

BIO IMAGING TECHNOLOGIES INC
Form 10KSB
March 29, 2004
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, 2003

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:

Title of each class

Name of each exchange on which registered

None

None

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

Common Stock, \$.00025 par value per share

NASDAQ National Market

Check whether the issuer: (1) filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act during the past 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes: 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, 2003: \$24,971,184

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

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

Class

Number of Shares

Edgar Filing: BIO IMAGING TECHNOLOGIES INC - Form 10KSB

Common Stock, \$.00025 par value

10,754,864

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 2004 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>	24
	8. <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	24
	8A. <u>Controls and Procedures</u>	24
PART III	9. <u>Directors and Executive Officers</u>	25
	10. <u>Executive Compensation</u>	25
	11. <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	25
	12. <u>Certain Relationships and Related Transactions</u>	25
	13. <u>Exhibits, List and Reports on Form 8-K</u>	25
	14. <u>Principal Accountant Fees and Services</u>	25
	<u>SIGNATURES</u>	26
	<u>EXHIBIT INDEX</u>	27
	<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, magnetic resonance imaging, x-rays, dual energy x-ray absorptiometry, or DEXA, position emission tomography, single photon emission computerized tomography and ultrasound.

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

Regulatory submission of medical images, quantitative data and text;

DEXA quality assurance and quality control to the pharmaceutical and medical device industry for studies requiring bone densitometry and body composition measurements; and

Bio-Imaging ET&CSM services, which focus on education, training and certification for medical imaging equipment, facilities and staff.

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

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

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

Edgar Filing: BIO IMAGING TECHNOLOGIES INC - Form 10KSB

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

We were incorporated in Delaware in 1987 under the name Wise Ventures, Inc. Our name was changed to Bio-Imaging Technologies, Inc. in 1991. The address of our principal executive offices is 826 Newtown-Yardley Road, Newtown, Pennsylvania, 18940, and our telephone number is 267-757-3000. Our Internet website is www.bioimaging.com. We also utilize the Internet website www.capmed.com for the CapMed division of our business. We make available on our Internet website all of our public filings with the Securities and Exchange Commission. However, nothing on our Internet website is intended to be incorporated by reference into this Form 10-KSB or any other filing made by us with the Securities and Exchange Commission.

Table of Contents

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.

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 clients' 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.

Edgar Filing: BIO IMAGING TECHNOLOGIES INC - Form 10KSB

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

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

Table of Contents

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&CSM 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&CSM 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

Edgar Filing: BIO IMAGING TECHNOLOGIES INC - Form 10KSB

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

Phase III - Clinical Trials

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

Phase IV - Post Approval Studies

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

Table of Contents

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

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

Musculoskeletal Therapeutics

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

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

Cancer Therapeutics

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

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

Central Nervous System Therapeutics

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

Diagnostic Imaging Agents

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

Cardiovascular Therapeutics

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

Table of Contents

Market Trends

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

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

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

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

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

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

Intellectual Property

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

Government Regulation

Edgar Filing: BIO IMAGING TECHNOLOGIES INC - Form 10KSB

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

Table of Contents

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

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

Changes in the FDA's policy for the evaluation of therapeutic oncology agents may have a positive impact on the time to market of such therapeutics. According to the guidelines announced in March 1996, approval times for new cancer therapies can be shortened if evidence of tumor shrinkage is verifiable and demonstrable through the use of objective measurement techniques. These guidelines place much greater reliance on the use of medical image data to demonstrate objective tumor shrinkage. In addition, in March 1997, the FDA announced new guidelines aimed at accelerating all therapeutic categories through the use of imaging markers such as surrogate endpoints for measuring therapeutic effectiveness. We believe the FDA's initiatives to streamline and accelerate the submission and review process of therapeutic agents may have a favorable impact on our business.

