BIO IMAGING TECHNOLOGIES INC
Form 10KSB
March 28, 2003
Table of Contents

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, 2002

Commission File No. 1-11182

BIO-IMAGING TECHNOLOGIES, 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, $.00025 par value per share	**American Stock Exchange Boston Stock Exchange**

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

None

Check whether the Registrant: (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. ¨

State Registrant s revenues for fiscal year ended December 31, 2002: $20,468,081

State the aggregate market value of the voting stock held by non-affiliates of the Registrant: $17,268,945 at February 28, 2003 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 Stock, as of February 28, 2003:

Class	Number of Shares
Common Stock, $.00025 par value	8,659,327

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 2003 Annual Meeting of Stockholders are incorporated by reference into Part III of this Report.

Table of Contents

TABLE OF CONTENTS

i

Table of Contents

PART I

Item 1. Business.

General

Bio-Imaging Technologies, Inc. (Bio-Imaging or the Company) is a pharmaceutical contract service organization, providing services that support the product development process of the pharmaceutical, biotechnology and medical device industries. The Company specializes in assisting its clients in the design and management of the medical-imaging component of clinical trials for all modalities, which consist of computerized tomography (CT), magnetic resonance imaging (MRI), x-rays, dual energy x-ray absorptiometry (DEXA), position emission tomography single photon emission computerized tomography (PET SPECT) and ultrasound.

The Company utilizes proprietary processes and software applications in providing its services to pharmaceutical companies conducting clinical studies in which medical imaging modalities are used to evaluate the efficacy (effectiveness) and safety of pharmaceuticals, biologics or medical devices. The Company s digital image processing and computer analysis techniques enable it to make highly precise measurements and biostatistical inferences about drug or device effects. The resulting data enable the Company s clients and their regulatory reviewers (primarily the U.S. Food and Drug Administration (the FDA) and comparable European agencies) to evaluate product efficacy and safety. In addition, the Company has 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. The Company s services also include the regulatory submission of medical images, quantitative data and text.

The Company continues to believe that it is at an early stage of market penetration and is directing its marketing and sales efforts towards those clinical development areas that heavily depend upon medical imaging. These areas include therapeutic and diagnostic anti-inflammatory, oncology, central nervous system, osteoporosis and cardiovascular.

The Company has a European facility in Leiden, the Netherlands that provides centralized image processing services for European clients. The Company manages its services for European based clinical trials from this facility. The Company s European facility has the same capabilities as the Company s U.S. headquarters.

The Company also provides DEXA quality assurance and quality control (QA/QC) to the pharmaceutical and medical device industry for studies requiring bone densitometry and body composition measurements.

The Company also offers a service called Bio-Imaging ET&C[SM]. Bio-Imaging ET&C[SM] focuses on education, training and certification for medical imaging equipment, facilities and staff.

On October 1, 2001, the Company acquired effective control of the Intelligent Imaging business unit (Intelligent Imaging) of Quintiles, Inc., a North Carolina corporation and a wholly-owned subsidiary of Quintiles Transnational Corporation (Quintiles), All Intelligent Imaging personnel

at the time of the acquisition became employed by the Company and all of the clinical projects, which were handled by Intelligent Imaging, are now being managed by the Company. Intelligent Imaging specializes in providing digital medical imaging services for clinical trials and the health care industry.

The Company was incorporated in Delaware in 1987 under the name Wise Ventures, Inc. The Company s name was changed to Bio-Imaging Technologies, Inc. in 1991. The address of the Company s principal executive offices is 826 Newtown-Yardley Road, Newtown, Pennsylvania, 18940, and its telephone number is 267-757-3000. The Company s Internet website is www.bioimaging.com. The Company makes available on its Internet website all of its public filings with the Securities and Exchange Commission, however, nothing on the

Table of Contents

Company s Internet website is intended to be incorporated by reference into this Form 10-KSB or any other filing made by the Company with the Securities and Exchange Commission.

Business Services

Core Laboratory Services

Bio-Imaging is a leading provider of medical imaging management services for clinical development purposes. The Company s imaging core laboratory facilities in the U.S.A. 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 analog (film) and digital image data in a secure environment that complies with regulatory guidelines for clinical data management.

