

BIO IMAGING TECHNOLOGIES INC  
Form 10KSB  
March 31, 2005  
Table of Contents

---

**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, 2004

Commission File No. 1-11182

---

**BIO-IMAGING TECHNOLOGIES, INC.**

(Name of Small Business Issuer in Its Charter)

---

Delaware  
(State or Other Jurisdiction of  
Incorporation or Organization)

826 Newtown-Yardley Road,  
Newtown, Pennsylvania

11-2872047  
(I.R.S. Employer  
Identification No.)

18940-1721

Edgar Filing: BIO IMAGING TECHNOLOGIES INC - Form 10KSB

(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:**

| <u>Title of each class</u> | <u>Name of each exchange on which registered</u> |
|----------------------------|--|
| 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:  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 issuer's revenues for fiscal year ended December 31, 2004: \$29,690,775

State the aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant: \$21,863,998 at February 28, 2005 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 28, 2005:

**Class**

**Number of Shares**

Edgar Filing: BIO IMAGING TECHNOLOGIES INC - Form 10KSB

---

Common Stock, \$.00025 par value

---

11,061,695

Transitional Small Business Disclosure Format Yes:  No:

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 2005 Annual Meeting of Stockholders are incorporated by reference into Part III of this Report.

---

**Table of Contents**

**TABLE OF CONTENTS**

| <u>Item</u>  | <u>Page</u> |
|--|-------------|
| PART I   |             |
| 1. <u>Business</u>   | 1           |
| 2. <u>Properties</u>   | 14          |
| 3. <u>Legal Proceedings</u>  | 14          |
| 4. <u>Submission of Matters to a Vote of Security Holders</u>  | 14          |
| PART II  |             |
| 5. <u>Market for Common Equity, Related Stockholder Matters and Small Business Issuer Purchases of Equity Securities</u> | 15          |
| 6. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>                          | 16          |
| 7. <u>Financial Statements</u>   | 25          |
| 8. <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>                           | 25          |
| 8A. <u>Controls and Procedures</u>   | 25          |
| 8B. <u>Other Information</u>   | 25          |
| PART III   |             |
| 9. <u>Directors and Executive Officers</u>   | 26          |
| 10. <u>Executive Compensation</u>  | 26          |
| 11. <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>                | 26          |
| 12. <u>Certain Relationships and Related Transactions</u>  | 26          |
| 13. <u>Exhibits</u>  | 26          |
| 14. <u>Principal Accountant Fees and Services</u>  | 26          |
| <u>SIGNATURES</u>  | 27          |
| <u>EXHIBIT INDEX</u>   | 28          |
| <u>FINANCIAL STATEMENTS</u>  | F-1         |

**Table of Contents**

**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 (CT), magnetic resonance imaging (MRI), x-rays, dual energy x-ray absorptiometry (DXA/DEXA), positron emission tomography (PET), single photon emission computerized tomography (SPECT), quantitative coronary angiography (QCA), cardiac MRI and CT, intravascular ultrasound (IVUS), peripheral quantitative angiography (QVA) 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<sup>SM</sup> 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 December 2004, we acquired 100% of the stock of Heart Core B.V., referred to as Heart Core, a privately held company located in Leiden, the Netherlands. Heart Core is a global provider of centralized imaging analysis services in the field of cardiovascular, pulmonary and

## Edgar Filing: BIO IMAGING TECHNOLOGIES INC - Form 10KSB

orthopedic clinical research.

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

## **Table of Contents**

Road, Newtown, Pennsylvania, 18940, and our telephone number is 267-757-3000. Our Internet website is [www.bioimaging.com](http://www.bioimaging.com). We also utilize the Internet website [www.capmed.com](http://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.

## **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 clients' 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.

## Edgar Filing: BIO IMAGING TECHNOLOGIES INC - Form 10KSB

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



## **Table of Contents**

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 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<sup>SM</sup> 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<sup>SM</sup> 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

## **Table of Contents**

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 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 pharmaceutical companies 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.

## **Table of Contents**

### *Cardiovascular Therapeutics*

We provide our services to clients developing drugs and medical devices for the diagnosis and treatment of cardiovascular diseases and conditions that are evaluated with the aid of medical imaging. In December 2004, we completed the acquisition of Heart Core, a provider of centralized imaging analysis services in the field of cardiovascular clinical research. We now offer various cardiovascular, quantitative, image-analysis services including: quantitative coronary angiography (QCA), cardiac MRI and CT, ultrasound, intravascular ultrasound (IVUS) and peripheral quantitative angiography (QVA). Heart Core has participated in numerous multinational trials for leading pharmaceutical, biotechnology and medical device companies throughout the world.

### **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.

Due to several factors, including, without limitation, competition from commercial competitors and academic research centers, the risk of project cancellations, slowing of patient enrollment in on-going studies or delay of future project awards, among others, we cannot assure you that demand for our services and technologies will grow, sustain growth, or that additional revenue generating opportunities will be realized by us.

### **Intellectual Property**

## Edgar Filing: BIO IMAGING TECHNOLOGIES INC - Form 10KSB

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,

## **Table of Contents**

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 and efficacy of the drug or device for its recommended conditions or use. We advise our clients in the execution of clinical trials and other drug and device development tasks. We do not administer drugs to or utilize medical devices on patients.

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

Changes in the FDA's policy for the evaluation of therapeutic oncology agents may have a positive impact on the time to market of such therapeutics. According to 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 June 2004, the FDA released 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.

## Edgar Filing: BIO IMAGING TECHNOLOGIES INC - Form 10KSB

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.



## **Table of Contents**

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

### **Marketing and Sales**

We provide and market our services on an international basis primarily to pharmaceutical 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. Our marketing activities include exhibiting at major trade shows, advertising in trade journals and the sponsoring of industry associations.

### **Significant Clients**

During fiscal 2004, one client, Novartis Pharmaceuticals Corp., or Novartis, accounted for 10% of our project revenues encompassing 18 distinct projects. However, no one contract with Novartis 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, 2004, we had 269 employees, four of whom are executive officers.

Of our employees, as of December 31, 2004, 15 were engaged in sales and marketing, 231 were engaged in client related projects and 23 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 28, 2005, 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

**Table of Contents**

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

***Risks Related to Our Company and Business***

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

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

unexpected or undesired clinical results;

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

insufficient patient enrollment in a study;

insufficient investigator recruitment;

failure to perform our obligations under the contract; or

the failure of products to satisfy safety requirements.

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

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

The loss, reduction in scope or delay of a large contract or the loss or delay of multiple contracts could materially adversely affect our business, although our contracts entitle us to receive all fees earned up to the time of termination. The loss of business from our client Novartis 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, Novartis, encompassing 18 distinct projects, amounted to 10% of service revenues for the year ended December 31, 2004. Revenues from one client, NPS, encompassing four distinct projects, amounted to 14% of service revenues for the year ended December 31, 2003. The loss of business from a significant client or our failure to continue to obtain new business to replace completed or canceled projects would have a material adverse effect on our business and revenues.

## **Table of Contents**

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

Our reported contracted/committed backlog of \$38.5 million at December 31, 2004 is based on anticipated 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 and subsequent client authorized services related to the cancellation of the project. The duration of the projects included in our backlog range from less than three months to seven years. We cannot assure that this backlog will be indicative of future results. A number of factors may affect backlog, including:

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

the loss or delay of projects;

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

the cancellation of such contracts by our clients.

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.

*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 2004 were \$25,068,670, an increase of 15.3% over service revenues for fiscal 2003 of \$21,747,636. Our continuing sales and marketing efforts have increased the number of projects under management from 184 in 2003 to 224 in 2004. We had 269 employees as of December 31, 2004 as compared to 223 employees as of December 31, 2003. In addition, we acquired one company in November 2003 and another company in December 2004. 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;

successfully integrate our acquired companies and businesses;

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. If we do undertake transactions of this sort, the process of integrating an acquired business, technology or product

## **Table of Contents**

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. 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 employment agreements with Mr. Weinstein and Mr. Kaminer, this does not necessarily mean that they will remain with us. Although we have executive retention agreements with our executive officers, we do not have employment agreements with any other key personnel. Furthermore, our performance also depends on our ability to attract and retain management and qualified professional and technical operating staff. Competition for these skilled personnel is intense. The loss of services of any key executive, or inability to continue to attract and retain qualified staff, could have a material adverse effect on our business, results of operations and financial condition. We do not maintain any key employee insurance on any of our executives.

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

In fiscal 2004, a small portion of our service revenues were denominated in foreign currency. Our financial statements are denominated in United States dollars. In the event a greater portion of our service revenues are denominated in a foreign currency changes in foreign currency exchange rates could affect our results of operations and financial condition. Most of the contracts of Heart Core are denominated in foreign currency. Fluctuations in foreign currency exchange rates could materially impact the operating costs of our European facility in Leiden, the Netherlands, including the operations of Heart Core, which are primarily EURO denominated.

## **Risks Related to Our Industry**

*Our failure to compete effectively in the competitive industry could cause our revenues to decline.*

Significant factors in determining whether we will be able to compete successfully include:

consultative and clinical trials design capabilities;

reputation for on-time quality performance;

expertise and experience in specific therapeutic areas;

the scope of service offerings;

strength in various geographic markets;

the price of services;

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

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

our size; and

the service and product offerings of our competitors.

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



## **Table of Contents**

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 have substantially greater capital, technical and other resources than we do. In addition, certain of our competitors that are smaller specialized companies may compete effectively against us because of their concentrated size and focus.

***Changes in outsourcing trends in the pharmaceutical and biotechnology industries could adversely affect our operating results and growth rate.***

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

Additionally, numerous governments have undertaken efforts to control growing healthcare costs through legislation, regulation and voluntary agreements with medical care providers and pharmaceutical companies. If future regulatory cost containment efforts limit the profits that can be derived 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.

***Our CapMed division may not reach profitability.***

Our CapMed division had a loss from operations of \$829,370 in fiscal 2004. There can be no assurance that this division will generate enough revenues to cover their cost or to be profitable. If our CapMed division continues to incur such losses, our businesses, results of operations and financial condition could be materially adversely affected.

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

## Edgar Filing: BIO IMAGING TECHNOLOGIES INC - Form 10KSB

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.

## **Table of Contents**

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

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

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

The success of our business is dependent upon continued acceptance by the FDA and other regulatory authorities of the data and analyses generated by our services in connection with the evaluation of the safety and efficacy of new drugs and devices. The FDA has formal guidelines that encourage the use of surrogate measures, through submission of digital image data, for evaluation of drugs to treat life-threatening or debilitating conditions. We cannot assure you that the FDA or other regulatory authorities will accept the data or analyses generated by us in the future and, even assuming acceptance, the FDA or other regulatory authorities may not require the application of imaging techniques to 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 devices, the need for our services would be eliminated or substantially reduced, and, as a result, our business, results of operations and financial condition could be materially adversely affected.

*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, 2004, we had the following capital structure:

Edgar Filing: BIO IMAGING TECHNOLOGIES INC - Form 10KSB

|  |            |
|--|------------|
| Common stock outstanding   | 11,027,320 |
| Common stock issuable upon:  |            |
| Exercise of options which are outstanding  | 1,943,758  |
| Exercise of options which have not been granted                                    | 143,550    |
| Total common stock outstanding assuming exercise or conversion of all of the above | 13,114,628 |

## **Table of Contents**

As of December 31, 2004, we had outstanding options to purchase 1,943,758 shares of common stock at exercise prices ranging from \$0.63 to \$7.03 per share (exercisable at a weighted average of \$2.21 per share), of which 1,613,302 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, 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, 2004, we had 11,027,320 shares of our common stock issued and outstanding. Of this amount, 6,721,771 shares are freely tradable and 4,305,549 shares are registered on a Form S-3 with the Securities and Exchange Commission.

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. and certain of their affiliates, beneficially owned 38% of the outstanding shares of common stock on a fully diluted as-converted to common stock basis at December 31, 2004, and such stockholders will have significant influence over the outcome of all matters submitted to our stockholders for approval, including the election of our directors and other corporate actions. In addition, such influence by these affiliates could have the effect of discouraging others from attempting to take us over, thereby increasing the likelihood that the market price of the common stock will not reflect a premium for control.

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

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

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

## Edgar Filing: BIO IMAGING TECHNOLOGIES INC - Form 10KSB

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;

## **Table of Contents**

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 our common stock. Between January 1, 2004 and December 31, 2004, our common stock has traded at a low of \$3.75 per share and a high of \$8.30 per share. Between January 1, 2005 and February 28, 2005, our common stock has traded at a low of \$2.59 per share and a high of \$5.51 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 developed, will be maintained. As a result, our stockholders may find it difficult to dispose of shares of our common stock and, as a result, may suffer a loss of all or a substantial portion of their investment.

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

We have an authorized class of 1,750,000 shares of undesignated preferred stock that may be issued by our 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 our company. In addition, we are subject to provisions of Delaware corporate law which, subject to certain exceptions, will prohibit us from engaging in any business combination with a person who, together with affiliates and associates, owns 15% or more of our common stock for a period of three years following the date that the person came to own 15% or more of our common stock unless the business combination is approved in a prescribed manner.

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

## **Item 2. Properties.**

We lease 54,400 square feet of office space located in Newtown, Pennsylvania. This lease expires June 2010 and provides for a fixed base rent of \$83,000 per month with an annual inflation increase. We lease 5,000 square feet of additional office space located in Newtown, Pennsylvania for \$4,000 per month in base rent expiring November 2005. In addition, we lease 15,500 square feet of office space in Leiden, the Netherlands. This lease, denominated in EURO, expires in May 2008 and provides for a base rent of \$25,800 per month, based upon the conversion rate as of December 31, 2004, with an annual inflation increase. We believe that these facilities will be adequate for our needs for the foreseeable future.

**Item 3. Legal Proceedings.**

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

**Item 4. Submission of Matters to a Vote of Security Holders.**

None.