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

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

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

Competition

We continue to experience competition from commercial competitors and academic research centers. The biopharmaceutical services industry is highly competitive, and we face numerous potential competitors in our business, including hundreds of contract research organizations. We primarily compete against small specialty contract research organizations, or CROs, and to a lesser extent, universities and teaching hospitals. As competition increases, we will look to provide value-added services and undertake marketing and sales programs to differentiate our services based on our expertise and experience in specific therapeutic and diagnostic areas, our technical expertise, our regulatory and clinical development experience, our quality performance and our international capabilities. Our competitive position also depends upon our ability to attract and retain qualified personnel and develop and preserve proprietary technology, processes and know-how. Competition in our industry has resulted in additional pressure being placed on price, service and quality. Although we believe that we are well positioned against our competitors due to our experience in clinical trials and regulatory compliance along with our international presence, we cannot assure you that our competitors or clients will not provide or develop services similar or superior to those provided by us. This competition could have a material adverse impact on us.

Table of Contents

Marketing and Sales

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

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

Significant Clients

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

Employees

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

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

Risk Factors

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

Risks Related to Our Company and Business

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

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

unexpected or undesired clinical results;

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

insufficient patient enrollment in a study;

insufficient investigator recruitment;

failure to perform our obligations under the contract; or

the failure of products to satisfy safety requirements.

Table of Contents

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

We cannot assure you that our clients will continue to use our services or that we will be able to replace, in a timely or effective manner, departing clients with new clients that generate comparable revenues. Further, we cannot assure you that our clients will continue to generate consistent amounts of revenues over time. We have not recently experienced cancellations or delays due to any of the factors identified above.

The loss, reduction in scope or delay of a large contract or the loss or delay of multiple contracts could materially adversely affect our business, although our contracts entitle us to receive all fees earned up to the time of termination. The loss of all of the business from our client NPS would have a material adverse effect on our financial condition.

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

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

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

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

clients reduce their research and development expenditures.

Revenues from one client, NPS, encompassing four distinct projects, amounted to 14% of service revenues for the year ended December 31, 2003 and 13% of service revenues for the year ended December 31, 2002. The loss of business from a significant client or our failure to continue to obtain new business would have a material adverse effect on our business and revenues.

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

Our reported contracted/committed backlog of approximately \$41.3 million at December 31, 2003 is based on anticipated net service revenue from uncompleted projects with clients. Backlog is the amount of revenue that remains to be earned and recognized on signed and verbally agreed to contracts. Contracts included in backlog are subject to termination by our clients at any time. In the event that the client cancels a contract, we would be entitled to receive payment for all services performed up to the cancellation date. The duration of the projects included in our backlog range from less than three months to seven years. We cannot assure that this backlog will be indicative of future results. A number of factors may affect backlog, including:

Edgar Filing: BIO IMAGING TECHNOLOGIES INC - Form 10KSB

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.

Table of Contents

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

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

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

continue to improve operating, administrative and information systems;

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

track the progress of on-going client projects; and

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

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

assimilate differences in foreign business practices and regulations;

hire and retain qualified personnel; and

overcome language and cultural barriers.

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

We may acquire additional businesses, technologies and products if we determine that these additional businesses, technologies and products complement our existing business or otherwise serve our strategic goals. We currently have no commitments or agreements with respect to any acquisitions. If we do undertake transactions of this sort, the process of integrating an acquired business, technology or product may result in operating difficulties and expenditures and may absorb significant management attention that would otherwise be available for ongoing development of our business. Moreover, we may never realize the anticipated benefits of any acquisition. We believe that the integration associated with our acquisition of Intelligent Imaging has been substantially completed, and that we did not experience any significant difficulties in such integration. Future acquisitions could result in potentially dilutive issuances of our securities, the incurrence of debt and contingent liabilities and amortization expenses related to intangible assets, which could adversely affect our results of operations and financial condition.

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

Future success depends on the personal efforts and abilities of the principal members of our senior management to provide strategic direction, develop business, manage operations and maintain a cohesive and stable environment. Specifically, we are dependent upon Mark L. Weinstein, President and Chief Executive Officer, David A. Pitler, Senior Vice President Operations, Colin G. Miller, Ph.D., Senior Vice President Business Development and Ted I. Kaminer, Senior Vice President and Chief Financial Officer. Although we have an employment agreement with each of Mr. Weinstein and Mr. Kaminer, this does not necessarily mean that either of them will remain with us. We do not have employment agreements with any other key personnel. Furthermore, our performance also depends on our ability to attract and retain management and qualified professional and technical operating staff. Competition for these skilled personnel is intense. The loss of services

Table of Contents

of any key executives, or inability to continue to attract and retain qualified staff, could have a material adverse effect on our business, results of operations and financial condition. We do not maintain any key employee insurance on any of our executives.

