 to 400 patients suffering from the disease or condition under study. Such trials help determine the best effective dose, confirm that the drug works as expected and provide initial safety data.

Phase III - Clinical Trials

Phase III clinical trials are generally conducted over one to four years and involve efficacy and safety studies in broader populations of hundreds or thousands of patients and many investigational sites, such as hospitals and clinics. These trials are sometimes referred to as pivotal studies for submission to the regulatory agencies. Generally, Phase III studies are intended to provide additional information on drug safety and efficacy, and the evaluation of the risk-benefit of the drug and information for the adequate labeling of the product.

Phase IV - Post Approval Studies

Phase IV studies are studies conducted after a pharmaceutical drug or device has been approved for use. These studies are generally conducted over a two to four year period and involve either a continuation of a

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Phase III patient population or the recruitment of a new patient population. As there continues to be pressure to expedite approval of pharmaceuticals and medical devices, there is an increase in the number of conditional approvals based on the conduct of additional Phase IV studies.

We further focus our marketing efforts on Phase II, III and IV clinical trials for the following classes of drugs:

Musculoskeletal Therapeutics

Anti-inflammatory clinical trials, such as those focused on arthritis, include radiologic evaluation of the bones and joints to determine drug efficacy. We believe that demand among drug developers for our services will increase as new classes of biotechnology-derived drugs enter and progress through the clinical development pipeline.

Osteoporosis is a disease characterized by thinning bones, which leads to fractures in the elderly. The FDA guidance document for developing treatments for this disease recognized DEXA as one of the primary efficacy and safety measurement tools available. Furthermore, all data needs to go through a quality assurance laboratory. This is now standard practice in all studies using DEXA instruments whether for osteoporosis oncology or anti-obesity or muscle wasting assessment.

Cancer Therapeutics

Many pharmaceutical companies are currently developing new therapies for the treatment of cancer. For solid tumor studies, medical imaging modalities are used to determine the response of treated and untreated tumors. These medical images are evaluated by medical specialists during the course of oncology clinical trials to determine the extent of disease and changes in tumor size over time.

The FDA s guidelines aimed at accelerating access to new drugs for the review and approval of new cancer therapies place greater emphasis on shrinkage of tumors as an early indicator of anti-tumor efficacy. We believe that these FDA guidelines may have a favorable impact on our business as pharmaceutical and biotechnology companies may have an increased need for regulatory compliant medical imaging services to conduct their oncology clinical trials.

Central Nervous System Therapeutics

Various pharmaceutical companies are currently developing drugs for treatment of diseases and conditions of the central nervous system, most of which are evaluated with the aid of medical imaging. Most later-stage clinical trials for these serious and costly conditions involve the evaluation of medical image data. We believe that the central nervous system clinical trials business may increase as more therapies progress through the research pipeline.

Diagnostic Imaging Agents

We provide our services to clients developing diagnostic imaging agents that are designed to diagnose disease conditions more quickly and accurately in their development in order to facilitate earlier and more accurate treatment.

Cardiovascular Therapeutics

Various pharmaceutical companies are currently developing drugs for the diagnosis and treatment of cardiovascular diseases and conditions that are evaluated with the aid of medical imaging. We provide our services to clients developing diagnostic agents for the detection and treatment of these conditions.

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Market Trends

We believe that demand for our services should grow because of a variety of favorable regulatory, technological and market trends:

The FDA initiatives to streamline the regulatory submission and review process that are being implemented should have a beneficial impact on us. The FDA is investing in new information technology and is continuing the process of formulating and disseminating guidelines for standardizing the submission of electronic data, including medical images. We expect submission of image data to be a requirement in key therapeutic and diagnostic areas for evaluating the effectiveness of a drug or imaging agent.

Consolidation, restructuring and downsizing in the pharmaceutical industry in response to downward pressure on certain pharmaceutical and biotechnology companies drug prices has resulted in increased outsourcing of certain research and development activities.

Overall, growth in pharmaceutical and biotechnology research and development spending is increasing. As a result, we believe that the outsourcing of development activities should like-wise increase.

New classes of drugs to treat conditions traditionally evaluated by imaging are entering or progressing through the clinical development pipeline, leading to increased demand for medical imaging-related services. In addition, we believe that digital technologies for data acquisition and management are penetrating the radiology community.

We believe that as pharmaceutical and biotechnology companies increasingly attempt to expand the market for new drugs by conducting clinical trials and pursuing regulatory approval in multiple countries simultaneously, contract service organizations with a global presence and expertise will continue to benefit.