**Table of Contents****PART II****Item 5. Market for Common Equity, Related Stockholder Matters and Small Business Issuer Purchases of Equity Securities.**

Our common stock began trading on the NASDAQ National Market on December 18, 2003 under the symbol BITI. Prior to listing on the NASDAQ National Market, our common stock was traded on the American Stock Exchange under the symbol BIT from February 25, 2003. Our common stock was quoted on the NASD OTC Bulletin Board under the symbol BITI prior to being listed on the American Stock Exchange.

The following table sets forth the high and low bid quotations for our common stock as reported on the NASDAQ National Market for each of the quarters from the quarter ended December 31, 2003 through December 31, 2004. Such quotations reflect interdealer prices, without retail mark-up, mark-down or commission and may not represent actual transactions.

| <b>Quarter<br/>Ended</b>                | <b>Common<br/>Stock</b> |            |
|---|-------------------------|------------|
|   | <b>High</b>             | <b>Low</b> |
| December 31, 2003                       | 6.75                    | 5.60       |
| (December 18, 2003 - December 31, 2003) |                         |            |
| March 31, 2004                          | 8.05                    | 5.76       |
| June 30, 2004                           | 6.18                    | 4.23       |
| September 30, 2004                      | 4.99                    | 3.75       |
| December 31, 2004                       | 5.69                    | 3.95       |

The following table sets forth the high and low sales prices for our common stock as reported on the American Stock Exchange for each of the quarters from the quarter ended March 31, 2003 through December 31, 2003.

| <b>Quarter<br/>Ended</b>              | <b>Common<br/>Stock</b> |            |
|---------------------------------------|-------------------------|------------|
|                                       | <b>High</b>             | <b>Low</b> |
| March 31, 2003                        | 3.95                    | 2.15       |
| June 30, 2003                         | 6.30                    | 3.02       |
| September 30, 2003                    | 8.10                    | 5.10       |
| December 31, 2003                     |                         |            |
| (October 1, 2003 - December 17, 2003) | 7.35                    | 5.41       |

## Edgar Filing: BIO IMAGING TECHNOLOGIES INC - Form 10KSB

As of March 21, 2005, the number of holders of record of our common stock was 98 and the approximate number of beneficial holders of our common stock was 1,700.

In December 2004, in connection with the Heart Core acquisition, we paid total consideration of \$2,258,025, consisting of \$1,410,150 and 175,853 shares of our common stock. \$1,269,135 and 158,268 shares of common stock were issued directly to the sellers and \$141,015 and 17,585 shares of common stock were issued to an escrow agent pursuant to the terms of the acquisition. The escrow is being held as security for the payment of any unknown claims and will be released in December 2007.

In February 2005, in connection with his employment agreement dated February 1, 2002, we issued 30,000 shares of restricted stock to Mark L. Weinstein, our President and Chief Executive Officer, as required pursuant to the terms of his employment agreement.

We did not employ an underwriter in connection with the issuance of the securities described above. We believe that the issuance of the foregoing securities was exempt from registration under Section 4(2) of the

## **Table of Contents**

Securities Act of 1933, as amended, as transactions not involving a public offering. Each of the recipients were sophisticated or accredited investors, acquired the securities for investment purposes only and not with a view to distribution and had adequate information about our company.

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

## **Item 6. Management's Discussion and Analysis of Financial Condition and Results of Operations.**

### **Overview**

We are a 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 (CT), magnetic resonance imaging (MRI), x-rays, dual energy x-ray absorptiometry (DXA/DEXA), positron emission tomography (PET), single photon emission computerized tomography (SPECT), quantitative coronary angiography (QCA), cardiac MRI and CT, intravascular ultrasound (IVUS), peripheral quantitative angiography (QVA) and ultrasound. We provide services that include the processing and analysis of medical images and the data-basing and regulatory submission of medical images, quantitative data and text. We also offer a service called Bio-Imaging ET&C<sup>SM</sup>, which focuses on education, training and certification for medical imaging equipment, facilities and staff.

Our sales cycle, referring to the period from the presentation by us to a potential client to the engagement of us by such client, has historically been approximately 12 months. In addition, the contracts under which we perform services typically cover a period of 12 to 60 months and the volume and type of services performed by us generally vary during the course of a project. We cannot assure you that our project revenues will remain at levels sufficient to maintain profitability. Service revenues were generated from 84 clients encompassing 224 distinct projects for fiscal 2004. This compares to 68 clients encompassing 184 distinct projects for fiscal 2003.

Our contracted/committed backlog, referred to as backlog, is the amount of service revenue that remains to be earned and recognized on both signed and verbally agreed to contracts. Our backlog was \$38.5 million as of December 31, 2004. This compares to \$41.3 million as of December 31, 2003, a decrease of 7%. This decrease is primarily due to project cancellations that occurred during the fourth quarter of 2004. Contracts included in backlog are subject to termination by our clients at any time. In the event that a contract is cancelled by the client, we would be entitled to receive payment for all services performed up to the cancellation date. The duration of the projects included in our backlog range from less than 3 months to 5 years. We believe that our backlog assists our management as an indicator of our long-term business. However, we do not believe that backlog is a reliable predictor of near-term results because service revenues may be incurred in a given period on contracts that were not included in the previous reporting period's backlog and/or contract cancellations or project delays may occur in a given period on contracts that were included in the previous reporting period's backlog.

We believe that demand for our services and technologies will continue to grow as the use of digital technologies for data acquisition and management increases in the radiology and drug development communities. We also believe that there is a growing recognition within the bio-pharmaceutical industry of the advantages in using an independent centralized core laboratory for analysis of medical-imaging data and compliance with the regulatory demands for the submission of such data. In addition, the FDA is gaining experience with electronic submissions and is continuing to develop sophisticated guidelines for computerized submission of clinical trial data, including medical images. Furthermore, we believe that the increased use of digital medical images in clinical trials, especially for important drug classes such as anti-inflammatory,

## Edgar Filing: BIO IMAGING TECHNOLOGIES INC - Form 10KSB

neurologic and oncologic therapeutics and diagnostic image agents, generate large amounts of image data from a large number of imaging sources. These studies require processing, analysis, data management and submission services best handled by

## **Table of Contents**

vendors with scalable logistical capabilities and extensive experience working with research facilities worldwide. Due to several factors, including, without limitation, competition from commercial competitors and academic research centers and the risk of project cancellations, slowing of patient enrollment in on-going studies or delay of future project awards, among others, we cannot assure you that demand for our services and technologies will grow, sustain growth, or that additional revenue generating opportunities will be realized by us.

In December 2004, we acquired 100% of the stock of Heart Core, a privately held company located in Leiden, the Netherlands, referred to as Heart Core. Heart Core is a global provider of centralized imaging analysis services in the field of cardiovascular, pulmonary and orthopedic clinical research. We paid total consideration of \$2,258,025, consisting of \$1,410,150 and 175,853 shares of our common stock. \$1,269,135 and 158,268 shares of common stock were issued directly to the sellers, and \$141,015 and 17,585 shares of common stock were issued to an escrow agent pursuant to the terms of the acquisition. The escrow is being held as security for the payment of any unknown claims and will be released in December 2007. The negotiations between us and Heart Core were conducted on an arms-length basis.

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. The negotiations between us and CapMed were conducted on an arms-length basis. In connection with the acquisition, CapMed received aggregate consideration of \$550,000, consisting of \$211,828 in cash paid directly to CapMed's creditors and \$338,171 of our common stock, which amounted to a total of 51,724 shares, of which 40,361 were issued to CapMed and 11,363 were issued to an escrow agent pursuant to the terms of the acquisition.

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

## **Critical Accounting Policies, Estimates and Risks**

In December 2001 and 2003, the Securities and Exchange Commission, referred to as the SEC, issued disclosure guidance for critical accounting policies. The SEC defines critical accounting policies as those that require application of management's most difficult, subjective or complex judgments, often as a result of the

## Table of Contents

need to make estimates about the effect of matters that are inherently uncertain and may change in subsequent periods. The notes to the consolidated financial statements include a summary of significant accounting policies and methods used in the preparation of our Consolidated Financial Statements. The following is a brief discussion of the more significant accounting policies and methods used us.

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

On an on-going basis, we evaluate our estimates. The most significant estimates relate to the recognition of revenue and profits based on the proportional performance method of accounting for fixed service contracts, allowance for doubtful accounts and income taxes.

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

*Revenue Recognition.* Service revenues are recognized over the contractual term of our customer contracts using the proportional performance method, which is based on hours incurred as a percentage of total estimated hours. Service revenues are not recognized until we have a signed contract from a customer which: (i) contains fixed or determinable fees; and (ii) collectability of such fees is reasonably assured. Any change to recognized service revenue as a result of revisions to estimated total hours are recognized in the period the estimate changes. Our revenue recognition policy entails a number of estimates including an estimate of the total hours that are expected to be incurred on a project, which is used as the basis for determining the portion of our revenue to be recognized for each period. The revenue recognized in any period might have been materially affected if different assumptions or conditions prevailed. The timing of our recognition of revenue would be revised if there were changes in the total estimated hours (other than scope changes in a project which typically result in a revision to the contract). We review our total estimated hours monthly. Provisions for losses expected to be incurred on contracts are recognized in full in the period in which it is determined that a loss will result from performance of the contractual arrangement.

We enter into contracts that contain fixed or determinable fees. The fees in the contracts are based on the scope of work we are contracted to perform; there are unitized fees per service and fixed fees with a total estimated for the contract based upon the estimated unitized service expected to be performed, as well as the service to be delivered under the fixed fee component of the contract. The units are estimated based on the information provided by the customer, and we bill the customer for actual units completed in accordance with the terms of the contract. In the event that a contract is cancelled by the client, we would be entitled to receive payment for all services performed up to the cancellation date.

We also incur direct costs at the outset of a customer service arrangement prior to receiving a final signed contract. Accordingly, we defer these costs and delay the recording of any revenue until the contract is executed. If a customer does not execute the contract, we immediately expense the deferred costs, offset by any deferred service revenue associated with these costs.

*Allowance for Doubtful Accounts.* We maintain allowances for doubtful accounts on a specific identification method for estimated losses resulting from the inability of our customers to make required payments. If the financial condition of our customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances may be required, which would reduce our net income in the period that we determine that the additional allowances are needed.



**Table of Contents**

*Long-lived Assets, Intangibles and Goodwill.* Management periodically evaluates the net realizable value of long-lived assets, including property and equipment, relying on a number of factors including operating results, business plans, economic projections and anticipated future cash flows. If these factors indicate that the carrying value of a long lived asset exceeds the net realizable value, the Company will record an impairment and reduce the carrying value of the asset to the net realizable value.

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

*Income Taxes.* We record a valuation allowance to reduce our deferred tax assets to an amount that is more likely than not to be realized. In assessing the need for the valuation allowance, we consider our future taxable income and on-going prudent and feasible tax planning strategies. In the event that we were to determine that, in the future, we would be able to realize our deferred tax assets in excess of its net recorded amount, an adjustment to the deferred tax asset would be made, thereby increasing net income in the period such determination was made. Likewise, should we determine that it is more likely than not that we will be unable to realize all or part of our net deferred tax asset in the future, an adjustment to the deferred tax asset would be charged, thereby decreasing net income in the period such determination was made. We recognize contingent liabilities for any tax related exposures when those exposures are both probable and estimable.

**Results of Operations***Fiscal Years Ended December 31, 2004 and 2003*

|                                     | 2004                 | % of<br>Total<br>Revenue | 2003                 | % of<br>Total<br>Revenue | \$ Change           | %<br>Change  |
|-------------------------------------|----------------------|--------------------------|----------------------|--------------------------|---------------------|--------------|
| Service revenues                    | \$ 25,068,670        | 84.4%                    | \$ 21,747,636        | 86.3%                    | \$ 3,321,034        | 15.3%        |
| Reimbursement revenues              | \$ 4,622,105         | 15.6%                    | \$ 3,463,071         | 13.7%                    | \$ 1,159,034        | 33.5%        |
| <b>Total revenues</b>               | <b>\$ 29,690,775</b> | <b>100.0%</b>            | <b>\$ 25,210,707</b> | <b>100.0%</b>            | <b>\$ 4,480,068</b> | <b>17.8%</b> |
| Cost of revenues                    | \$ 20,451,633        | 68.9%                    | \$ 16,875,166        | 66.9%                    | \$ 3,576,467        | 21.2%        |
| General and administrative expenses | \$ 4,452,535         | 15.0%                    | \$ 4,079,419         | 16.2%                    | \$ 373,116          | 9.1%         |
| Sales and marketing expenses        | \$ 3,182,125         | 10.7%                    | \$ 2,057,878         | 8.2%                     | \$ 1,124,247        | 54.6%        |
| <b>Total costs and expenses</b>     | <b>\$ 28,086,293</b> | <b>94.6%</b>             | <b>\$ 23,012,463</b> | <b>91.3%</b>             | <b>\$ 5,073,830</b> | <b>22.0%</b> |
| Income from operations              | \$ 1,604,482         | 5.4%                     | \$ 2,198,244         | 8.7%                     | \$ (593,762)        | (27.0)%      |
| Interest (income) expense - net     | \$ (2,864)           | 0.0%                     | \$ 130,655           | 0.5%                     | \$ (133,519)        | (102.2)%     |
| Income before income tax            | \$ 1,607,346         | 5.4%                     | \$ 2,067,589         | 8.2%                     | \$ (460,243)        | (22.3)%      |



Edgar Filing: BIO IMAGING TECHNOLOGIES INC - Form 10KSB

|                                |            |      |              |        |                |          |
|--------------------------------|------------|------|--------------|--------|----------------|----------|
| Income tax (benefit) provision | \$ 658,434 | 2.2% | \$ (270,264) | (1.1)% | \$ (928,698)   | (343.6)% |
| Net income                     | \$ 948,912 | 3.2% | \$ 2,337,853 | 9.3%   | \$ (1,388,941) | (59.4)%  |

Service revenues were \$25,068,670 for fiscal 2004 and \$21,747,636 for fiscal 2003, an increase of \$3,321,034, or 15.3%. The increase in service revenues is due to an increase in the number of projects resulting from the overall market growth for medical imaging related services for clinical trials. Service revenues were generated from 84 clients encompassing 224 distinct projects for fiscal 2004. This compares to 68 clients encompassing 184 distinct projects for fiscal 2003. One client, Novartis Pharmaceuticals Corp., encompassing

## Table of Contents

18 distinct projects represented 10.4% of our service revenues for fiscal 2004, while for the comparable period last year, one client, NPS Pharmaceuticals Corp., encompassing four distinct projects represented 14.0% of our service revenues. No other client accounted for more than 10% of service revenues in fiscal 2004 or fiscal 2003. Service revenues generated from our client base, while still concentrated as measured by the number of clients, has continued to become more dispersed over time, and we believe more diversification is evident when revenue concentration is measured by the number of individual projects. Our primary scope of work in both periods included medical-imaging core laboratory services and image-based information management services.