Medical image data are received by Bio-Imaging facilities from clinical trial sites, located throughout the World. The Company has developed procedures for data tracking and quality control that it believes to be of significant value to its clients. The Company s 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. The Company believes its 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.

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

Information Management Services

Bio-Imaging s information management services focus on providing specialized solutions for improving the quality, speed and flexibility of image data management for clinical trials. The Company s Computer Assisted Masked Reading (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 the Company s 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.

The Company has also developed remote CAMR (rCAMR) systems which 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 Bio-Imaging to provide real-time reads for inclusion/exclusion criteria, or safety reads. The Company believes that the rCAMR system is the optimal tool for this type of work because it allows Bio-Imaging, at the 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.

The Company has developed a proprietary image database software application, Bio/ImageBase®, that enables the Company s clients to submit their medical images and related clinical data to the FDA in a digital

Table of Contents

format. Using data stored on CD-ROM or DVD disks, Bio/ImageBase® allows clients and their FDA medical reviewers to review medical images and related clinical data. The Company believes 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.

The Company s Bio/ImageBase® software has been installed at client sites and on certain computer systems at the FDA. The Company has been using its Bio/ImageBase® software to submit medical 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℠ focuses on education, training and certification for medical imaging equipment, facilities and staff. A program of Instrument Quality Control (IQC) 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℠ will train entry-level physicians and allied health professionals in routine clinical practice.

Other Services

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

Target Markets

The Company s 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.

Bio-Imaging focuses its 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 (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, an evaluation of the risk-benefit of the drug and information for the adequate labeling of the product.

Table of Contents

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

Bio-Imaging focuses its marketing efforts further on clinical trials for the following classes of drugs:

Anti-Inflammatory Therapeutics

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

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. Bio-Imaging believes that these FDA guidelines may have a favorable impact on its 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. The Company believes that its central nervous system clinical trials business may increase as more therapies progress through the research pipeline.

Osteoporosis

Osteoporosis is the disease of 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 antiobesity or muscle wasting assessment.

Diagnostic Imaging Agents

Bio-Imaging provides its services to clients developing diagnostic imaging agents which are designed to diagnose disease conditions more quickly and accurately in their development in order to facilitate earlier and more accurate treatment.

Table of Contents

Cardiovascular Therapeutics

Various pharmaceutical companies are currently developing drugs for the diagnosis and treatment of cardiovascular diseases and conditions which are evaluated with the aid of medical imaging. The Company provides its services to clients developing diagnostic agents for the detection and treatment of these conditions.

Market Trends

The Company believes that demand for its 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 which are being implemented should have a beneficial impact on the Company. 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. The Company expects 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. Currently, over $8 billion in research services are outsourced to clinical contract research organizations. Industry estimates place growth of outsourcing between 12% to 16% per year for at least the next three years.

Overall, growth in pharmaceutical and biotechnology research and development spending is increasing and is fairly non-cyclical. As a result, the Company believes that the growth in outsourcing of development activities should continue to remain steady.

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, the Company believes digital technologies for data acquisition and management are rapidly penetrating the radiology community.

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. The Company believes it is well-positioned to take advantage of these trends due to its U.S. and European operations.

The Company also believes that because of its extensive experience and expertise it can consistently deliver these specialized development services more quickly and efficiently than a pharmaceutical or biotechnology company could perform internally.

Intellectual Property

Proprietary protection for the Company s computer-imaging programs, processes and know-how is important to its business. Bio-Imaging has developed certain technically derived procedures and computer software applications that are intended to increase the effectiveness and quality of its services. The Company relies upon trademarks, copyrights, trade secrets, know-how and continuing technological innovation to develop and maintain its competitive position. The Company has obtained registered trademark protection for the Bio/ImageBase® and has claimed trademark protection for CAMR, rCAMR and Intelligent Imaging. The Company holds patents for the two DEXA phantoms, titled Spine and Variable Composition Phantoms, which it sells to trial sites. The Company has registered its Stylized Man Design with the U.S. Patent and Trademark Office. Furthermore, Bio-Imaging requires all employees, consultants and contractors to execute confidential disclosure agreements as a condition of employment or engagement by the Company. There can be no assurance,