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

In fiscal 2003, we derived a small portion of service revenues from international operations. Our financial statements are denominated in United States dollars. In the event we derive a greater portion of our service revenues from international operations, factors associated with international operations, including changes in foreign currency exchange rates, could affect our results of operations and financial condition. Fluctuations in foreign currency exchange rates could materially impact the operating costs of our facility in the Netherlands, which are primarily EURO denominated.

Risks Related to Our Industry

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

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

consultative and clinical trials design capabilities;

reputation for on-time quality performance;

expertise and experience in specific therapeutic areas;

the scope of service offerings;

strength in various geographic markets;

the price of services;

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

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

our size; and

the service and product offerings of our competitors.

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

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

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

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

Table of Contents

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

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

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

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

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

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

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

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

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

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

Table of Contents

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, 2003, we had the following capital structure:

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

As of December 31, 2003, we had outstanding options to purchase approximately 1,807,927 shares of common stock at exercise prices ranging from \$0.63 to \$4.74 (exercisable at a weighted average of \$1.41 per share), of which approximately 1,542,579 options were then exercisable. Exercise of our outstanding options into our common stock may significantly and negatively affect the market price for our common stock as well as decrease your percentage ownership and voting power. In addition, at December 31, 2003, we had outstanding a convertible promissory note in the principal amount of \$666,664. The number of shares of common stock into which the note may be converted is calculated by dividing the outstanding principal balance of the note, plus all accrued and unpaid interest, by the greater of: (i) 75% of the average closing price of our common stock over the ten consecutive trading days ending prior to the date of conversion; or (ii) \$0.906 per share. As of December 31, 2003, the note was convertible into 145,068 shares of our common stock. Under the formula contained in the note, at the minimum price per share of \$0.906, the maximum number of shares of our common stock to be issued to Quintiles, Inc., based upon the outstanding principal amount and accrued interest at December 31, 2003, would be 741,351 shares. In addition, we may conduct future offerings of our common stock or other securities with rights to convert the securities into shares of our common stock. As a result of these and other events that increase the number of our outstanding shares, your percentage ownership and voting power and the price of our common stock may decrease.

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

Future sales of shares of our common stock by existing holders of our common stock or by holders of outstanding options, upon the exercise thereof, could have a negative impact on the market price of our common stock. As of December 31, 2003, we had 10,710,481 shares of our common stock issued and outstanding. Of this amount, 6,404,932 are freely tradable and 4,305,549 are registered on a Form S-3 with the Securities and Exchange Commission.

Table of Contents

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

Our affiliates have significant control over our common stock, allowing them to have significant influence over the outcome of all matters submitted to our stockholders for approval, which influence may conflict with our interests and the interests of our other stockholders.

Our directors, officers and principal stockholders, including Covance Inc., Quintiles, Inc. and certain of their affiliates, beneficially owned approximately 37% of the outstanding shares of common stock on a fully diluted as-converted to common stock basis at December 31, 2003, and such stockholders will have significant influence over the outcome of all matters submitted to our stockholders for approval, including the election of our directors and other corporate actions. In addition, such influence by these affiliates could have the effect of discouraging others from attempting to take us over, thereby increasing the likelihood that the market price of the common stock will not reflect a premium for control.

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

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

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

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

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

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

operating results;

analysts' reports;

market conditions in the industry;

changes in governmental regulations; and

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

Table of Contents

The market has also experienced significant decreases in value. This volatility and the recent market decline has affected the market prices of securities issued by many companies, often for reasons unrelated to their operating performance, and may adversely affect the price of our common stock. Between January 1, 2003 and December 31, 2003, our common stock has traded at a low of \$2.15 per share and a high of \$8.10 per share.