Reimbursement revenues consist of reimbursements received from our customers for pass-through costs. Reimbursement revenues fluctuate significantly over the course of any given project and quarter to quarter variations are a reflection of this project timing. Therefore, our management believes that reimbursement revenues are not a significant indicator of our overall performance trends. Bio-Imaging, at the request of our clients, may directly pay the independent radiologist who reviews our client's imaging data. These costs are passed directly to our clients and are included in Reimbursement Revenue and Cost of Revenues. Amounts for such reimbursements were immaterial in prior years and have been reclassified in our 2003 Consolidated Statements of Income from Cost of Revenues to Reimbursement Revenues to conform with the current year presentation. This reclassification had no effect on income from operations, net income, cash flows or the balance sheets.

Cost of revenues was \$20,451,633 for fiscal 2004 and \$16,875,166 for fiscal 2003, an increase of \$3,576,467, or 21.2%. Cost of revenues for fiscal 2004 and 2003 was comprised of professional salaries and benefits, allocated overhead and pass-through costs. The increase in cost of revenues is primarily attributable to an increase in reimbursement revenues of \$1.2 million and an increase of \$1.9 million in staffing levels required for project related tasks for fiscal 2004. We expect that our cost of revenues in fiscal 2005 will increase in comparison to fiscal 2004 primarily due to the increased cost of revenues in the second six months of fiscal 2004 carrying into fiscal 2005 and to the full annual expenses related to Heart Core. The Heart Core acquisition closed on December 10, 2004. This increase will be partially offset by total cost reductions implemented during the first quarter of 2005 amounting to approximately \$500,000 per quarter, the effect of which will be initially realized in the second quarter of 2005.

The increase in cost of revenues as a percentage of total revenues to 68.9% for fiscal 2004 from 66.9% for fiscal 2003 is primarily attributable to the larger increase in cost of revenues. The cost of revenues as a percentage of total revenues also fluctuates due to work-flow variations in the utilization of staff and the mix of services provided by us in any given period.

General and administrative expenses were \$4,452,535 for fiscal 2004 and \$4,079,419 for fiscal 2003, an increase of \$373,116, or 9.1%. General and administrative expenses in fiscal 2004 and 2003 consisted primarily of professional salaries and benefits, depreciation and amortization, professional and consulting services, office rent and corporate insurance. The increase is primarily due to expenses associated with the CapMed division of \$376,200. Excluding CapMed, general and administrative expenses remained relatively flat with the prior year. We expect that our general and administrative expense will increase in 2005 due to anticipated expenditures for Sarbanes-Oxley compliance and a general increase in the fees associated with being a publicly traded company.

The decrease in general and administrative expenses as a percentage of total revenues to 15.0% for fiscal 2004 from 16.2% for fiscal 2003 is primarily due to a lesser increase in personnel needed to support the growth in our service revenues as compared to the increase in our total revenues.

Sales and marketing expenses was \$3,182,125 for fiscal 2004 and \$2,057,878 for fiscal 2003, an increase of \$1,124,247, or 54.6%. Sales and marketing expenses in fiscal 2004 and 2003 were comprised of direct sales and marketing costs, professional salaries and benefits and allocated overhead. The increase is primarily due to expenses associated with the CapMed division of \$564,300 and an increase in expenses associated with tradeshow attendance of \$125,000, an increase in marketing expenses of \$90,000 and an increase in personnel



**Table of Contents**

and commission expense of \$345,000. We expect that sales and marketing expenses will increase in fiscal 2005 as we continue to expand our market presence in the United States and Europe.

The increase in sales and marketing expenses as a percentage of total revenues to 10.7% for fiscal 2004 from 8.2% for fiscal 2003 is primarily due to increased expenses associated with our CapMed division.

Net interest income was \$2,864 for fiscal 2004 and net interest expense was \$130,655 for fiscal 2003, an increase of \$133,519, or 102.2%. This increase is primarily due to interest income earned on a higher average cash balance for fiscal 2004 as compared to fiscal 2003. Net interest expense for fiscal 2004 and 2003 resulted from interest expense incurred on equipment lease obligations and the promissory note issued by us to Quintiles, Inc., referred to as the Quintiles Note.

Income before income taxes was \$1,607,346 for fiscal 2004 and \$2,067,589 for fiscal 2003, a decrease of \$460,243, or 22.3%. This decrease is due to the loss before income taxes in the fourth quarter of fiscal 2004 resulting from a cancellation rate in the fourth quarter of fiscal 2004 that was significantly higher than historical norms. The cancellations were the result of sponsors halting studies for clinical or strategic considerations. The convergence of cancellation rates higher than historical norms, an overall slowing of patient enrollment in ongoing studies and the delay of several anticipated projects resulted in our unfavorable fourth quarter fiscal 2004 results.

Our income tax provision for fiscal 2004 was \$658,434 versus an income tax benefit for fiscal 2003 of \$270,264. The income tax benefit in fiscal 2003 resulted from recording a deferred tax benefit for the future tax savings anticipated from using the net operating loss carryforwards available at December 31, 2003. As a result, our effective income tax rate was 41% for fiscal 2004.

Net income was \$948,912 for fiscal 2004 and \$2,337,853 for fiscal 2003, a decrease of \$1,388,941, or 59.4%. This decrease in net income is due to lower income before income taxes and the tax provision of \$658,434 in fiscal 2004 versus a tax benefit of \$270,264 in fiscal 2003. This resulted in a decrease in net income as a percentage of total revenues to 3.2% for fiscal 2004 from 9.3% for fiscal 2003.

**Liquidity and Capital Resources**

|   | <u>2004</u>    | <u>2003</u>    |
|---|----------------|----------------|
| Net cash (used in) provided by operating activities | \$ (282,942)   | \$ 2,887,619   |
| Net cash used in investing activities               | \$ (3,062,338) | \$ (1,914,223) |
| Net cash (used in) provided by financing activities | \$ (294,033)   | \$ 9,752,791   |

At December 31, 2004, we had cash and cash equivalents of \$9,650,140. Working capital at December 31, 2004 was \$13,121,407.

Net cash used in operating activities for fiscal 2004 was \$282,942 as compared to net cash provided by operating activities of \$2,887,619 for fiscal 2003. This decrease is primarily due to the decrease in net income from 2003 to 2004 of \$1,388,941 and an increase in accounts receivable from 2003 to 2004 of \$3,155,821.

Net cash used in investing activities primarily represents our investment in capital and leasehold improvements of \$1,848,927 and net cash paid for the Heart Core acquisition of \$1,213,411. We currently anticipate that capital expenditures for fiscal 2005 will be approximately \$2 million. These expenditures primarily represent additional upgrades in our networking, data storage and core laboratory capabilities for both the United States and European operations.

Net cash used in financing activities is primarily attributable to the full payment of the Quintiles Note of \$666,666 and payments on capital leases of \$659,513 offset by proceeds from the sales leaseback transactions of \$902,486 in fiscal 2004.

**Table of Contents**

The following table lists our cash contractual obligations as of December 31, 2004:

| <b>Contractual obligations</b>            | <b>Payments Due By Period</b> |                             |                     |  |
|---|-------------------------------|-----------------------------|---------------------|--|
|   | <b>Total</b>                  | <b>Less than<br/>1 year</b> | <b>1-3 years</b>    | <b>4-5 years<br/>After 5<br/>years</b> |
| Capital lease obligations                 | \$ 1,629,008                  | \$ 722,086                  | \$ 906,922          |  |
| Facility rent operating leases            | \$ 7,391,221                  | \$ 1,366,514                | \$ 4,205,245        | \$ 1,819,462                           |
| Employment agreements                     | \$ 212,500                    | \$ 197,917                  | \$ 14,583           |  |
| <b>Total contractual cash obligations</b> | <b>\$ 9,232,729</b>           | <b>\$ 2,286,517</b>         | <b>\$ 5,126,750</b> | <b>\$ 1,819,462</b>                    |

On May 15, 2004, we renewed and amended our agreement with Wachovia Bank, National Association. The renewed and amended agreement is for an unsecured committed line of credit of \$5,000,000. Interest is payable at the LIBOR Market Index Rate plus 2.0%. The agreement requires us, among other things, to maintain certain financial covenants. The committed line of credit matures June 30, 2005 and may be renewed on an annual basis. At December 31, 2004, we had no borrowings under the committed line of credit and are compliant with the financial covenants.

In connection with our acquisition of Intelligent Imaging, as of February 1, 2002, we were obligated to pay quarterly payments of principal of \$41,667 under the Quintiles Note, plus accrued interest thereon, and one payment of principal of \$500,000 on November 1, 2004, unless the Quintiles Note was previously converted into shares of our common stock. The Quintiles Note bore interest at the rate in effect on the business day immediately prior to the date on which payments are due under the Quintiles Note equal to the three-month LIBOR as published from time to time in the Wall Street Journal plus 3%, compounded annually based on a 365-day year. On November 1, 2004, we made the final payment on the Quintiles Note. This payment was comprised of the remaining principal balance of \$541,663.

In December 2004, in connection with the Heart Core acquisition, we paid total consideration of \$2,258,025, consisting of \$1,410,150 and 175,853 shares of our common stock. \$1,269,135 and 158,268 shares of common stock were issued directly to the sellers, and \$141,015 and 17,585 shares of common stock were issued to an escrow agent pursuant to the terms of the acquisition. The escrow is being held as security for the payment of any unknown claims and will be released in December 2007. The negotiations between us and Heart Core were conducted on an arms-length basis.

We have neither paid nor declared dividends on our common stock since our inception and do not plan to pay dividends on our common stock in the foreseeable future.

We have not entered into any off-balance sheet transactions, arrangements or other relationships with unconsolidated entities or other persons.

We anticipate that our existing capital resources together with cash flow from operations and borrowing capacity under the existing line of credit, will be sufficient to meet our foreseeable cash needs. However, we cannot assure you that our operating results will continue to achieve profitability on an annual basis in the future. The inherent operational risks associated with:

our ability to gain new client contracts;

project cancellations;

the variability of the timing of payments on existing client contracts; and

other changes in our operating assets and liabilities

may have a material adverse affect on our future liquidity.

## **Table of Contents**

We may seek to raise additional capital from equity or debt sources in order to take advantage of unanticipated opportunities, such as more rapid expansion, acquisitions of complementary businesses or the development of new services. We cannot assure you that additional financing will be available, if at all, on terms acceptable to us.

Our fiscal year 2005 operating plan contains assumptions regarding revenue and expenses. The achievement of our operating plan depends heavily on the timing of work performed by us on existing projects and our ability to gain and perform work on new projects. Project cancellations, or delays in the timing of work performed by us on existing projects or our inability to gain and perform work on new projects could have an adverse impact on our ability to execute our operating plan and maintain adequate cash flow. In the event actual results do not meet the operating plan, our management believes it could execute contingency plans to mitigate these effects. Our plans include additional financing, to the extent available, through the line of credit discussed above. Considering the cash on hand and based on the achievement of the operating plan and management's actions taken to date, management believes it has the ability to continue to generate sufficient cash to satisfy our operating requirements in the normal course of business for at least the next 12 months and the foreseeable future.

## **Recently Issued Accounting Statements**

In December 2004, the Financial Accounting Standards Board ( FASB ) issued FASB Statement No. 123(R) ( FAS 123(R) ), *Share-Based Payment*. FAS 123(R) revises FASB Statement No. 123 ( FAS 123 ), *Accounting for Stock-Based Compensation*. Also, FAS 123(R) supersedes Accounting Principles Board ( APB ) Opinion No. 25, *Accounting for Stock Issued to Employees*, and amends FASB Statement No. 95, *Statement of Cash Flows*. For public companies, FAS 123(R) is effective for periods beginning after June 15, 2005.

FAS 123(R) requires companies to expense the fair value of employee stock options and other forms of stock-based compensation. Specifically, FAS 123(R) requires companies to (i) use fair value to measure stock-based compensation awards and (ii) cease using the intrinsic value method of accounting under APB 25 that resulted in no expense for many awards of stock options for which the exercise price of the option equaled the price of the underlying stock at the grant date. In addition, FAS 123(R) retains the modified grant date model from FAS 123 in that compensation cost is measured at the grant date fair value of the award and adjusted to reflect actual forfeitures and the outcome of certain conditions. The fair value of an award is not re-measured after its initial estimation on the grant date, except in certain cases. FAS 123(R)'s transition provisions provide a number of alternatives to address implementation issues and to increase the comparability of compensation cost.

We expect to adopt the Modified Prospective Application ( MPA ) method, without restatement of prior interim periods on July 1, 2005. Under the MPA method without restatement approach, we would recognize compensation cost for (1) awards that were granted or modified after the fiscal year beginning after December 15, 1994, (2) any portion of awards that have not vested by July 1, 2005, and (3) any outstanding liability awards. Compensation cost for the portion of awards for which the requisite service has not been rendered that are outstanding at July 1, 2005, will be recognized using the measurement data and attribution method used in our FAS 123 pro forma disclosures (See Note 1) as those services are received after July 1, 2005.