Table of Contents

however, that the Company can limit unauthorized or wrongful disclosures of trade secrets or otherwise confidential information. In addition, to the extent the Company relies on trade secrets and know-how to maintain its competitive technological position, there can be no assurance that others may not develop independently the same, similar or superior techniques. Although the Company s intellectual property rights are important to the results of its operations, the Company believes that other factors such as independence, process knowledge, technical expertise and experience are more important, and that, overall, these technological capabilities offer significant benefits to its 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 comparable 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 which 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. The Company advises its clients in the execution of clinical trials and other drug and device developmental tasks. The Company does not administer drugs to or utilize medical devices on patients.

The success of the Company s business is dependent upon continued acceptance by the FDA and other regulatory authorities of the data and analyses generated by the Company s services in connection with the evaluation of the safety and efficacy of new drugs and devices. The FDA has formal guidelines which encourage the use of surrogate measures, through submission of digital image data, for evaluation of drugs to treat life-threatening or debilitating conditions. There can be no assurance, however, that the FDA or other regulatory authorities will accept the data or analyses generated by the Company in the future and, even assuming acceptance, there can be no assurance 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. The Company believes the FDA s initiatives to streamline and accelerate the submission and review process of therapeutic agents may have a favorable impact on the Company s business.

In October 1998, the FDA released a draft guidance for the industry relating to how medical imaging should be defined, handled and evaluated in clinical trials. In June 2000, the FDA released another draft guidance which provided more details on the October 1998 draft guidance. The Company believes that the guidance documents comports with the methodologies and processes utilized by the Company in providing medical information management services for its clients.

The Company believes that its 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 the Company s prospects.

6

Table of Contents

The current European market regulation is more fragmented than in the U.S.A., therefore, such European agencies have a tendency to follow FDA guidelines.

Competition

As a sign of growth in the clinical trials-related medical imaging services business, the Company continues to experience competition from commercial competitors and academic research centers. As competition increases, Bio-Imaging will look to provide value-added services and undertake marketing and sales programs to differentiate its services based on its expertise and experience in specific therapeutic and diagnostic areas, its technical expertise, its regulatory and clinical development experience, its quality performance and its international capabilities. Competition in the Company s industry has resulted in additional pressure being placed on price, service and quality. Although the Company believes that it is well positioned against its competitors due to its experience in clinical trials and regulatory compliance along with its international presence, there can be no assurance that the Company s competitors or clients will not provide or develop services similar or superior to those provided by the Company. Any such competition could have a material adverse impact on the Company. The Company s competitive position also depends upon its ability to attract and retain qualified personnel and develop and preserve proprietary technology, processes and know-how.

Marketing and Sales

Bio-Imaging provides and markets its services on an international basis primarily to pharmaceutical and biotechnology companies. The Company s sales and marketing activities are directed by a Vice President of Business Development, and supported by in-house staff and field business development personnel.

The Company s selling efforts are focused on North America and Western Europe. Sales efforts are directed from both of the Company s headquarters in Pennsylvania and Leiden, the Netherlands. The Company s marketing activities include exhibiting at major trade shows, advertising in trade journals and the sponsoring of industry associations. The Company continues to evaluate appropriate co-marketing activities and strategic alliances, in particular with contract research organizations, to augment its own business development efforts.

Significant Clients

During fiscal 2002, one client accounted for approximately 13% of the Company s project revenues encompassing four projects. No other customers accounted for more than 10% of project revenues. These contracts are terminable by the Company s clients at any time and for any reason. The loss of such clients, or a reduction in services provided to such clients, would have a material adverse effect on the Company s business, financial condition and results of operations.

Employees

As of December 31, 2002, the Company had 175 employees, five of whom are officers of the Company.