Intellectual Property

Proprietary protection for our computer-imaging programs, processes and know-how 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 Bio/ImageBase, CAMR, rCAMR, Intelligent Imaging and Personal Health Key. We hold patents for the two DEXA phantoms, titled Spine and Variable Composition Phantoms, which we sell to trial sites. We have a patent pending on our Personal Health Key. 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

The research and development, manufacture and marketing of drugs and medical devices are subject to stringent regulation by the FDA in the United States and by similar authorities in other countries. In addition, regulations imposed by other federal agencies, as well as state and local authorities, may impact such research and development, manufacturing and marketing.

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

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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 developmental 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 the guidelines announced in March 1996, 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 much greater reliance on the use of medical image data to demonstrate objective tumor shrinkage. In addition, in March 1997, the FDA announced new guidelines aimed at accelerating all therapeutic categories through the use of imaging markers such 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 may have a favorable impact on our business.

In May 2003, the FDA released draft guidance for the industry relating to how medical imaging should be defined, handled and evaluated in clinical trials. We believe that this guidance comports with the methodologies and processes utilized by us in providing medical information management services for our clients.

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 prospects.

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

We continue to experience competition from commercial competitors and academic research centers. The biopharmaceutical services industry is highly competitive, and we face numerous potential competitors in our business, including hundreds of contract research organizations. We primarily compete against small specialty contract research organizations, or CROs, and to a lesser extent, universities and teaching hospitals. 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.

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Marketing and Sales

We provide and market our services on an international basis primarily to pharmaceutical and biotechnology companies. Our sales and marketing activities are directed by a Senior Vice President of Business Development and supported by in-house staff and field business development personnel.

Our selling efforts are focused on North America and Western Europe. Sales efforts are directed from both of our headquarters in Pennsylvania and Leiden, the Netherlands. Our marketing activities include exhibiting at major trade shows, advertising in trade journals and the sponsoring of industry associations.

Significant Clients

During fiscal 2003, one client, NPS Pharmaceuticals, Inc., or NPS, accounted for approximately 14% of our project revenues encompassing four projects. However, no one contract with NPS accounted for more than 10% of project revenues. No other customer accounted for more than 10% of project revenues. These contracts are terminable by our client at any time and for any reason. The loss of this client, or a reduction in services provided to this client, would have a material adverse effect on our business, financial condition and results of operations.

Employees

As of December 31, 2003, we had 223 employees, four of whom are executive officers.

Of our employees, as of December 31, 2003, ten were engaged in sales and marketing, 189 were engaged in client related projects and 24 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, competition for such personnel is intensifying. Although all of our employees are covered by confidentiality and non-competition agreements, we cannot assure you that such agreements will be enforceable. As of February 29, 2004, we have employment agreements with two of our executive officers. See Item 10. Executive Compensation. We consider relations with our employees to be good.

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.

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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. We have not recently experienced cancellations or delays due to any of the factors identified above.

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 loss of all of the business from our client NPS would have a material adverse effect on our financial condition.

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:

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.

Revenues from one client, NPS, encompassing four distinct projects, amounted to 14% of service revenues for the year ended December 31, 2003 and 13% of service revenues for the year ended December 31, 2002. The loss of business from a significant client or our failure to continue to obtain new business 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 approximately $41.3 million at December 31, 2003 is based on anticipated net service revenue from uncompleted projects with clients. Backlog is the amount of 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 the client cancels a contract, 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 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.

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

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We have experienced substantial expansion in the past, and if we fail to properly manage that expansion, our business may suffer.

Our business has expanded substantially in the past. Service revenues for fiscal 2003 were $21,747,636, an increase of approximately 26.5% over service revenues for fiscal 2002 of $17,189,762. Our continuing sales and marketing efforts have increased the number of projects under management from 141 in 2001 to 186 in 2002. Although the number of projects under management for 2003 remained relatively constant with 2002, the value of these projects has increased and, therefore, the amount of work required has also increased. We had 223 employees in 2003 and 175 employees in 2002. Rapid expansion could strain our operational, human and financial resources. If we fail to properly manage this expansion, our results of operations and financial condition might be adversely affected. In order to manage our expansion, we must:

effectively market our services to pharmaceutical, biotechnology and medical device companies;

continue to improve operating, administrative and information systems;

accurately predict future personnel and resource needs to meet client contract commitments;

track the progress of on-going client projects; and

attract and retain qualified management, sales, professional and technical operating personnel.

We will face additional risks in expanding foreign operations. Specifically, we might find it difficult to:

assimilate differences in foreign business practices and regulations;

hire and retain qualified personnel; and

overcome language and cultural barriers.

We may engage in future acquisitions, which may be expensive and time consuming and from which we may not realize anticipated benefits.