We are currently assessing the impact of FAS 123(R) on our 2005 financial statements and believe that this will have a material affect on our results of operations.

We have undergone a study of our stock-based compensation plans in anticipation of the adoption of FAS 123(R) and recent changes in tax laws with regard to deferred compensation. Currently, we do not anticipate a change in our current compensation strategy or structure, but continue to look for ways to compensate individuals via avenues that align the interests of individuals with the interests of shareholders through ownership of company stock.



In December 2004, the FASB issued FASB Staff Position No. FAS 109-2 ( FAS 109-2 ), *Accounting and Disclosure Guidance for the Foreign Earnings Repatriation Provision within the American Jobs Creation Act of*

## **Table of Contents**

2004. The AJCA introduces a limited time 85% dividends received deduction on the repatriation of certain foreign earnings to a U.S. taxpayer (repatriation provision), provided certain criteria are met. FAS 109-2 provides accounting and disclosure guidance for the repatriation provision. We do not expect the adoption of this new tax provision to have a material impact on our consolidated financial statements.

In December 2004, the FASB issued SFAS Statement No. 153, *Exchanges of Non-monetary Assets*. The Statement is an amendment of APB Opinion No. 29 to eliminate the exception for non-monetary exchanges of similar productive assets and replaces it with a general exception for exchanges on non-monetary assets that do not have commercial substance. The effective date is for exchanges occurring in fiscal periods beginning after June 15, 2005. Bio-Imaging believes that the adoption of this standard will have no material impact on our consolidated financial statements.

## **Existing Contracts**

During fiscal 2004, we signed \$32.3 million in project contracts as compared to \$27.1 million for the same period in the prior year. As of December 31, 2004, we had entered into agreements with 64 companies, encompassing 141 projects, to provide services in the aggregate amount of \$73 million through December 2009, of which services valued at \$38.5 million remain to be completed. Such contracts are subject to termination by us or our clients at any time or for any reason. In addition, clients' clinical trials or other projects are subject to timing and scope changes. Therefore, total service revenue generated by us during the life of these contracts may be less than initial contract values.

## **Disclosure About Market Risk**

### *Interest Rate Risk*

We invest in high-quality financial instruments, primarily money market funds, federal agency notes, asset backed securities, corporate debt securities and United States treasury notes, with an effective duration of the portfolio of less than nine months and no security with an effective duration in excess of two years, which we believe are subject to limited credit risk. We currently do not hedge our interest rate exposure. Due to the short-term nature of our investments, we do not believe that we have any material exposure to interest rate risk arising from our investments.

### *Foreign Currency Risk*

Our financial statements are denominated in United States dollars, and we currently do not hedge our exchange rate exposure. Fluctuations in foreign currency exchange rates could materially increase the operating costs of our facility in the Netherlands, including the operations of Heart Core, which are primarily EURO denominated. If the exchange rate undergoes a change of 10%, we believe that it would have a material impact on our results of operations due to the increased cost of our Netherlands facility. In addition, certain of our contracts are denominated in foreign currency. We believe that any adverse fluctuation in the foreign currency markets relating to these contracts will not result in any material adverse effect on our financial condition or results of operations. In the event we derive a greater portion of our service revenues from international operations, factors associated with international operations, including changes in foreign currency exchange rates, could affect our results of operations and financial condition.



**Table of Contents**

**Item 7. Financial Statements.**

The financial statements required to be filed pursuant to this Item 7 are included in this Annual Report on Form 10-KSB. A list of the financial statements filed herewith is found at Item 13. Exhibits, List, and Reports on Form 8-K.

**Item 8. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.**

None.

**Item 8A. Controls and Procedures.**

*Evaluation of disclosure controls and procedures.* Based on their evaluation of our disclosure controls and procedures (as defined in Rules 13a-14(c) and 15d-14(c) under the Exchange Act) as of a date within 90 days of the filing date of this Annual Report on Form 10-KSB, our president and chief executive officer (principal executive officer) and our chief financial officer (principal accounting and financial officer) have concluded that our disclosure controls and procedures are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and are operating in an effective manner for the period covered by this report.

*Changes in internal controls.* There were no significant changes in our internal controls or in other factors that could significantly affect these controls subsequent to the date of our most recent evaluation.

**Item 8B. Other Information.**

None.

**Table of Contents**

**PART III**

**Item 9. Directors and Executive Officers.**

The information relating to our directors, nominees for election as directors and executive officers under the headings "Election of Directors" and "Executive Officers" in our definitive proxy statement for the 2005 Annual Meeting of Stockholders is incorporated herein by reference to such proxy statement.

We have adopted a written code of business conduct and ethics that applies to our principal executive officer and principal financial and accounting officer, or persons performing similar functions. We intend to disclose any amendments to, or waivers from, our code of business conduct and ethics that are required to be publicly disclosed pursuant to rules of the Securities and Exchange Commission and the NASDAQ National Market by filing such amendment or waiver with the Securities and Exchange Commission.

**Item 10. Executive Compensation.**

The discussion under the heading "Executive Compensation" in our definitive proxy statement for the 2005 Annual Meeting of Stockholders is incorporated herein by reference to such proxy statement.

**Item 11. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.**

The discussion under the heading "Security Ownership of Certain Beneficial Owners and Management" in our definitive proxy statement for the 2005 Annual Meeting of Stockholders is incorporated herein by reference to such proxy statement.

**Item 12. Certain Relationships and Related Transactions.**

The discussion under the heading "Certain Relationships and Related Transactions" in our definitive proxy statement for the 2005 Annual Meeting of Stockholders is incorporated herein by reference to such proxy statement.

**Item 13. Exhibits and Financial Statement Schedules.**

(1) Financial Statements.

Reference is made to the Index to Financial Statements on Page F-1.

(2) Financial Statement Schedules.

None.

(3) Exhibits.

Reference is made to the Index to Exhibits on Page 40.

**Item 14. Principal Accountant Fees and Services.**

The discussion under the heading "Principal Accountant Fees and Services" in our definitive proxy statement for the 2005 Annual Meeting of Stockholders is incorporated herein by reference to such proxy statement.

**Table of Contents****SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized this 31st day of March, 2005.

BIO-IMAGING TECHNOLOGIES, INC.

By:           /s/ MARK L. WEINSTEIN          

**Mark L. Weinstein,**

**President and Chief Executive Officer**

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

| <u>Signature</u>   | <u>Title</u>  | <u>Date</u>    |
|--|---|----------------|
| <u>          /s/ MARK L. WEINSTEIN          </u><br><b>Mark L. Weinstein</b>                         | President and Chief Executive Officer and<br>Director (principal executive officer)               | March 31, 2005 |
| <u>          /s/ TED I. KAMINER          </u><br><b>Ted I. Kaminer</b>                               | Senior Vice President and Chief Financial Officer<br>(principal financial and accounting officer) | March 31, 2005 |
| <u>          /s/ JEFFREY H. BERG, PH.D.          </u><br><b>Jeffrey H. Berg, Ph.D.</b>               | Director  | March 31, 2005 |
| <u>          /s/ RICHARD CIMINO          </u><br><b>Richard Cimino</b>                               | Director  | March 31, 2005 |
| <u>          /s/ E. MARTIN DAVIDOFF, ESQ., CPA          </u><br><b>E. Martin Davidoff, Esq., CPA</b> | Director  | March 31, 2005 |
| <u>          /s/ DAVID E. NOWICKI, D.M.D.          </u><br><b>David E. Nowicki, D.M.D.</b>           | Chairman of the Board and Director  | March 31, 2005 |
| <u>          /s/ DAVID STACK          </u><br><b>David Stack</b>                                     | Director  | March 31, 2005 |

Edgar Filing: BIO IMAGING TECHNOLOGIES INC - Form 10KSB

/s/ JAMES A. TAYLOR, Ph.D.

Director

March 31, 2005

---

**James A. Taylor, Ph.D.**

/s/ PAULA BROWN STAFFORD

Director

March 31, 2005

---

**Paula Brown Stafford**



**Table of Contents****EXHIBIT INDEX**

| <b>Exhibit No.</b> | <b>Description of Exhibit</b>   |
|--------------------|---|
| 2.1                | Asset Purchase Agreement dated October 25, 2001, by and between Bio-Imaging Technologies, Inc. and Quintiles, Inc. Incorporated by reference to Exhibit 2.1 of our Current Report on Form 8-K dated October 25, 2001.   |
| 3.1                | Restated Certificate of Incorporation of Bio-Imaging Technologies, Inc. Incorporated by reference to Exhibit 3.1 of our Registration Statement on Form S-1 (File Number 33-47471), which became effective on June 18, 1992. Amendments incorporated by reference to Exhibit 3.1 of our Annual Report on Form 10-K for the year ended September 30, 1993 and to Exhibit 3.1 of our Quarterly Report on Form 10-QSB for the quarter ended March 31, 1995. |
| 3.2                | Amended and Restated By-Laws of Bio-Imaging Technologies, Inc. Incorporated by reference to Exhibit 3.1 of our Quarterly Report on Form 10-QSB for the quarter ended June 30, 2001.   |
| 4.1                | Specimen Common Stock Certificate. Incorporated by reference to Exhibit 4.1 of our Registration Statement on Form S-1 (File Number 33-47471), which became effective on June 18, 1992.  |
| 4.2                | Registration Agreement dated October 13, 1994, between Bio-Imaging Technologies, Inc. and Corning Pharmaceuticals Services Inc., now Covance Inc. Incorporated by reference to Exhibit 4.1 of our Current Report on Form 8-K dated October 13, 1994.  |
| 4.3                | Registration Rights Agreement dated as of October 25, 2001, by and between Bio-Imaging Technologies, Inc. and Quintiles, Inc. Incorporated by reference to Exhibit 2 of our Current Report on Form 8-K/A dated October 25, 2001.  |
| 4.4                | Promissory Note dated October 25, 2001, made by Bio-Imaging Technologies, Inc. in favor of Quintiles, Inc. Incorporated by reference to Exhibit 4.1 of our Current Report on Form 8-K dated October 25, 2001.   |
| 4.5                | Promissory Note for \$5,000,000, dated May 15, 2004, made by Bio-Imaging Technologies, Inc. in favor of Wachovia Bank, National Association.  |
| 10.1*              | 2002 Stock Incentive Plan, adopted by the stockholders of Bio-Imaging Technologies, Inc. on February 27, 2002. Incorporated by reference to Exhibit 99.1 of our Registration Statement on Form S-8 dated April 2, 2002.   |
| 10.2*              | 401(k) Plan. Incorporated by reference to Exhibit 10.7 of our Registration Statement on Form S-1 (File Number 33-47471), which became effective on June 18, 1992.   |
| 10.3               | Form of Employee s Invention Assignment, Confidential Information and Non-Competition Agreement. Incorporated by reference to Exhibit 10.9 of our Annual Report on Form 10-K for the fiscal year ended September 30, 1992.  |
| 10.4               | Stock Purchase Agreement dated October 13, 1994, between Bio-Imaging Technologies, Inc. and Covance Inc. Incorporated by reference to Exhibit 10.2 of our Current Report on Form 8-K dated October 13, 1994.  |
| 10.5*              | Invention Assignment and Confidential Information Agreement dated January 20, 2000, by and between Bio-Imaging Technologies, Inc. and Mark L. Weinstein. Incorporated by reference to Exhibit 10.1 of our Quarterly Report on Form 10-QSB for the quarter ended December 31, 1999.  |
| 10.6*              | Employment Agreement dated March 28, 2005, by and between Bio-Imaging Technologies, Inc. and Mark L. Weinstein.   |

**Table of Contents**

| <b>Exhibit No.</b> | <b>Description of Exhibit</b>  |
|--------------------|--|
| 10.7               | Security Agreement dated April 30, 2002, made by Bio-Imaging Technologies, Inc. in favor of Wachovia Bank, National Association. Incorporated by reference to Exhibit 10.4 of our Quarterly Report on Form 10-QSB for the quarter ended June 30, 2002.       |
| 10.8               | First Modification of Office Space Lease between 826 Newtown Associates, LP and Bio-Imaging Technologies, Inc. dated January 11, 2002. Incorporated by reference to Exhibit 10.2 of our Quarterly Report on Form 10-QSB for the quarter ended June 30, 2002. |
| 10.9               | Office Space Lease dated September 22, 1999, between Yardley Road Associates, L.P. and Bio-Imaging Technologies, Inc. Incorporated by reference to Exhibit 10.9 of our Annual Report on Form 10-KSB for the fiscal year ended September 30, 1999.            |
| 10.10              | Office Space Lease dated September 11, 2000, between Angelo Investment Company and Bio-Imaging Technologies, Inc. Incorporated by reference to Exhibit 10.11 of our Annual Report on Form 10-KSB for the fiscal year ended September 30, 2000.               |
| 10.11*             | Employment Agreement dated February 6, 2003, by and between Bio-Imaging Technologies, Inc. and Ted I. Kaminer. Incorporated by reference to Exhibit 10.1 of our Quarterly Report on Form 10-QSB/A for the quarter ended March 31, 2003.                      |
| 10.12              | Loan Agreement dated May 15, 2004, by and between Bio-Imaging Technologies, Inc. and Wachovia Bank, National Association.  |
| 10.13              | Securities Purchase Agreement dated September 15, 2003, by and between Bio-Imaging Technologies, Inc. and certain institutional investors. Incorporated by reference to Exhibit 10.1 of our Current Report on Form 8-K dated September 15, 2003.             |
| 10.14              | Registration Rights Agreement dated September 15, 2003, by and between Bio-Imaging Technologies, Inc. and certain institutional investors. Incorporated by reference to Exhibit 10.2 of our Current Report on Form 8-K dated September 15, 2003.             |
| 10.15*             | Form of Executive Retention Agreement by and between Bio-Imaging Technologies, Inc. and certain executive officers. Incorporated by reference to Exhibit 10.1 of our Quarterly Report on Form 10-QSB for the quarter ended September 30, 2004.               |
| 10.16              | Asset Purchase Agreement, dated November 20, 2003, by and between Bio-Imaging Technologies, Inc. and CapMed, Inc.  |
| 10.17              | Stock Purchase Agreement, dated December 10, 2004, by and between Bio-Imaging Technologies, Inc. and Heart Core B.V.   |
| 10.18              | Fourth Modification of Office Space Lease between 826 Newtown Associates, LP and Bio-Imaging Technologies, Inc. dated September 29, 2004.  |
| 21                 | List of Subsidiaries of Registrant. Incorporated by reference to Exhibit 21.1 of our Annual Report on Form 10-KSB for the fiscal year ended September 30, 1997.  |
| 23.1               | Consent of PricewaterhouseCoopers LLP.   |
| 31.1               | Certification of principal executive officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.  |
| 31.2               | Certification of principal financial and accounting officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.   |

**Table of Contents**

**Exhibit**

| <b>No.</b> | <b>Description of Exhibit</b>  |
|------------|--|
| 32.1       | Certification of principal executive officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. 1350.                |
| 32.2       | Certification of principal financial and accounting officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. 1350. |

\* A management contract or compensatory plan or arrangement required to be filed as an exhibit pursuant to Item 13(a) of Form 10-KSB. Included herewith.