Our common stock began trading on the NASDAQ National Market on December 18, 2003 and has a limited trading market. Prior to that time, our common stock was trading on the American Stock Exchange since February 2003. We cannot assure that an active trading market will develop or, if 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 us. 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 approximately 31,500 square feet of office space located in Newtown, Pennsylvania. This lease expires June 2010 and provides for a fixed base rent of approximately \$52,000 per month with an annual inflation increase. We lease approximately 5,000 square feet of additional office space located in Newtown, Pennsylvania for approximately \$4,000 per month in base rent expiring November 2005. We are also subleasing office space in Newtown, Pennsylvania for monthly fixed base rents of approximately \$9,000 for approximately 6,000 square feet and approximately \$4,500 for approximately 2,400 square feet. The subleases expire in April 2004 and August 2006. We are currently negotiating an extension of these subleases to June 2010, to coincide with the expiration of the lease of our headquarters. In addition, we lease approximately 9,000 square feet of office space in Leiden, the Netherlands. This lease, denominated in EURO, expires in April 2008 and provides for a base rent of approximately \$20,677, based upon the conversion rate as of December 31, 2003, per month 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 the quarter ended December 31, 2003. Such quotations reflect interdealer prices, without retail mark-up, mark-down or commission and may not represent actual transactions.

Quarter Ended	Common Stock	
	High	Low
December 31, 2003 (December 18, 2003 – December 31, 2003)	6.75	5.60

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.

Quarter Ended	Common Stock	
	High	Low
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

The following table sets forth the high and low bid quotations for our common stock as reported on the NASD OTC Bulletin Board for each of the quarters from the quarter ended March 31, 2002 through December 31, 2002. Such quotations reflect interdealer prices, without retail mark-up, mark-down or commission and may not represent actual transactions.

Quarter	Common	
Ended	Stock	
<u> </u>	<u>High</u>	<u>Low</u>
March 31, 2002	1.51	1.08
June 30, 2002	1.71	1.16
September 30, 2002	2.15	1.18
December 31, 2002	2.45	1.55

Our common stock was also previously listed on the Boston Stock Exchange under the symbol BIT, but it was not traded during each of the quarters from the quarter ended March 31, 2002 through March 31, 2003. As a result of our listing of our common stock on the American Stock Exchange, we removed our common stock listing from the Boston Stock Exchange.

As of April 18, 2003, the approximate number of holders of record of our common stock was 117 and the approximate number of beneficial holders of our common stock was 1,700.

Table of Contents

On September 15, 2003, we consummated a private placement of 1,762,000 shares of our 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 our placement agents for this offering. We agreed to pay the placement agents cash commissions equal to 6% of the gross proceeds of this offering and a 1% non-accountable expense allowance. We expect to use the net proceeds received from this financing of \$9,874,250 for general corporate purposes, including working capital and capital expenditures, and for possible acquisitions. These securities have been registered with the Securities and Exchange Commission.

In November 2003, in connection with the CapMed acquisition, we paid total consideration to CapMed 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.

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 Securities Act of 1933, as amended, as transactions not involving a public offering. Each of the recipients 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 imaging modalities, including computerized tomography, magnetic resonance imaging, x-rays, dual energy x-ray absorptiometry, positron emission tomography, single photon emission computerized tomography 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&CSM, 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 68 clients encompassing 184 distinct projects for fiscal 2003. This compares to 67 clients encompassing 186 distinct projects for fiscal 2002. The relatively constant number of projects is primarily due to our sales and marketing efforts being focused on larger average value contracts.

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 approximately \$41.3 million as of December 31, 2003. This compares to

Edgar Filing: BIO IMAGING TECHNOLOGIES INC - Form 10KSB

approximately \$36.5 million as of December 31, 2002, an increase of 13.2%. 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 7 years. We believe that our backlog assists our management as an indicator of our long-term business. However,

Table of Contents

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 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, the increased use of digital medical images in clinical trials, especially for important drug classes such as anti-inflammatory, 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 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, 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 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 and increased use of digital medical images in clinical trials 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.

Table of Contents

Critical Accounting Policies, Estimates and Risks

Financial Reporting Release No. 60, was issued by the Securities and Exchange Commission, requiring all companies to include a discussion of critical accounting policies or methods used in the preparation of financial statements. The notes to the consolidated financial statements includes 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.

In addition, Financial Reporting Release No. 61 was recently released by the SEC to require all companies to include a discussion to address, among other things, liquidity, off-balance sheet arrangements, contractual obligations and commercial commitments.

Our discussion and analysis of our financial condition and results of operations are based upon its 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 first recognized when 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.

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.

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 would immediately expense the deferred costs, which would reduce net income in the period that the customer terminated the relationship, offset by any 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

Table of Contents

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.