Of the Company s employees, as of December 31, 2002, nine were engaged in sales and marketing, 146 were engaged in client related projects and 20 were engaged in administration and management. A significant number of the Company s management and professional employees have prior industry experience. Bio-Imaging believes that it has been successful in attracting skilled and experienced personnel, however, competition for such personnel is intensifying. Although all of the Company s employees are covered by confidentiality and non-competition agreements, there can be no assurance that such agreements will be enforceable. As of February 18, 2003, Bio-Imaging had employment contracts with two of its executive officers. See Item 10. Executive Compensation. Bio-Imaging considers relations with its employees to be good.

Table of Contents

Factors that Might Affect the Company s Business, Future Operating Results, Financial Condition and/or Stock Price

The more prominent risks and uncertainties inherent in the Company s business are described below. However, additional risks and uncertainties may also impair its business operations. If any of the following risks actually occur, the Company s business, financial condition or results of operations may suffer.

The Company may bear financial losses because contracts may be delayed or terminated or reduced in scope for reasons beyond the Company s control.

The Company s clients may terminate or delay their contracts for a variety of reasons, including, but not limited to:

the failure of products to satisfy safety requirements;

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; or

the Company s failure to perform its obligations under the contract.

In addition, the Company believes 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.

The loss, reduction in scope or delay of a large contract or the loss or delay of multiple contracts could materially adversely affect the Company s business, although the Company s contracts entitle them to receive all fees earned by the Company up to the time of termination.

The Company depends on a small number of industries and clients for all of the Company s business, and the loss of one such significant client could cause revenues to drop quickly and unexpectedly.

The Company depends on research and development expenditures by pharmaceutical, biotechnology and medical device companies to sustain its business. The Company s 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 the Company; or

clients reduce their research and development expenditures.

For the year ended December 31, 2002, revenues from one client, encompassing 4 distinct projects, amounted to 13%, of service revenues. The loss of business from this one significant client or failure of the Company to continue to obtain new business would have a material adverse effect on the Company s business and revenues.

The Company s contracted/committed backlog may not be indicative of future results.

The Company reported contracted/committed backlog of $36.5 million at December 31, 2002 (Backlog), based on anticipated net service revenue from uncompleted projects with clients. Backlog is the amount of

Table of Contents

revenue that remains to be earned and recognized on signed and agreed to contracts. The Company cannot assure that the Backlog reported 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; and a change in the scope of work during the course of a project; and
- the cancellation of such contracts by the Company s 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.

Failure by the Company to compete effectively in the competitive industry will cause the Company s revenues to decline.

Significant factors in determining whether the Company 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; and
- the Company s size.

If services are not competitive based on these or other factors, the Company s business, financial condition and results of operations will be materially harmed.

The Company has experienced substantial expansion in the past, and must properly manage that expansion.

The Company s business has expanded substantially in the past. Rapid expansion could strain the Company s operational, human and financial resources. If the Company fails to properly manage this expansion, its results of operations and financial condition might be adversely affected. In order to manage its expansion, the Company must:

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.

The Company will face additional risks in expanding foreign operations. Specifically, the Company might find it difficult to:

assimilate differences in foreign business practices and regulations;

hire and retain qualified personnel; and

overcome language and cultural barriers.

Table of Contents

Changes in outsourcing trends in the pharmaceutical and biotechnology industries could adversely affect 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 the Company s clients in these industries also affect its business. For example, the practice of many companies in these industries has been to hire outside organizations like Bio-Imaging to conduct clinical research projects. This practice has grown significantly in the last decade, and the Company has 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, the Company s 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 on new drugs, the Company s clients might reduce their research and development spending, which could reduce its business.

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

Any failure on the Company s part to comply with applicable regulations could result in the termination of on-going clinical research or the disqualification of data for submission to regulatory authorities.

Changes in governmental regulation could decrease the need for the services the Company provides, which would negatively affect the Company s future business opportunities.

In recent years the United States Congress and state legislatures have considered various types of health care reform in order to control growing health care costs. The United States Congress and state legislatures may again address health care reform in the future. The Company is 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 health care 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 the clients research and development expenditures, which could, in turn, decrease the business opportunities available to the Company 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. The Company cannot predict the likelihood of any of these events.