(b) Financial Statement Schedules.

None.

**Table of Contents**

**BIO-IMAGING TECHNOLOGIES, INC. AND SUBSIDIARIES**

**CONTENTS**

|  |     |
|--|-----|
| <u>Report of Independent Registered Public Accounting Firm</u>                                       | F-2 |
| Consolidated Financial Statements:   |     |
| <u>Consolidated Balance Sheets as of December 31, 2004 and 2003</u>                                  | F-3 |
| <u>Consolidated Statements of Income for the year ended December 31, 2004 and 2003</u>               | F-4 |
| <u>Consolidated Statements of Stockholders' Equity for the year ended December 31, 2004 and 2003</u> | F-5 |
| <u>Consolidated Statements of Cash Flows for the year ended December 31, 2004 and 2003</u>           | F-6 |
| <u>Notes to Consolidated Financial Statements</u>  | F-7 |

F-1

**Table of Contents**

**Report of Independent Registered Public Accounting Firm**

To the Board of Directors

and Stockholders of

Bio-Imaging Technologies, Inc.:

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of income, stockholders' equity and cash flows present fairly, in all material respects, the financial position of Bio-Imaging Technologies, Inc at December 31, 2004 and 2003, and the results of their operations and their cash flows for each of the years then ended in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

Philadelphia, Pennsylvania

March 31, 2005

F-2

**Table of Contents****BIO-IMAGING TECHNOLOGIES, INC. AND SUBSIDIARIES****CONSOLIDATED BALANCE SHEETS**

|  | <b>December 31,</b>  |                      |
|--|----------------------|----------------------|
|  | <b>2004</b>          | <b>2003</b>          |
| <b>ASSETS</b>  |                      |                      |
| <i>Assets:</i>   |                      |                      |
| Cash and cash equivalents  | \$ 9,650,140         | \$ 13,289,453        |
| Accounts receivable, net of allowance for doubtful accounts of \$14,167 and \$26,821, respectively   | 7,957,736            | 4,429,117            |
| Prepaid expenses and other current assets  | 889,208              | 573,978              |
| Deferred income taxes  | 1,551,916            | 1,613,498            |
| <b>Total current assets</b>  | <b>20,049,000</b>    | <b>19,906,046</b>    |
| Property and equipment, net  | 5,101,569            | 4,661,720            |
| Intangibles and goodwill   | 2,905,025            | 938,594              |
| Other assets   | 318,220              | 400,254              |
| <b>Total Assets</b>  | <b>\$ 28,373,814</b> | <b>\$ 25,906,614</b> |
| <b>LIABILITIES AND STOCKHOLDERS EQUITY</b>   |                      |                      |
| <i>Liabilities:</i>  |                      |                      |
| Accounts payable   | \$ 1,269,855         | \$ 984,997           |
| Accrued expenses and other current liabilities   | 1,859,022            | 1,602,806            |
| Deferred revenue   | 3,076,630            | 3,070,359            |
| Current maturities of capital lease obligations and convertible note   | 722,086              | 1,281,997            |
| <b>Total current liabilities</b>   | <b>6,927,593</b>     | <b>6,940,159</b>     |
| Long-term capital lease obligations  | 906,922              | 770,702              |
| Deferred income taxes  | 889,976              | 661,018              |
| Other liability  | 131,681              | 108,347              |
| <b>Total liabilities</b>   | <b>8,856,172</b>     | <b>8,480,226</b>     |
| <b>Commitments and Contingencies</b>   |                      |                      |
| <i>Stockholders Equity:</i>  |                      |                      |
| Preferred stock - \$.00025 par value; authorized 3,000,000 shares, 0 issued and outstanding at December 31, 2004 and 2003  |                      |                      |
| Common stock - \$.00025 par value; authorized 18,000,000 shares, issued and outstanding 11,027,320 and 10,710,481 shares at December 31, 2004 and 2003, respectively | 2,757                | 2,678                |
| Additional paid-in capital   | 22,016,231           | 20,873,968           |
| Accumulated deficit  | (2,501,346)          | (3,450,258)          |
| <b>Stockholders equity</b>   | <b>19,517,642</b>    | <b>17,426,388</b>    |
| <b>Total liabilities and stockholders equity</b>   | <b>\$ 28,373,814</b> | <b>\$ 25,906,614</b> |



The accompanying notes are an integral part of these statements.

F-3

**Table of Contents****BIO-IMAGING TECHNOLOGIES, INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF INCOME**

|  | For the year ended |                     |
|--|--------------------|---------------------|
|  | December 31,       |                     |
|  | 2004               | 2003                |
| Service revenues   | \$ 25,068,670      | \$ 21,747,636       |
| Reimbursement revenues   | 4,622,105          | 3,463,071           |
| <b>Total revenues</b>  | <b>29,690,775</b>  | <b>25,210,707</b>   |
| Cost and expenses:   |                    |                     |
| Cost of revenues   | 20,451,633         | 16,875,166          |
| General and administrative expenses  | 4,452,535          | 4,079,419           |
| Sales and marketing expenses   | 3,182,125          | 2,057,878           |
| <b>Total cost and expenses</b>   | <b>28,086,293</b>  | <b>23,012,463</b>   |
| <b>Income from operations</b>  | <b>1,604,482</b>   | <b>2,198,244</b>    |
| Interest (income) expense net  | (2,864)            | 130,655             |
| <b>Income before income tax</b>  | <b>1,607,346</b>   | <b>2,067,589</b>    |
| Income tax provision (benefit)   | 658,434            | (270,264)           |
| <b>Net income</b>  | <b>\$ 948,912</b>  | <b>\$ 2,337,853</b> |
| Basic earnings per common share  | \$ 0.09            | \$ 0.25             |
| Weighted average number of common shares                                       | 10,812,185         | 9,275,752           |
| Diluted earnings per common share  | \$ 0.08            | \$ 0.22             |
| Weighted average number of common shares and dilutive common equivalent shares | 12,228,746         | 10,848,979          |

The accompanying notes are an integral part of these statements.



**Table of Contents****BIO-IMAGING TECHNOLOGIES, INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY**

|  | <u>Common Stock</u> |               | <u>Additional</u>                | <u>Accumulated</u> | <u>Stockholders</u> |
|--|---------------------|---------------|----------------------------------|--------------------|---------------------|
|  | <u>Shares</u>       | <u>Amount</u> | <u>Paid-in</u><br><u>Capital</u> |                    |                     |
| Balance at January 1, 2003                                     | 8,427,653           | \$ 2,107      | \$ 9,405,412                     | \$ (5,788,111)     | \$ 3,619,408        |
| Stock options exercised  | 280,555             | 70            | 275,318                          |                    | 275,388             |
| Tax benefit on exercise of stock options                       |                     |               | 413,596                          |                    | 413,596             |
| Shares issued for contingent liability incurred in acquisition | 188,549             | 47            | 567,675                          |                    | 567,722             |
| Shares issued in private placement                             | 1,762,000           | 441           | 9,873,809                        |                    | 9,874,250           |
| Shares issued for intangible assets                            | 51,724              | 13            | 338,158                          |                    | 338,171             |
| Net income   |                     |               |                                  | 2,337,853          | 2,337,853           |
| Balance at December 31, 2003                                   | 10,710,481          | 2,678         | 20,873,968                       | (3,450,258)        | 17,426,388          |
| Stock options exercised  | 140,986             | 35            | 129,625                          |                    | 129,660             |
| Shares issued for acquisition                                  | 175,853             | 44            | 847,831                          |                    | 847,875             |
| Tax benefit on exercise of stock options                       |                     |               | 164,807                          |                    | 164,807             |
| Net income   |                     |               |                                  | 948,912            | 948,912             |
| Balance at December 31, 2004                                   | 11,027,320          | \$ 2,757      | \$ 22,016,231                    | \$ (2,501,346)     | \$ 19,517,642       |

The accompanying notes are an integral part of these statements.

**Table of Contents****BIO-IMAGING TECHNOLOGIES, INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF CASH FLOWS**

|   | For the year ended  |                      |
|---|---------------------|----------------------|
|   | December 31,        |                      |
|   | 2004                | 2003                 |
| <i>Cash flows from operating activities:</i>  |                     |                      |
| Net income  | \$ 948,912          | \$ 2,337,853         |
| Adjustments to reconcile net income to net cash provided by operating activities, net of acquisition: |                     |                      |
| Depreciation and amortization   | 1,759,789           | 1,075,742            |
| Provision (benefit) for deferred income taxes   | 364,648             | (418,965)            |
| Sales leaseback gains   | 34,018              |                      |
| Bad debt benefit  | (12,654)            | (38,179)             |
| Non-cash stock based compensation expense   | 13,704              | 26,266               |
| Changes in operating assets and liabilities:  |                     |                      |
| Increase in accounts receivable   | (3,155,821)         | (463,168)            |
| Increase in prepaid expenses and other current assets   | (334,663)           | (175,455)            |
| Decrease in other assets  | 82,034              | 91,976               |
| Increase in accounts payable  | 284,857             | 325,091              |
| (Decrease) increase in accrued expenses and other current liabilities                                 | (297,372)           | 273,973              |
| Increase (decrease) in deferred revenue   | 6,272               | (194,301)            |
| Increase in other liabilities   | 23,334              | 46,786               |
| <b>Net cash (used in) provided by operating activities</b>  | <b>(282,942)</b>    | <b>2,887,619</b>     |
| <i>Cash flows used in investing activities:</i>   |                     |                      |
| Purchases of property and equipment   | (1,848,927)         | (1,641,209)          |
| Net cash paid for acquisitions  | (1,213,411)         | (273,014)            |
| <b>Net cash used in investing activities</b>  | <b>(3,062,338)</b>  | <b>(1,914,223)</b>   |
| <i>Cash flows from financing activities:</i>  |                     |                      |
| Payments under equipment lease obligations  | (659,513)           | (505,923)            |
| Payments under promissory note  | (666,666)           | (166,668)            |
| Proceeds from exercise of stock options   | 129,660             | 275,388              |
| Net proceeds from private placement   |                     | 9,874,250            |
| Proceeds from sales leaseback   | 902,486             | 275,744              |
| <b>Net cash (used in) provided by financing activities</b>  | <b>(294,033)</b>    | <b>9,752,791</b>     |
| Net (decrease) increase in cash and cash equivalents  | (3,639,313)         | 10,726,187           |
| Cash and cash equivalents at beginning of period  | 13,289,453          | 2,563,266            |
| <b>Cash and cash equivalents at end of period</b>   | <b>\$ 9,650,140</b> | <b>\$ 13,289,453</b> |

**Supplemental disclosure of cash flow information:**

Edgar Filing: BIO IMAGING TECHNOLOGIES INC - Form 10KSB

|   |                             |                             |
|---|-----------------------------|-----------------------------|
| Cash paid during the period for interest  | \$ 129,409                  | \$ 139,942                  |
| Cash paid during the period for income taxes  | \$ 270,225                  |                             |
| <b>Supplemental schedule of noncash investing and financing activities:</b>                           |                             |                             |
| Equipment purchases under capital lease obligations   | \$ 902,486                  | \$ 760,697                  |
| Contingent liability converted to common stock incurred in connection with acquisition                |                             | \$ 567,722                  |
| <i>Acquired business and assets:</i>  |                             |                             |
| Accounts receivable   | \$ 360,144                  |                             |
| Other assets  | 14,585                      |                             |
| Property and equipment  | 132,720                     |                             |
| Intangible assets and goodwill  | 2,184,422                   | 855,585                     |
| Net current liabilities assumed   | (567,016)                   |                             |
| Deferred income taxes   | (63,569)                    | (244,400)                   |
| Common stock issued   | (847,875)                   | (338,171)                   |
|   | <u>                    </u> | <u>                    </u> |
| Cash paid for acquired business and assets, net of cash acquired of \$196,739 in 2004 and \$0 in 2003 | \$ 1,213,411                | \$ 273,014                  |
|   | <u>                    </u> | <u>                    </u> |

The accompanying notes are an integral part of these statements.

**Table of Contents**

**BIO-IMAGING TECHNOLOGIES, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1. Principal Business Activity and Significant Accounting Policies**

*Description of Business*

Bio-Imaging Technologies, Inc. and Subsidiaries ( Bio-Imaging or the Company ) is a pharmaceutical contract service organization, operating in two business segments, the pharmaceutical services division provide 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 ), positron emission tomography ( PET ), single photon emission computerized tomography ( SPECT ), quantitative coronary angiography ( QCA ), cardiac MRI and CT, intravascular ultrasound ( IVUS ), peripheral quantitative angiography ( QVA ) and ultrasound. The Company provides services which include the processing and analysis of medical images and the data-basing and regulatory submission of medical images, quantitative data and text. The Company s CapMed division includes the Personal Health Record ( PHR ) software 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.