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, 2003 and 2002*

	2003	% of Total Revenue	2002	% of Total Revenue	\$ Change	% Change
Service revenues	\$ 21,747,636	87.1%	\$ 17,189,762	84.0%	\$ 4,557,874	26.5%
Reimbursement revenues	\$ 3,223,548	12.9%	\$ 3,278,319	16.0%	\$ (54,771)	(1.7)%
Total revenues	\$ 24,971,184	100.0%	\$ 20,468,081	100.0%	\$ 4,503,103	22.0%
Cost of revenues	\$ 16,635,643	66.6%	\$ 14,089,801	68.8%	\$ 2,454,842	17.4%
General and administrative expenses	\$ 4,079,419	16.3%	\$ 3,098,388	15.1%	\$ 981,031	31.7%
Sales and marketing expenses	\$ 2,057,878	8.2%	\$ 1,728,945	8.4%	\$ 328,933	19.0%
Total costs and expenses	\$ 22,772,940	91.2%	\$ 18,917,134	92.4%	\$ 3,855,806	20.4%
Income from operations	\$ 2,198,244	8.8%	\$ 1,550,947	7.6%	\$ 647,297	41.7%
Interest expense - net	\$ 130,655	0.5%	\$ 122,175	0.6%	\$ 8,480	6.9%
Income before income tax	\$ 2,067,589	8.3%	\$ 1,428,772	7.0%	\$ 638,817	44.7%
Income tax (benefit) provision	\$ (270,264)	(1.1)%	\$ 288,935	1.4%	\$ (559,199)	(193.5)%
Net income	\$ 2,337,853	9.4%	\$ 1,139,837	5.6%	\$ 1,198,016	105.1%

Service revenues was \$21,747,636 for fiscal 2003 and \$17,189,762 for fiscal 2002, an increase of \$4,557,874 or 26.5%. The increase in service revenues was due to an increase in the dollar value of projects resulting from the overall market growth for medical imaging related services for clinical trials and what we believe to be our increasing market share.

Edgar Filing: BIO IMAGING TECHNOLOGIES INC - Form 10KSB

Service revenues were generated from 68 clients encompassing 184 distinct projects for fiscal 2003. This compares to 67 clients encompassing 186 distinct projects for fiscal 2002. The decrease in the number of projects is primarily due to our sales and marketing efforts being focused on larger average value contracts. One client, NPS, encompassing four projects represented 14.0% of our service revenues for fiscal 2003, while for the comparable period last year, one client, NPS, encompassing four projects represented 13.0% of our service revenues. No other client accounted for more than 10% of service revenues. 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.

Table of Contents

Reimbursement revenues consist of pass-through costs reimbursed by the customer. 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.

Cost of revenues was \$16,635,643 for fiscal 2003 and \$14,089,801 for fiscal 2002, an increase of \$2,454,842 or 17.4%. Cost of revenues for fiscal 2003 and 2002 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 staffing levels required for project related tasks for fiscal 2003. We expect that our cost of revenues will continue to increase in fiscal 2004 as revenue increases.

The decrease in cost of revenues as a percentage of total revenues to 66.6% for fiscal 2003 from 68.8% for fiscal 2002 is primarily attributable to our increase in total revenues with a lesser increase in costs associated with project related costs. 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 was \$4,079,419 for fiscal 2003 and \$3,098,388 for fiscal 2002, an increase of \$981,031 or 31.7%. General and administrative expenses in fiscal 2003 and 2002 consisted primarily of professional salaries and benefits, depreciation and amortization, professional and consulting services, office rent and corporate insurance. The increase in general and administrative expenses is primarily attributable to an increase in personnel and professional services, with approximately 70% of the increase attributable to an increase in personnel, including the addition of certain management positions, to support the growth in our service revenues, and approximately 30% of the increase attributable to an increase in professional services associated with general corporate matters including increased legal, accounting, and regulatory compliance demands on public companies. We expect that our general and administrative expenses will continue to increase in fiscal 2004 as revenue increases.

The increase in general and administrative expenses as a percentage of total revenues to 16.3% for fiscal 2003 from 15.1% for fiscal 2002 is primarily due to an increase in personnel to support the growth in our service revenues as well as an increase in our professional service fees.