Governmental agencies throughout the world, but particularly in the United States, strictly regulate the drug development/approval process. The Company s 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 the Company may have difficulty satisfying, could eliminate or substantially reduce the need for the Company s services. Therefore, as a result the Company s 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 the Company s business opportunities available.

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

Future success depends on the personal efforts and abilities of the principal members of the Company s senior management to provide strategic direction, develop business, manage operations and maintain a cohesive and stable environment. Specifically, the Company is dependent upon Mark L. Weinstein, President and Chief Executive Officer, David A. Pitler, Vice President Operations and Colin G. Miller, Ph.D., Vice President

Table of Contents

Business Development. Although the Company has an employment agreement with Mr. Weinstein, this does not mean Mr. Weinstein will remain with the Company. The Company does not have employment agreements with any other key personnel. Furthermore, the Company s performance also depends on its 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 executives, or inability to continue to attract and retain qualified staff, could have a material adverse affect on the Company s business, results of operations and financial condition.

The Company may be exposed to liability claims as a result of involvement in clinical trials.

The Company may be exposed to liability claims as a result of involvement in clinical trials. There can be no assurance that liability claims will not be asserted against the Company as a result of work performed for its clients. Furthermore, there can be no assurance that the Company s clients will agree to indemnify the Company, or that the Company will have sufficient insurance to satisfy any such liability claims. If a claim is brought against the Company and the outcome is unfavorable to the Company, such outcome could have a material adverse impact on the Company.

The Company s revenues and earnings are exposed to exchange rate fluctuations.

In 2002, the Company derived a small portion of service revenues from international operations. The Company s financial statements are denominated in U.S. dollars. As a result, factors associated with international operations, including changes in foreign currency exchange rates, could affect the Company s results of operations and financial condition.

The Company s earnings may be adversely affected if it changes its accounting policy with respect to employee stock options.

Stock options are an important component of compensation packages for most of the Company s mid- and senior-level employees. The Company currently does not deduct the expense of employee stock option grants from its 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 International Accounting Standards Board and other accounting standards-setting bodies. If the Company were to change its accounting policy with respect to the treatment of employee stock option grants, its earnings could be materially adversely affected.

We previously used Arthur Andersen LLP as our independent public accountants.

The audited consolidated statements of income, stockholders equity and cash flows of the Company and its subsidiaries as of September 30, 2001 included in this Annual Report on Form 10-KSB were audited by Arthur Andersen LLP, independent public accountants (Arthur Andersen), then as stated in their report thereon dated as of October 31, 2001, which is included herein. On March 14, 2002, Arthur Andersen was indicted on federal obstruction of justice charges arising from the federal government s investigation of Enron Corporation. On April 15, 2002, upon the recommendation of the Audit Committee of the Company s board of directors, the Company s board of directors approved the dismissal of Arthur Andersen as the Company s independent public accountants and the appointment of PricewaterhouseCoopers LLP to serve as the Company s independent public accountants for the fiscal year ending December 31, 2002 and for the transition period ending December 31, 2001.

Arthur Andersen was convicted on federal obstruction of justice charges on June 15, 2002, ceased practicing before the Securities and Exchange Commission on August 31, 2002, and was sentenced to five years probation on October 16, 2002. Arthur Andersen has not consented to the inclusion of their audit report dated as of October 31, 2001 in this Annual Report on Form 10-KSB. As a result, you may not be able to recover any amount from Arthur Andersen in connection with any claim that may arise out of Arthur Andersen s audit of the financial statements described above.

Table of Contents

Shares of the Company s Common Stock eligible for public sale may have a negative impact on its market price.

Future sales of shares of common stock, $0.00025 par value (the Common Stock), by existing holders of Common Stock or by holders of outstanding options, upon the exercise thereof, under Rule 144 of the Securities Act or otherwise, could have a negative impact on the market price of the Common Stock. The Company is unable to estimate the number of shares that may be sold under Rule 144 since this will depend on the market price for the Common Stock of the Company, the personal circumstances of the sellers and other factors. Any sale of substantial amounts of Common Stock or other securities of the Company in the open market may adversely affect the market price of the securities offered hereby and may adversely affect the Company s ability to obtain future financing in the capital markets as well as create a potential market overhang.