*Principles of Consolidation*

The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, Oxford Bio-Imaging Research, Inc. and Bio-Imaging Technologies Holding B.V. All intercompany transactions and balances have been eliminated.

*Use of Estimates*

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

*Fair Value of Financial Instruments*

## Edgar Filing: BIO IMAGING TECHNOLOGIES INC - Form 10KSB

The carrying values of the Company's financial instruments, which include cash equivalents, accounts receivable, accounts payable and other accrued expenses approximate their fair values due to their short maturities. Based on borrowing rates currently available to the Company for loans with similar terms, the carrying value of notes payable and capital lease obligations approximates fair value.

### *Cash and Cash Equivalents*

The Company maintains cash in excess of FDIC insurance limits in certain financial institutions. The Company considers cash equivalents to be highly liquid investments with a maturity at the time of purchase of three months or less.

The Company has a standby letter of credit which approximated \$166,000 at December 31, 2004 and 2003. This letter of credit represents an irrevocable guarantee to fulfill the office facilities operating lease obligation.

F-7

**Table of Contents**

**BIO-IMAGING TECHNOLOGIES, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Since there is no market value for this instrument, it is not practicable to estimate the fair value which has been stated at cost. Management does not expect any material loss to result from this instrument.

***Revenue Recognition***

Service revenues are recognized over the contractual term of the Company's customer contracts using the proportional performance method, which is based on hours incurred as a percentage of total estimated hours. Service revenues are first recognized when the Company has a signed contract from a customer which: (i) contains fixed or determinable fees; and (ii) collectability of such fees is reasonably assured. Any change to recognized service revenue as a result of revisions to estimated total hours are recognized in the period the estimate changes.

The Company enters into contracts that contain fixed or determinable fees. The fees in the contracts are based on the scope of work we are contracted to perform; there are unitized fees per service and fixed fees with a total estimated for the contract based upon the estimated unitized service expected to be performed, as well as the service to be delivered under the fixed fee component of the contract. The units are estimated based on the information provided by the customer, and the Company bills the customer for actual units completed in accordance with the terms of the contract. In the event that a contract is cancelled by the client, we would be entitled to receive payment for all services performed up to the cancellation date.

The Company's revenue recognition policy entails a number of estimates including an estimate of the total hours that are expected to be incurred on a project, which is used as the basis for determining the portion of the Company's revenue to be recognized for each period. The revenue recognized in any period might have been materially affected if different assumptions or conditions prevailed. The timing of the Company's recognition of revenue would be revised if there were changes in the total estimated hours (other than scope changes in a project which typically result in a revision to the contract). The Company reviews its total estimated hours monthly. Provisions for losses expected to be incurred on contracts are recognized in full in the period in which it is determined that a loss will result from performance of the contractual arrangement.

The Company also incurs direct costs at the outset of a customer service arrangement prior to receiving a final signed contract. Accordingly, the Company defers these costs and delays the recording of any revenue until the contract is executed. If a customer does not execute the contract, the Company immediately expenses the deferred costs, offset by any deferred service revenue associated with these costs.

Unbilled services represent revenue recognized which pursuant to contractual terms have not yet been billed to the client. In general, amounts become billable pursuant to contractual milestones or in accordance with predetermined payment schedules. Unbilled services are generally billable within one year from the respective balance sheet date. Deferred revenue is recorded for cash received from clients for services that have not yet been earned at the respective balance sheet date.

## Edgar Filing: BIO IMAGING TECHNOLOGIES INC - Form 10KSB

Bio-Imaging, at the request of its clients, may directly pay the independent radiologist who reviews the client's imaging data. These costs are passed directly to the clients and are included in Reimbursement Revenue and Cost of Revenues. Amounts for such reimbursements were immaterial in prior years and have been reclassified in the 2003 Consolidated Statements of Income from Cost of Revenues to Reimbursement Revenues to conform with the current year presentation. This reclassification had no effect on income from operations, net income, cash flows or the balance sheets.

F-8

**Table of Contents****BIO-IMAGING TECHNOLOGIES, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)*****Allowance For Doubtful Accounts***

The Company maintains allowances for doubtful accounts on a specific identification method for estimated losses resulting from the inability of its customers to make required payments. If the financial condition of its customers were to deteriorate, resulting in an impairment of the customers ability to make payments, additional allowances may be required. The Company does not have any off-balance-sheet credit exposure related to its customers and the trade accounts receivable does not bear interest.

|                                    | <b>December 31,</b> |                     |
|------------------------------------|---------------------|---------------------|
|                                    | <b>2004</b>         | <b>2003</b>         |
| Billed trade accounts receivable   | \$ 3,718,465        | \$ 2,315,973        |
| Unbilled trade accounts receivable | 4,252,845           | 2,139,965           |
| Employee receivables               | 593                 |                     |
| <b>Total receivables</b>           | <b>\$ 7,971,903</b> | <b>\$ 4,455,938</b> |
| <i>Allowance Rollforward:</i>      |                     |                     |
| Balance at January 1, 2003         | \$ 65,000           |                     |
| Additions                          |                     |                     |
| Write offs (net of recoveries)     | (38,179)            |                     |
| Balance at December 31, 2003       | 26,821              |                     |
| Additions                          | 1,563               |                     |
| Write offs (net of recoveries)     | (14,217)            |                     |
| Balance at December 31, 2004       | <b>\$ 14,167</b>    |                     |

***Property and Equipment***

Property and equipment is recorded at historical cost and depreciated over the estimated useful lives of the respective assets. Amortization of leasehold improvements is provided for over the lesser of the related lease term, or the useful lives of the related assets. The cost and related accumulated depreciation of assets fully depreciated, sold, retired or otherwise disposed of are removed from the respective accounts and any resulting gains or losses are included in the statements of income.



Management periodically evaluates the net realizable value of long-lived assets, including property and equipment, relying on a number of factors including operating results, business plans, economic projections and anticipated future cash flows. If these factors indicate that the carrying value of a long lived asset exceeds the net realizable value, the Company will record an impairment and reduce the carrying value of the asset to the net realizable value.

*Capitalized Software Development*

The Company capitalizes development costs for a software project once the preliminary project stage is completed, management commits to funding the project and it is probable that the project will be completed and the software will be used to perform the function intended. The Company ceases capitalization at such time as the computer software project is substantially complete and ready for its intended use. The determination that a software project is eligible for capitalization and the ongoing assessment of recoverability of capitalized software development costs require considerable judgment by management with respect to certain external factors including, but not limited to, anticipated future revenue, estimated economic life and changes in software and hardware technologies. The Company capitalized software development costs of \$611,613 and \$460,000 for the

**Table of Contents****BIO-IMAGING TECHNOLOGIES, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

year ended December 31, 2004 and 2003, respectively. Accumulated amortization related to capitalized computer software costs amounted to \$274,000 and \$47,000 at December 31, 2004 and 2003, respectively. Capitalized software development costs are included as a component of property and equipment.

***Income Taxes***

The Company accounts for income taxes under the provisions of SFAS No. 109, Accounting for Income Taxes, which utilizes the liability method. Deferred taxes are determined based on the estimated future tax effects of differences between the financial statement and tax bases of assets and liabilities at currently enacted tax laws and rates. A valuation allowance is provided against the carrying value of deferred tax assets when management believes it is more likely than not that the deferred tax assets will not be realized. The Company recognizes contingent liabilities for any tax related exposures when those exposures are both probable and estimable.

***Foreign Currency Translation***

The United States Dollar is the functional currency for the Company's foreign subsidiaries.

***Earnings Per Share***

SFAS No. 128 Earnings per Share requires the presentation of basic earnings per share and diluted earnings per share. Basic earnings per common share are calculated by dividing the net income available to Common Stockholders by the weighted average number of shares of Common Stock outstanding during the period. Diluted earnings per common share is calculated by dividing net income by the weighted average number of shares of Common Stock outstanding, adjusted for the effect of potentially dilutive securities using the treasury stock method.

The computation of basic earnings per common share and diluted earnings per common share is as follows:

| <b>For the year ended</b> |             |
|---------------------------|-------------|
| <b>December 31,</b>       |             |
| <hr/>                     |             |
| <b>2004</b>               | <b>2003</b> |

Edgar Filing: BIO IMAGING TECHNOLOGIES INC - Form 10KSB

|  |            |              |
|--|------------|--------------|
| Net income basic   | \$ 948,912 | \$ 2,337,853 |
| Interest expense on convertible note   | 27,336     | 37,454       |
| Net income diluted   | 976,248    | 2,375,307    |
| Denominator basic:   |            |              |
| Weighted average number of common shares                                       | 10,812,185 | 9,275,752    |
| Basic earnings per common share  | \$ 0.09    | \$ 0.25      |
| Denominator diluted:   |            |              |
| Weighted average number of common shares                                       | 10,812,185 | 9,275,752    |
| Common share equivalents of outstanding stock options                          | 1,284,894  | 1,429,149    |
| Common share equivalents related to the convertible promissory note            | 131,667    | 144,078      |
| Weighted average number of common shares and dilutive common equivalent shares | 12,228,746 | 10,848,979   |
| Diluted earnings per common share  | \$ 0.08    | \$ 0.22      |

At December 31, 2004, the Company has one stock-based employee compensation plan, which is described in detail in Note 6. The Company accounts for this plan under the recognition and measurement principles of

**Table of Contents****BIO-IMAGING TECHNOLOGIES, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

APB Opinion No. 25, Accounting for Stock Issued to Employees, and related Interpretations. No stock-based employee compensation cost is reflected in net income, as all options granted under this plan had an exercise price equal to the market value of the underlying Common Stock on the date of grant. However, the Company has recorded stock-based compensation expense for restricted shares granted to a Company executive. The following table illustrates the effect on net income and earnings per share if the Company had applied the fair value recognition provisions of FASB Statement No. 123, Accounting for Stock-Based Compensation, as amended by FASB Statement No. 148 Accounting for Stock-Based Compensation Transition and Disclosure, to account for stock-based employee compensation.

|   | For the year ended<br>December 31, |                     |
|---|------------------------------------|---------------------|
|   | 2004                               | 2003                |
| Net income, as reported   | \$ 948,912                         | \$ 2,337,853        |
| Add: Stock-based employee compensation expense included in reported net income, net of related tax effects                                  | 8,222                              | 15,760              |
| Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects | (744,091)                          | (804,086)           |
| <b>Pro forma net income</b>   | <b>\$ 213,043</b>                  | <b>\$ 1,549,527</b> |
| <b>Earnings per share:</b>  |                                    |                     |
| Basic as reported   | \$ 0.09                            | \$ 0.25             |
| Basic pro forma   | \$ 0.02                            | \$ 0.17             |
| Diluted as reported   | \$ 0.08                            | \$ 0.22             |
| Diluted pro forma   | \$ 0.02                            | \$ 0.14             |

The weighted average fair value of options granted for the year ended December 31, 2004 and 2003 was \$3.40 and \$2.91, respectively. The fair value of each option granted is estimated on the date of grant using the Black-Scholes option pricing model with the following weighted average assumptions:

|                         | 2004   | 2003    |
|-------------------------|--------|---------|
| Risk-free interest rate | 3.50%  | 3.01%   |
| Expected dividend yield | 0.00%  | 0.00%   |
| Expected volatility     | 67.00% | 105.00% |
| Expected life in years  | 4.00   | 6.00    |

**Reclassifications**

## Edgar Filing: BIO IMAGING TECHNOLOGIES INC - Form 10KSB

The Company has reclassified certain 2003 financial statement amounts to conform to the 2004 financial statement presentation.

### ***Recently Issued Accounting Statements***

In December 2004, the Financial Accounting Standards Board ( FASB ) issued FASB Statement No. 123(R) ( FAS 123(R) ), *Share-Based Payment*. FAS 123(R) revises FASB Statement No. 123 ( FAS 123 ), *Accounting for Stock-Based Compensation*. Also, FAS 123(R) supersedes Accounting Principles Board ( APB ) Opinion No. 25, *Accounting for Stock Issued to Employees*, and amends FASB Statement No. 95, *Statement of Cash Flows*. For public companies, FAS 123(R) is effective for periods beginning after June 15, 2005.

FAS 123(R) requires companies to expense the fair value of employee stock options and other forms of stock-based compensation. Specifically, FAS 123(R) requires companies to (i) use fair value to measure

**Table of Contents**

**BIO-IMAGING TECHNOLOGIES, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

stock-based compensation awards and (ii) cease using the intrinsic value method of accounting under APB 25 that resulted in no expense for many awards of stock options for which the exercise price of the option equaled the price of the underlying stock at the grant date. In addition, FAS 123(R) retains the modified grant date model from FAS 123 in that compensation cost is measured at the grant date fair value of the award and adjusted to reflect actual forfeitures and the outcome of certain conditions. The fair value of an award is not re-measured after its initial estimation on the grant date, except in certain cases. FAS 123(R)'s transition provisions provide a number of alternatives to address implementation issues and to increase the comparability of compensation cost.

The Company expects to adopt the Modified Prospective Application (MPA) method, without restatement of prior interim periods on July 1, 2005. Under the MPA method without restatement approach, the Company would recognize compensation cost for (1) awards that were granted or modified after the fiscal year beginning after December 15, 1994, (2) any portion of awards that have not vested by July 1, 2005, and (3) any outstanding liability awards. Compensation cost for the portion of awards for which the requisite service has not been rendered that are outstanding at July 1, 2005, will be recognized using the measurement data and attribution method used in the Company's FAS 123 pro forma disclosures as those services are received after July 1, 2005.

The Company is currently assessing the impact of FAS 123(R) on its 2005 financial statements and believes that this will have a material effect on its results of operations.