Sales and marketing expenses was \$2,057,878 for fiscal 2003 and \$1,728,945 for fiscal 2002, an increase of \$328,933 or 19.0%. Sales and marketing expenses in fiscal 2003 and 2002 were comprised of direct sales and marketing costs, professional salaries and benefits and allocated overhead. The increase in sales and marketing expenses is primarily attributable to higher salaries and sales commission commensurate with the increase in service revenue during this period, increased trade show attendance and increased marketing expenses, with approximately 28% of the increase attributable to the higher salaries and sales commission, approximately 7% of the increase attributable to the increase in trade show attendance and approximately 16% of the increase attributable to the increase in marketing expenses. We expect that sales and marketing expenses will increase in fiscal 2004 as we continue to expand our market presence in the United States and Europe.

Sales and marketing expenses as a percentage of total revenues of 8.2% for fiscal 2003 and 8.4% for fiscal 2002, essentially did not fluctuate.

Net interest expense was \$130,655 for fiscal 2003 and \$122,175 for fiscal 2002, an increase of \$8,480 or 6.9%. This increase is primarily due to interest expense incurred on additional equipment lease obligations, offset by more interest income on a higher cash balance, in fiscal 2003. Net interest expense for fiscal 2003 and 2002 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.

Edgar Filing: BIO IMAGING TECHNOLOGIES INC - Form 10KSB

Income before income taxes was \$2,067,589 for fiscal 2003 and \$1,482,772 for fiscal 2002, an increase of \$584,817 or 39.4%. This increase in income before income taxes for fiscal 2003 was attributable to the increased revenues associated with an increase in services performed on projects for which we were contracted offset, in

Table of Contents

part, by the costs associated with increased staffing levels necessary to perform the newly contracted services. The increase in income before income taxes as a percentage of total revenues to 8.3% for fiscal 2003 from 7.0% for fiscal 2002 is primarily due to increased revenues associated with an increase in services performed on projects for which we were contracted with a lesser increase in costs of revenue as a percentage of total revenues for fiscal 2003. We believe that both the presentation of a comparison of income before income taxes for fiscal 2003 and fiscal 2002 and the presentation of income before income taxes as a percentage of total revenues for fiscal 2003 and fiscal 2002 provide useful information to investors regarding our financial condition and results of operations because they exclude the income tax benefit of \$270,264 in fiscal 2003 and the income tax provision of \$288,935 in fiscal 2002, which will not be applicable in future periods.

Our income tax benefit for fiscal 2003 was \$270,264 versus an income tax provision of \$288,935 in fiscal 2002. 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, we believe our effective income tax rate will be approximately 40% for fiscal 2004.

Net income was \$2,337,853 for fiscal 2003 and \$1,139,837 for fiscal 2002, an increase of \$1,198,016 or 105.1%. This increase in net income for fiscal 2003 was attributable to the increased revenues associated with an increase in services performed on projects for which we were contracted offset, in part, by the costs associated with increased staffing levels necessary to perform the newly contracted services and \$270,264 income tax benefit in fiscal 2003 as compared to an income tax provision of \$288,935 in fiscal 2002.

The increase in net income as a percentage of total revenues to 9.4% for fiscal 2003 from 5.6% for fiscal 2002 is primarily due to the income tax benefit in fiscal 2003 as compared to the income tax provision in fiscal 2002.

Liquidity and Capital Resources

	<u>2003</u>	<u>2002</u>
Net cash provided by operating activities	\$ 2,887,619	\$ 3,502,950
Net cash used in investing activities	\$ (1,914,223)	\$ (991,979)
Net cash provided by (used in) financing activities	\$ 9,752,791	\$ (447,415)

At December 31, 2003, we had cash and cash equivalents of \$13,289,453. Working capital at December 31, 2003 was \$12,965,887.

Net cash provided by operating activities of \$2,887,619 for fiscal 2003 was due to net income for the period, an adjustment to reflect \$1,075,742 of non-cash depreciation and amortization, an adjustment of (\$418,965) for the benefit for deferred income taxes and changes in certain assets and liabilities, such as, an increase in accrued expenses and other current liabilities of \$273,973 in fiscal 2003 versus an increase of \$918,994 in fiscal 2002 primarily due to accruals for compensation and consulting fees that were not paid at December 31, 2002. This was offset by a decrease in deferred revenue of \$194,301 in fiscal 2003 as compared to an increase of \$1,552,688 in fiscal 2002 due to lesser up-front deposits received upon contract signings.