The Company s affiliates have significant control over the Company s Common Stock.

The Company s directors, officers and principal stockholders, including Covance Inc. (formerly Corning Pharmaceutical Services, Inc.), Quintiles and certain of their affiliates, beneficially own approximately 45% of the outstanding shares of Common Stock on a fully diluted as-converted to Common Stock basis at February 28, 2003, and such stockholders will have significant influence over the outcome of all matters submitted to the stockholders for approval, including the election of directors of the Company and other corporate actions. In

addition, such influence by these affiliates could have the effect of discouraging others from attempting to take over the Company thereby increasing the likelihood that the market price of the Common Stock will not reflect a premium for control.

Certain provisions of the Company s charter, by-laws and Delaware law could make a takeover difficult.

The Company has an authorized class of 3,000,000 shares of preferred stock, of which 1,250,000 shares were issued as Series A Preferred Stock, but have since been converted to Common Stock. The remaining 1,750,000 shares of undesignated preferred stock may be issued by the Board of Directors, on such terms and with such rights, preferences and designation as the Board 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 the Company. In addition, certain anti-takeover provisions of the Delaware General Corporation Law, among other things, restrict the ability of stockholders to effect a merger or business combination or obtain control of the Company, and may be considered disadvantageous by a stockholder.

Trading in the Company s Common Stock may be volatile, which may result in substantial declines in its market price.

The market price of the Company s 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 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 the Common Stock.

The Company has never paid cash dividends on its Common Stock and does not anticipate paying cash dividends in the foreseeable future. Instead, the Company intends to retain future earnings for reinvestment in the business.

Table of Contents

The Company s Common Stock began trading on the American Stock Exchange in February 2003 and has a limited trading market. The Company cannot assure that an active trading market will develop or, if developed, will be maintained. As a result, the Company s stockholders may find it difficult to dispose of shares of Common Stock and, as a result, may suffer a loss of all or a substantial portion of their investment.

In addition, delisting from the American Stock Exchange could adversely affect the liquidity and price of the Company s Common Stock and it could have a long-term impact on the Company s ability to raise future capital through a sale of Common Stock. Furthermore, it could make it more difficult for investors to obtain quotations or trade in the Company s stock.

Increasing political and social turmoil, such as terrorist and military actions, increase the difficulty for the Company and its strategic partners to forecast accurately and plan future business activities.

Recent political and social turmoil, including the terrorist attacks of September 11, 2001 and the current crisis in the Middle East, can be expected to put further pressure on economic conditions in the United States and worldwide. These political, social and economic conditions may make it difficult for the Company to plan future business activities. Specifically, if the current crisis in the Middle East continues to escalate, the Company s international operations could be adversely affected.

Item 2. Properties.

The Company leases approximately 31,500 square feet of office space located in Newtown, Pennsylvania. This lease expires June 2010 and provides for a fixed base rent of approximately $52,000 per month with an annual inflation increase. The Company leases approximately 5,000 square feet of additional office space located in Newtown, Pennsylvania for approximately $4,000 per month in base rent expiring November 2005. The Company is also subleasing approximately 6,000 and 2,400 square feet of office space in Newtown, Pennsylvania for monthly fixed base rents of approximately $9,000 and $4,500, respectively. The subleases expire April 2004 and August 2006. In addition, the Company leases approximately 4,000 square feet of office space in Leiden, the Netherlands. This lease, denominated in EURO, expires February 2005 and provides for a base rent of approximately $4,700, based upon the conversion rate as of December 31, 2002, per month with an annual inflation increase. The Company is currently negotiating rates for approximately 9,000 square feet in Leiden, the Netherlands. This office space would replace the current 4,000 square feet in Leiden, the Netherlands and the Company is negotiating with the landlord to terminate the current lease. In December 2002, the lease expired on the Plymouth Meeting, Pennsylvania office space. The Company did not renew this lease and the operations were consolidated into its Newtown office. The Company believes that these facilities will be adequate for its needs for the foreseeable future.

Item 3. Legal Proceedings.