The Company has undergone a study of its stock-based compensation plans in anticipation of the adoption of FAS 123(R) and recent changes in tax laws with regard to deferred compensation. Currently, the Company does not anticipate a change in its current compensation strategy or structure, but continue to look for ways to compensate individuals via avenues that align the interests of individuals with the interests of shareholders through ownership of company stock.

In December 2004, the FASB issued FASB Staff Position No. FAS 109-2 (FAS 109-2), *Accounting and Disclosure Guidance for the Foreign Earnings Repatriation Provision within the American Jobs Creation Act of 2004*. The AJCA introduces a limited time 85% dividends received deduction on the repatriation of certain foreign earnings to a U.S. taxpayer (repatriation provision), provided certain criteria are met. FAS 109-2 provides accounting and disclosure guidance for the repatriation provision. Bio-Imaging does not expect the adoption of this new tax provision to have a material impact on its consolidated financial statements.

In December 2004, the FASB issued SFAS Statement No. 153, *Exchanges of Non-monetary Assets*. The Statement is an amendment of APB Opinion No. 29 to eliminate the exception for non-monetary exchanges of similar productive assets and replaces it with a general exception for exchanges on non-monetary assets that do not have commercial substance. The effective date is for exchanges occurring in fiscal periods beginning after June 15, 2005. Bio-Imaging believes that the adoption of this standard will have no material impact on its consolidated financial statements.

**2. Acquisitions**

On October 1, 2001, the Company acquired effective control of the Intelligent Imaging business unit ( Intelligent Imaging ) of Quintiles, Inc., a North Carolina corporation ( Quintiles ), and a wholly-owned subsidiary of Quintiles Transnational Corporation (the Intelligent Imaging Acquisition ). The Intelligent Imaging Acquisition closed on October 25, 2001. The Company acquired the Intelligent Imaging business of Quintiles, Inc. to expand its medical image management services for pharmaceutical clinical trials. The negotiations between the Company and Quintiles were conducted on an arms-length basis. As a result of the acquisition, the Company acquired certain tangible property, contracts, leases, intellectual property and permits. Prior to the acquisition, Intelligent Imaging competed with the Company in providing digital medical imaging services for clinical trials in the health care industry.

---

**Table of Contents**

**BIO-IMAGING TECHNOLOGIES, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The assets acquired primarily included Intelligent Imaging's accounts receivable and equipment. In consideration for the assets purchased, the Company issued an uncollateralized, subordinated convertible promissory note, dated as of October 25, 2001, in the principal amount of \$1,000,000 (the Note). The Note bore interest at the rate in effect on the business day immediately prior to the date on which payments are due under the Note equal to the Three-Month London Interbank Offering Rate (the LIBOR Rate) as published from time to time in the Wall Street Journal plus 3%, compounded annually based on a 365-day year.

The Company was obligated to pay quarterly payments of principal of \$41,667 under the Note, plus accrued interest thereon, and one payment of principal of \$500,000 on November 1, 2004, unless the Note was previously converted into the Company's common stock, \$0.00025 par value per share (the Common Stock). On November 1, 2004, the final payment on the Quintiles Note was made. This payment was comprised of the remaining principal balance of \$541,663 and interest of \$7,045.

On November 20, 2003, the Company acquired the intellectual property of CapMed Corporation (CapMed), including the Personal Health Record (PHR) software 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. The negotiations between the Company and CapMed were conducted on an arms-length basis. In connection with the acquisition, the Company paid aggregate consideration of \$550,000, consisting of \$211,828 in cash paid directly to CapMed's creditors and \$338,171 of Common Stock, which amounted to a total of 51,724 shares, of which 40,361 were issued to CapMed and 11,363 were issued to an escrow agent pursuant to the terms of the acquisition. The Company also incurred acquisition costs of \$61,186. Differences between the book and tax basis of the assets acquired from CapMed have been reflected as a deferred tax liability and allocated to the acquired assets in the amount of \$244,400. The assets acquired have been classified as a long-term asset.

On December 10, 2004, the Company acquired 100% of the stock of Heart Core B.V. (Heart Core), a privately held company located in Leiden, the Netherlands. Heart Core is a global provider of centralized imaging analysis services in the field of cardiovascular, pulmonary and orthopedic clinical research. In connection with the Heart Core acquisition, the Company paid total consideration of \$2,258,025, consisting of \$1,410,150 and 175,853 shares of the Company's common stock. \$1,269,135 and 158,268 shares of common stock were issued directly to the sellers, and \$141,015 and 17,585 shares of common stock were issued to an escrow agent pursuant to the terms of the acquisition. The escrow is being held as security for the payment of any unknown claims and will be released in December 2007. The Company also incurred acquisition costs of \$329,192.

The following unaudited consolidated pro forma information has been prepared assuming Heart Core was acquired as of January 1, 2003, with pro forma adjustments for interest expense and income taxes. The pro forma information is presented for informational purposes only and is not indicative of what would have occurred if the Heart Core acquisition had been made on January 1, 2003. In addition, this pro forma information is not intended to be a projection of future operating results.

**For the year ended December 31,**



Edgar Filing: BIO IMAGING TECHNOLOGIES INC - Form 10KSB

|                            | <u>2004</u>   | <u>2003</u>   |
|----------------------------|---------------|---------------|
| Total revenue              | \$ 30,715,877 | \$ 26,364,988 |
| Net income                 | \$ 1,051,519  | \$ 2,455,314  |
| Basic earnings per share   | \$ 0.10       | \$ 0.26       |
| Diluted earnings per share | \$ 0.09       | \$ 0.23       |

F-13

**Table of Contents****BIO-IMAGING TECHNOLOGIES, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****3. Property and Equipment**

Property and equipment, at cost, consists of the following:

|   | December 31,        |                     | Estimated<br>Useful Life |
|---|---------------------|---------------------|--------------------------|
|   | 2004                | 2003                |                          |
| Equipment                                       | \$ 4,529,640        | \$ 4,255,224        | 5 years                  |
| Equipment under capital leases                  | 3,709,955           | 2,807,467           | 5 years                  |
| Furniture and fixtures                          | 606,019             | 477,314             | 7 years                  |
| Leasehold improvements                          | 406,479             | 365,918             | 5 years                  |
| Computer software costs                         | 1,751,911           | 1,140,298           | 5 years                  |
|   | <u>11,004,004</u>   | <u>9,046,221</u>    |                          |
| Less: Accumulated depreciation and amortization | (5,902,435)         | (4,384,501)         |                          |
|   | <u>\$ 5,101,569</u> | <u>\$ 4,661,720</u> |                          |

Accumulated depreciation related to equipment acquired under capital leases amounted to \$1,677,758 and \$1,124,000 at December 31, 2004 and 2003, respectively. Accumulated amortization related to capitalized computer software costs amounted to \$274,000 and \$47,000 at December 31, 2004 and 2003, respectively. Depreciation expense for the year ended December 31, 2004 and 2003 approximated \$1,552,000 and \$1,029,000, respectively.

**4. Acquired Intangible Assets**

Included in other assets, the following is the acquired intangible assets:

|                              | December 31, |      | Estimated<br>Useful<br>Life |
|------------------------------|--------------|------|-----------------------------|
|                              | 2004         | 2003 |                             |
| Amortized intangible assets: |              |      |                             |

Edgar Filing: BIO IMAGING TECHNOLOGIES INC - Form 10KSB

|                                       |                     |                   |         |
|---------------------------------------|---------------------|-------------------|---------|
| Technology                            | \$ 406,502          | \$ 406,502        | 5 years |
| Trademarks                            | 372,130             | 372,130           | 5 years |
| Customer backlog                      | 165,900             |                   | 3 years |
| Non-competition agreement             | 175,190             |                   | 3 years |
| Non-competition agreement             | 76,953              | 76,953            | 2 years |
|                                       | <u>1,196,675</u>    | <u>855,585</u>    |         |
| Accumulated amortization              | (217,990)           |                   |         |
|                                       | <u>\$ 978,685</u>   | <u>\$ 855,585</u> |         |
| <b>Unamortized intangible assets:</b> |                     |                   |         |
| Goodwill                              | <u>\$ 1,926,340</u> | <u>\$ 83,009</u>  |         |

The Company has evaluated the intangible assets and has determined that there is no impairment of the values at December 31, 2004.

**Table of Contents****BIO-IMAGING TECHNOLOGIES, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Future amortization of the intangible assets is as follows:

|            | <b>Year Ending<br/>December 31,<br/>2004</b> |
|------------|--|
| 2005       | \$ 304,693                                   |
| 2006       | 269,424                                      |
| 2007       | 261,819                                      |
| 2008       | 142,749                                      |
| 2009       |  |
| Thereafter |  |
|            | <b>\$ 978,685</b>                            |

**5. Accrued Expenses**

Accrued expenses and other current liabilities at December 31, 2004 and 2003 consist of the following:

|                         | <b>December 31,</b> |                     |
|-------------------------|---------------------|---------------------|
|                         | <b>2004</b>         | <b>2003</b>         |
| Accrued compensation    | \$ 343,927          | \$ 891,608          |
| Accrued consulting fees | 521,237             | 239,912             |
| Accrued income taxes    | 292,082             | 294,526             |
| Accrued other           | 701,776             | 176,760             |
|                         | <b>\$ 1,859,022</b> | <b>\$ 1,602,806</b> |

**6. Long-term Debt and Capital Lease Obligations**

## Edgar Filing: BIO IMAGING TECHNOLOGIES INC - Form 10KSB

Long-term debt and capital lease obligations consist of equipment lease obligations and the promissory note (the Note ) issued in connection with the Intelligent Imaging Acquisition (Note 1). The equipment lease obligations are payable in monthly installments ranging from \$400 to \$24,957, including interest at rates ranging from 5.35% to 11.5%, through December 2007, and are collateralized by the related equipment. In connection with the Intelligent Imaging Acquisition, beginning February 1, 2002, the Company was obligated to pay quarterly payments of principal of \$41,667 under the Note, plus accrued interest thereon, and one payment of principal of \$500,000 on November 1, 2004, unless the Note was previously converted into the Company's common stock, \$0.00025 par value per share (the Common Stock ). The Company has recorded \$0 and \$666,664 for the total obligation of this Note at December 31, 2004 and 2003, respectively. The Note bore interest at the rate in effect on the business day immediately prior to the date on which payments were due under the Note equal to the LIBOR Rate as published from time to time in the Wall Street Journal plus 3%, compounded annually based on a 365-day year. On November 1, 2004, the Company made the final payment on the Note. This payment was comprised of the remaining principal balance of \$541,663.

On May 15, 2004, the Company renewed and amended its agreement with Wachovia Bank, National Association. The renewed and amended agreement is for an unsecured committed line of credit of \$5,000,000. Interest is payable at the LIBOR Market Index Rate plus 2.0%. The agreement requires the Company, among other things, to maintain certain financial covenants. The Company must at all times maintain a current ratio of not less than 2.00 to 1.00 and maintain an effective tangible net worth of not less than \$16,000,000. In addition, the Company can not incur indebtedness in excess of \$3,000,000 with anyone other than Wachovia without their

**Table of Contents****BIO-IMAGING TECHNOLOGIES, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

consent. The committed line of credit matures June 30, 2005 and may be renewed on an annual basis. At December 31, 2004, the Company had no borrowings under the committed line of credit.

On December 31, 2003, the Company entered into a \$275,744 sale-leaseback transaction whereby the Company sold and leased back computer equipment. The resulting lease is being accounted for as a capital lease. There was no gain or loss recorded on the sale. The lease term is 3 years with an interest rate of 6.77%.

On June 23, 2004, the Company entered into a \$339,567 sale-leaseback transaction whereby the Company sold and leased back computer equipment and furniture. The resulting lease is being accounted for as a capital lease. There was no gain or loss recorded on the sale. The lease term is 3 years with an interest rate of 5.35%.

On September 29, 2004, the Company entered into a \$332,536 sale-leaseback transaction whereby the Company sold and leased back computer equipment and furniture. The resulting lease is being accounted for as a capital lease. There was a gain recorded on the sale in the amount of \$20,964 which is being deferred over the life of the lease. The lease term is for 3 years with an interest rate of 5.87%.

On December 31, 2004, the Company entered into a \$230,384 sale-leaseback transaction whereby the Company sold and leased back computer equipment and furniture. The resulting lease is being accounted for as a capital lease. There was a gain recorded on the sale in the amount of \$13,054 which is being deferred over the life of the lease. The lease term is for 3 years with an interest rate of 6.44%.

The following is a schedule, by year, of the future minimum payments under capital leases, together with the present value of the net minimum payments as of December 31, 2004:

|  |           |
|--|-----------|
| 2005                                     | 799,170   |
| 2006                                     | 704,357   |
| 2007                                     | 243,284   |
| 2008                                     |           |
| 2009 and thereafter                      |           |
|  |           |
| Total minimum capital lease payments     | 1,746,811 |
| Less amount representing interest        | (117,803) |
|  |           |
| Total present value of minimum payment   | 1,629,008 |
| Less current portion of such obligations | (722,086) |
|  |           |
| Long-term capital lease obligations      | 906,922   |

## **7. Stock Options**

In the first quarter of 2002, the Company's Board of Directors and stockholders approved the adoption of the 2002 Bio-Imaging Technologies, Inc. Stock Option Plan and authorized the issuance of 950,000 shares of the Company's Common Stock under the plan.

Each option is exercisable into one share of Common Stock. Options granted pursuant to the plan may be qualified incentive stock options, as defined in the Internal Revenue Code, or nonqualified options. The exercise price of qualified incentive stock options may not be less than the fair market value of the Company's Common Stock at the date of grant. The term of such stock options granted under the plan shall not exceed ten years and the vesting schedule of such stock option grants varies from immediate vesting on date of grant to vesting over a period of up to five years.