Net cash used in investing activities primarily represents our investment in capital and leasehold improvements. We currently anticipate that capital expenditures for fiscal 2004 will be approximately \$1,400,000. These expenditures represent additional upgrades in our networking, data storage and core laboratory capabilities for both the United States and European operations.

Net cash provided by financing activities is primarily attributable to \$9,874,250 of net proceeds from the issuance of 1,762,000 shares of our common stock in a private placement to certain institutional investors on September 15, 2003 at a price of \$6.125 per share.

Table of Contents

The following table lists our cash contractual obligations as of December 31, 2003:

Contractual obligations	Payments Due By Period				
	Total	Less than 1 year	1-3 years	4-5 years	After 5 years
Long-term debt obligations					
Capital lease obligations	\$ 1,386,035	\$ 615,333	\$ 770,702		
Facility rent operating leases	\$ 5,560,985	\$ 966,866	\$ 2,757,601	\$ 1,479,523	\$ 356,995
Purchase obligations					
Employment agreements	\$ 487,500	\$ 450,000	\$ 37,500		
Quintiles note	\$ 666,664	\$ 666,664			
Total contractual cash obligations	\$ 8,101,184	\$ 2,698,863	\$ 3,565,803	\$ 1,479,523	\$ 356,995

On May 9, 2003, we renewed and amended our agreement with Wachovia Bank, National Association. The renewed and amended agreement is for a committed line of credit of \$2,000,000, collateralized by our personal property. Interest is payable at Wachovia Bank's prime rate. The agreement requires us, among other things, to maintain a debt service coverage ratio not less than 1.25 to 1.00, measured annually and a liquidity ratio of not less than 2.00 to 1.00 at all times. The committed line of credit matures June 30, 2004 and may be renewed on an annual basis. At December 31, 2003, we had no borrowings under the committed line of credit and are compliant with the debt covenants.

In connection with our acquisition of Intelligent Imaging, as of February 1, 2002, we are 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 is previously converted into shares of our common stock. The Quintiles Note bears 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. We have recorded the balance of the Quintiles Note at December 31, 2003 of \$666,664 as a current liability.

On September 15, 2003, we consummated a private placement of 1,762,000 shares of our 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 our placement agents for this offering. We agreed to pay the placement agents cash commissions equal to 6% of the gross proceeds of this offering and a 1% non-accountable expense allowance. We expect to use the net proceeds received from this financing of \$9,874,250 for general corporate purposes, including working capital and capital expenditures, and for possible acquisitions.

These securities have been registered with the Securities and Exchange Commission.

In November 2003, in connection with the CapMed acquisition, we paid total consideration to CapMed of \$550,000, which consisted of \$211,828 of cash paid to CapMed's vendors and \$338,171 of equity issued to CapMed.

Edgar Filing: BIO IMAGING TECHNOLOGIES INC - Form 10KSB

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;

Table of Contents

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.

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 2004 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 cancellation, 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.

Existing Contracts

During fiscal 2003, we signed approximately \$27,100,000 in new project contracts as compared to approximately \$26,600,000 for the same period in the prior year. As of December 31, 2003, we had entered into agreements with 62 companies, encompassing 146 projects, to provide services in the aggregate amount of approximately \$62,900,000 through July 2009, of which services valued at approximately \$41,300,000 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, future revenue generated by us may not equal 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, 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, one of our contracts is denominated in foreign currency. We believe that any adverse fluctuation in the foreign currency markets relating to this contract 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.

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.

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 2004 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 2004 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 2004 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 2004 Annual Meeting of Stockholders is incorporated herein by reference to such proxy statement.

Item 13. Exhibits, List, and Reports on Form 8-K.

(a) (1) Financial Statements.

Edgar Filing: BIO IMAGING TECHNOLOGIES INC - Form 10KSB

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

(a) (2) Financial Statement Schedules.

None.

(a) (3) Exhibits.

Reference is made to the Index to Exhibits on Page 27.

(b) Reports on Form 8-K.

Report on Form 8-K furnished on November 15, 2003 (reporting our financial results for the quarter ended September 30, 2003, including our unaudited financial statements).