We 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. We currently have no commitments or agreements with respect to any acquisitions. If we do undertake transactions of this sort, the process of integrating an 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 acquisition. We believe that the integration associated with our acquisition of Intelligent Imaging has been substantially completed, and that we did not experience any significant difficulties in such integration. Future acquisitions could result in potentially dilutive issuances of our securities, the incurrence of debt and contingent liabilities and amortization expenses related to intangible assets, 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, David A. Pitler, Senior Vice President Operations, Colin G. Miller, Ph.D., Senior Vice President Business Development and Ted I. Kaminer, Senior Vice President and Chief Financial Officer. Although we have an employment agreement with each of Mr. Weinstein and Mr. Kaminer, this does not necessarily mean that either of them will remain with us. 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

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of any key executives, 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.

In fiscal 2003, we derived a small portion of service revenues from international operations. Our financial statements are denominated in United States dollars. 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. Fluctuations in foreign currency exchange rates could materially impact the operating costs of our facility in the Netherlands, which are primarily EURO denominated.

Risks Related to Our Industry

Our failure to compete effectively in the competitive industry will 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 will be materially harmed.

The biopharmaceutical services industry is highly competitive, and we face numerous competitors in our business, including hundreds of contract research organizations. 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 contract research organizations, or CROs, small specialty CROs, and to a lesser extent, universities and teaching hospitals. Some of these competitors, including the in-house departments of pharmaceutical companies, have 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.

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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 on new drugs, our clients might reduce their research and development spending, which could reduce our business.

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

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may not 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. If the governmental agencies do not accept data and analyses generated by our services in connection with the evaluation of new drugs and devises, 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.

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, 2003, we had the following capital structure:

Common stock outstanding	10,710,481
Common stock issuable upon:	
Exercise of options which are outstanding	1,807,927
Exercise of options which have not been granted	1,542,073
Conversion of outstanding convertible note	145,068
Total common stock outstanding assuming exercise or conversion of all of the above	14,205,549

As of December 31, 2003, we had outstanding options to purchase approximately 1,807,927 shares of common stock at exercise prices ranging from $0.63 to $4.74 (exercisable at a weighted average of $1.41 per share), of which approximately 1,542,579 options were then exercisable. Exercise of our outstanding options into 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, at December 31, 2003, we had outstanding a convertible promissory note in the principal amount of $666,664. The number of shares of common stock into which the note may be converted is calculated by dividing the outstanding principal balance of the note, plus all accrued and unpaid interest, by the greater of: (i) 75% of the average closing price of our common stock over the ten consecutive trading days ending prior to the date of conversion; or (ii) $0.906 per share. As of December 31, 2003, the note was convertible into 145,068 shares of our common stock. Under the formula contained in the note, at the minimum price per share of $0.906, the maximum number of shares of our common stock to be issued to Quintiles, Inc., based upon the outstanding principal amount and accrued interest at December 31, 2003, would be 741,351 shares. 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 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, 2003, we had 10,710,481 shares of our common stock issued and outstanding. Of this amount, 6,404,932 are freely tradable and 4,305,549 are registered on a Form S-3 with the Securities and Exchange Commission.

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We are unable to estimate the number of shares that may be sold since 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 the securities offered hereby and may adversely affect our ability to obtain future financing in the capital markets as well as create a potential market overhang.

Our affiliates 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 influence may conflict with our interests and the interests of our other stockholders.

Our directors, officers and principal stockholders, including Covance Inc., Quintiles, Inc. and certain of their affiliates, beneficially owned approximately 37% of the outstanding shares of common stock on a fully diluted as-converted to common stock basis at December 31, 2003, 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.

Our earnings may be adversely affected if we change our accounting policy with respect to employee stock options.

Stock options are an important component of compensation packages for most of our mid- and senior-level employees. We currently do not deduct the expense of employee stock option grants from our income. Many companies, however, are considering a change to their accounting policies to record the value of stock options issued to employees as an expense and changes in the accounting treatment of stock options are currently under consideration by the Financial Accounting Standards Board and other accounting standards-setting bodies. If we were to change our accounting policy with respect to the treatment of employee stock option grants, our earnings could be materially adversely affected. For example, if we applied the fair value recognition provisions under consideration, our net income for fiscal 2003 would have been $1,533,767, as compared to the reported net income of $2,337,853, and our net income for fiscal 2002 would have been $935,360, as compared to the reported net income of $1,139,837.

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.

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The market has also experienced significant decreases in value. This volatility and the recent market decline has affected 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, 2003 and December 31, 2003, our common stock has traded at a low of $2.15 per share and a high of $8.10 per share.

Our common stock began trading on the NASDAQ National Market on December 18, 2003 and has a limited trading market. Prior to that time, our common stock was trading on the American Stock Exchange since February 2003. We cannot assure that an active trading market will develop or, if develop