**Table of Contents****BIO-IMAGING TECHNOLOGIES, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The following table summarizes the transactions pursuant to the Company's stock option plan for the year ended December 31, 2004 and 2003:

|  | <b>Number<br/>of<br/>Options</b> | <b>Weighted Average<br/>Exercise Price</b> |
|--|----------------------------------|--|
| Options outstanding at December 31, 2002 | 1,743,207                        | \$ 0.91                                    |
| Options granted                          | 380,000                          | 3.56                                       |
| Options exercised                        | (280,555)                        | 0.98                                       |
| Options cancelled                        | (34,725)                         | 1.57                                       |
| Options outstanding at December 31, 2003 | 1,807,927                        | 1.41                                       |
| Options granted                          | 296,100                          | 6.44                                       |
| Options exercised                        | (140,986)                        | 0.92                                       |
| Options cancelled                        | (19,283)                         | 1.92                                       |
| Options outstanding at December 31, 2004 | 1,943,758                        | \$ 2.21                                    |

1,613,000 and 1,543,000 options are exercisable at December 31, 2004 and 2003, respectively, at a weighted average exercise price of \$1.51 and \$1.22, respectively.

At December 31, 2004, by range of exercise prices, the number of shares represented by outstanding options with their weighted average exercise price and weighted average remaining contractual life, in years, and the number of shares represented by exercisable options with their weighted average exercise price are as follows:

| <b>Options Outstanding</b>              |                               |  |  | <b>Options Exercisable</b>    |  |
|---|-------------------------------|--|--|-------------------------------|--|
| <b>Range of<br/>Exercise<br/>Prices</b> | <b>Number<br/>Outstanding</b> | <b>Weighted Average<br/>Remaining<br/>Contractual Life</b> | <b>Weighted<br/>Average<br/>Exercise<br/>Price</b> | <b>Number<br/>Exercisable</b> | <b>Weighted<br/>Average<br/>Exercise<br/>Price</b> |
| \$0.63-\$0.88                           | 785,758                       | 4.55 years   | \$ 0.71  | 776,175                       | \$ 0.71  |
| \$1.00-\$1.16                           | 284,000                       | 6.34 years   | \$ 1.10  | 284,000                       | \$ 1.10  |
| \$1.25-\$1.31                           | 239,850                       | 3.58 years   | \$ 1.27  | 235,183                       | \$ 1.27  |
| \$1.85-\$2.80                           | 112,500                       | 8.10 years   | \$ 2.77  | 51,833                        | \$ 2.78  |



Edgar Filing: BIO IMAGING TECHNOLOGIES INC - Form 10KSB

|               |           |            |         |           |         |
|---------------|-----------|------------|---------|-----------|---------|
| \$3.05-\$5.10 | 317,500   | 8.58 years | \$ 4.31 | 266,111   | \$ 4.26 |
| \$7.03        | 204,150   | 9.12 years | \$ 7.03 |           |         |
| <hr/>         | <hr/>     | <hr/>      | <hr/>   | <hr/>     | <hr/>   |
| \$0.63-\$7.03 | 1,943,758 | 6.03 years | \$ 2.21 | 1,613,302 | \$ 1.51 |
| <hr/>         | <hr/>     | <hr/>      | <hr/>   | <hr/>     | <hr/>   |

## 8. Equity

On September 15, 2003, the Company consummated a private placement of 1,762,000 shares of its common stock to certain institutional investors at a purchase price of \$6.125 per share, for an aggregate investment of \$10,792,250. C.E. Unterberg, Towbin and Emerging Growth Equities Ltd. acted as the placement agents for this offering. The Company agreed to pay the placement agents cash commissions equal to six percent (6%) of the gross proceeds of this offering and a one percent (1%) non-accountable expense allowance. The Company used a portion of the net proceeds received from this financing of \$9,874,250 for general corporate purposes, including working capital and capital expenditures, and for acquisitions. The Company expects to use the remainder of this financing for general corporate purposes, including working capital and capital expenditures, and for potential acquisitions. These securities have been registered with the Securities and Exchange Commission.

On November 20, 2003, the Company acquired the intellectual property of privately held CapMed, including the Personal Health Record ( PHR ) software and the patent-pending Personal HealthKey technology. The Company issued 51,724 shares of the Company s common stock to the CapMed owners with a market value of \$6.54 at the time of issuance.

**Table of Contents****BIO-IMAGING TECHNOLOGIES, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

On December 10, 2004, the Company acquired 100% of the stock of Heart Core. In connection with the Heart Core acquisition, the Company issued 158,268 shares of common stock directly to the sellers and 17,585 shares of common stock were issued to an escrow agent pursuant to the terms of the acquisition. The market value of the Company's common stock was \$4.82 at the time of issuance.

**9. Commitments**

The Company has entered into non-cancelable operating leases for office facilities which expire through June 2010.

Future minimum aggregate rental payments on the noncancelable portion of the lease are as follows:

|            | <b>Year Ending<br/>December 31,</b> |
|------------|-------------------------------------|
|            | <b>2004</b>                         |
|            | <b>_____</b>                        |
| 2005       | \$ 1,366,514                        |
| 2006       | 1,434,604                           |
| 2007       | 1,461,788                           |
| 2008       | 1,308,853                           |
| 2009       | 1,207,381                           |
| Thereafter | 612,081                             |
|            | <b>_____</b>                        |
|            | <b>\$ 7,391,221</b>                 |
|            | <b>_____</b>                        |

Rent expense charged to operations for the year ended December 31, 2004 and 2003 was \$1,364,000 and \$1,238,000, respectively.

The Company has an employment agreement with an executive officer that expires January 31, 2005 and an employment agreement with an executive officer that expires February 5, 2006. The aggregate amount due from January 1, 2005 through the expiration under these agreements was \$212,500. One agreement provided for the granting of 30,000 shares of Common Stock to the executive officer on January 31, 2005. Such shares were issued to the executive officer on January 31, 2005. The Company renewed the employment agreement with the executive officer that expired January 31, 2005 for two years ending January 31, 2007 with a renewal option for one year. The aggregate amount due under this agreement is \$580,000 through January 31, 2007.

**10. Employee Benefit Plan**

The Company sponsors the Bio-Imaging Technologies, Inc. Employees Savings Plan (the 401(k) Plan ), a defined contribution plan with a cash or deferred arrangement. Under the terms of the 401(k) Plan, eligible employees may elect to reduce their annual compensation up to the annual limit prescribed by the Internal Revenue Service. The Company may make discretionary matching contributions in cash, subject to plan limits. The Company made contributions of \$40,942 and \$43,091 for the year ended December 31, 2004 and 2003, respectively.

**11. Major Customers**

Revenue from one major customer, encompassing eighteen projects, accounted for 10% of service revenues for the year ended December 31, 2004. Revenue from one major customer, encompassing four projects, accounted for 14% of service revenues for the year ended December 31, 2003. No other customers accounted for more than 10% of service revenues.

Table of Contents**BIO-IMAGING TECHNOLOGIES, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Two customers accounted for 26% of accounts receivable at December 31, 2004 and two customers accounted for 23% of accounts receivable at December 31, 2003. No other customers accounted for more than 10% of accounts receivable.

**12. Income Taxes**

The income tax (benefit) provision consists of the following:

|                                | For the year ended |                     |
|--------------------------------|--------------------|---------------------|
|                                | December 31,       |                     |
|                                | 2004               | 2003                |
|                                | <u>2004</u>        | <u>2003</u>         |
| Current:                       |                    |                     |
| Federal                        | \$ 18,451          | \$ 23,908           |
| State and local                | 135,937            | 58,315              |
| Foreign                        | 139,398            | 66,478              |
|                                | <u>\$ 293,786</u>  | <u>\$ 148,701</u>   |
| Deferred:                      |                    |                     |
| Federal                        | 344,082            | (55,246)            |
| State and local                | 20,566             | 94,911              |
| Foreign                        |                    | 670,661             |
| Change in valuation allowance  |                    | (1,129,291)         |
|                                | <u>364,648</u>     | <u>(418,965)</u>    |
| Income tax (benefit) provision | <u>\$ 658,434</u>  | <u>\$ (270,264)</u> |

The Company's reconciliation of the expected federal provision (benefit) rate to the effective income tax rate is as follows:

For the year ended  
December 31,

|  | <u>2004</u> | <u>2003</u> |
|--|-------------|-------------|
| Tax provision at statutory rate                      | 34.0%       | 34.0%       |
| State and local income taxes, net of federal benefit | 6.4%        | 4.9%        |
| Permanent differences                                | 2.0%        | 0.7%        |
| Change in the valuation allowance (federal)          |             | (54.6)%     |
| Other  | (1.7)%      | 1.9%        |
| Effective income tax rate                            | 40.7%       | (13.1)%     |

F-19

Table of Contents**BIO-IMAGING TECHNOLOGIES, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The components of net deferred tax assets (liabilities) consist of the following:

|  | For the year ended |                   |
|--|--------------------|-------------------|
|  | December 31,       |                   |
|  | 2004               | 2003              |
| Deferred tax assets:                     |                    |                   |
| Accrued expenses                         | \$ 119,483         | \$                |
| Allowance for doubtful accounts          | 5,751              | 26,386            |
| AMT credit                               | 40,604             | 23,908            |
| Deferred revenue                         | 212,439            |                   |
| Federal net operating loss carryforwards | 1,878,485          | 2,068,387         |
| Total deferred tax assets                | <u>2,256,762</u>   | <u>2,118,681</u>  |
| Deferred tax liabilities:                |                    |                   |
| Excess of tax over book depreciation     | (709,500)          | (640,426)         |
| Amortization of intangibles              | (221,080)          | (20,593)          |
| Prepaid expenses                         | (256,242)          | (97,182)          |
| Total deferred tax liabilities           | <u>(1,186,823)</u> | <u>(758,201)</u>  |
| Valuation Allowance                      | (408,000)          | (408,000)         |
| Net deferred tax assets                  | <u>\$ 661,940</u>  | <u>\$ 952,480</u> |

The Company has a U.S. Federal net operating loss carryforward of \$5.5 million and \$5.7 million at December 31, 2004 and December 31, 2003, respectively. These losses will expire, if unused, in the years 2009 through 2022. Due to ownership changes that have occurred, management has estimated that \$1.1 million of these losses will likely expire unused due to Internal Revenue Code Section 382 limitations. Management has determined that there is sufficient future taxable income to utilize the unlimited net operating loss carryforward of \$4.4 million.

Differences between the book and tax basis of the assets acquired from Heart Core and CapMed have been reflected as a deferred tax liability and allocated to the acquired assets in the amount of \$63,569 and \$244,400, respectively.

The tax benefit of the stock option deductions have been recorded to additional paid in capital in the amount of \$164,807 and \$413,596 for the year ended December 31, 2004 and 2003, respectively.

The Company has not provided for U.S. federal income and foreign withholding taxes on approximately \$500,000 of undistributed earnings from its non-U.S. operations as of December 31, 2004 because such earnings are intended to be reinvested indefinitely outside of the United States.

On October 22, 2004, the President signed the American Jobs Creation Act of 2004 (the Act). The Act creates a temporary incentive for U.S. corporations to repatriate accumulated income earned abroad by providing an 85 percent dividends received deduction for certain dividends from controlled foreign corporations. The deduction is subject to a number of limitations and, as of today, uncertainty remains as to how to interpret numerous provisions in the Act. As such, the Company is not yet in a position to decide on whether, and to what extent, they might repatriate foreign earnings that have not yet been remitted to the U.S.

The Company, in the normal course of conducting business, maintains certain tax positions that may be subject to review by the Internal Revenue Service. The Company has not recorded any contingent liabilities for these tax exposures at December 31, 2004 and 2003, since they are not believed to be probable of occurring.

**Table of Contents****BIO-IMAGING TECHNOLOGIES, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****13. Foreign Operations**

Foreign customers accounted for 10% and 12% of service revenues for the year ended December 31, 2004 and 2003, respectively.

**14. Business Segments**

FASB Statement No. 131, Disclosures about Segments of an Enterprise and Related Information, requires companies to provide certain information about their operating segments. In November 2003, the Company acquired the intellectual property of CapMed Corporation. Accordingly, the Company now has two reportable segments: pharmaceutical contract services and the CapMed division. The pharmaceutical contract service segment provides services that support the product development process of the pharmaceutical, biotechnology and medical device industries. The CapMed segment offers 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 operating segments are managed separately because each offers different services and applications to different markets. Management evaluates the performance of each segment based upon operating earnings or losses before interest and income taxes.

Summarized financial information concerning the Company's reportable segments is shown in the following table:

|                                   | <b>Pharmaceutical<br/>Contract<br/>Services</b> | <b>CapMed<br/>Division</b> | <b>Consolidated<br/>Total</b> |
|-----------------------------------|---|----------------------------|-------------------------------|
| <b>Fiscal 2004</b>                |   |                            |                               |
| Total revenues                    | \$ 29,579,645                                   | \$ 111,130                 | \$ 29,690,775                 |
| Total cost and expenses           | \$ 27,145,793                                   | \$ 940,500                 | \$ 28,086,293                 |
| Income (loss) from operations     | \$ 2,433,852                                    | \$ (829,370)               | \$ 1,604,482                  |
| Total assets at December 31, 2004 | \$ 27,377,774                                   | \$ 996,040                 | \$ 28,373,814                 |
| <b>Fiscal 2003</b>                |   |                            |                               |
| Total revenues                    | \$ 25,210,707                                   |                            | \$ 25,210,707                 |
| Total cost and expenses           | \$ 23,012,463                                   |                            | \$ 23,012,463                 |
| Income from operations            | \$ 2,198,244                                    |                            | \$ 2,198,244                  |
| Total assets at December 31, 2003 | \$ 25,051,029                                   | \$ 855,585                 | \$ 25,906,614                 |

The Company maintains offices in Newtown, Pennsylvania and Leiden, the Netherlands. Total assets located in Newtown, Pennsylvania were \$26,774,968 and \$25,239,718 at December 31, 2004 and 2003, respectively. Total assets located in Leiden, the Netherlands were \$1,598,846 and \$666,896 at December 31, 2004 and 2003, respectively.