Report on Form 8-K filed on December 12, 2003 (reporting that our common stock has been approved for quotation on the NASDAQ National Market).

Report on Form 8-K filed on January 5, 2004 (reporting that certain directors have entered into Rule 10b5-1 trading plans).

Report on Form 8-K furnished on February 4, 2004 (reporting financial results for the fourth quarter and year ended December 31, 2003).

Item 14. Principal Accountant Fees and Services.

The discussion under the heading "Principal Accountant Fees and Services" in our definitive proxy statement for the 2004 Annual Meeting of Stockholders is incorporated herein by reference to such proxy statement.

Edgar Filing: BIO IMAGING TECHNOLOGIES INC - Form 10KSB

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

Director

March 29, 2004

James A. Taylor, Ph.D.

/s/ PAULA BROWN STAFFORD

Director

March 29, 2004

Paula Brown Stafford

Table of Contents**EXHIBIT INDEX**

Exhibit No.	Description of Exhibit
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 \$2,000,000, dated May 9, 2003, made by Bio-Imaging Technologies, Inc. in favor of Wachovia Bank, National Association. Incorporated by reference to Exhibit 4.1 of our Quarterly Report on Form 10-QSB for the quarter ended March 31, 2003.
10.1	Lease between the Plymouth Woods and Bio-Imaging Technologies, Inc. dated December 1997, as amended on February 25, 1999. Incorporated by reference to Exhibit 10.1 of our Annual Report on Form 10-KSB for the fiscal year ended September 30, 2001.
10.2*	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.
10.3*	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.
10.4	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.
10.5	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.
10.6*	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.
10.7*	Employment Agreement dated February 1, 2002, by and between Bio-Imaging Technologies, Inc. and Mark L. Weinstein. Incorporated by reference to Exhibit 10.5 of our Quarterly Report on Form 10-QSB for the quarter ended June 30, 2002.

Table of Contents

Exhibit

No.	Description of Exhibit
10.8	Loan Agreement dated April 30, 2002, by and between Bio-Imaging Technologies, Inc. and Wachovia Bank, National Association Incorporated by reference to Exhibit 10.3 of our Quarterly Report on Form 10-QSB for the quarter ended June 30, 2002.
10.9	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.
10.10	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.
10.11	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.
10.12	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.
10.13*	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.
10.14	Loan Agreement dated May 9, 2003, by and between Bio-Imaging Technologies, Inc. and Wachovia Bank, National Association. Incorporated by reference to Exhibit 10.2 of our Quarterly Report on Form 10-QSB/A for the quarter ended March 31, 2003.
10.15	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.
10.16	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.
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.
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 Auditors</u>	F-2
Consolidated Financial Statements:	
<u>Consolidated Balance Sheets as of December 31, 2003 and 2002</u>	F-3
<u>Consolidated Statements of Income for the year ended December 31, 2003 and 2002</u>	F-4
<u>Consolidated Statements of Stockholders' Equity for the year ended December 31, 2003 and 2002</u>	F-5
<u>Consolidated Statements of Cash Flows for the year ended December 31, 2003 and 2002</u>	F-6
<u>Notes to Consolidated Financial Statements</u>	F-7

F-1

Table of Contents

Report of Independent Auditors

To the Board of Directors

and Stockholders of

Bio-Imaging Technologies, Inc.:

In our opinion, the accompanying consolidated balance sheets and the consolidated statements of income, stockholders' equity and cash flows present fairly, in all material respects, the financial position of Bio-Imaging Technologies, Inc. and its subsidiaries at December 31, 2003 and 2002, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2003 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 auditing standards generally accepted in the United States of America, which 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 23, 2004

F-2

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

	December 31,	
	2003	2002
ASSETS		
<i>Current Assets:</i>		
Cash and cash equivalents	\$ 13,289,453	\$ 2,563,266
Accounts receivable, net of allowance for doubtful accounts of \$26,821 and \$65,000, respectively	4,429,117	3,927,770
Prepaid expenses and other current assets	573,978	398,523
Deferred income taxes	1,613,498	364,319
Total current assets	19,906,046	7,253,878
Property and equipment, net	4,661,720	3,611,299
Other assets	1,338,848	575,238
Total Assets	\$ 25,906,614	\$ 11,440,415
LIABILITIES AND STOCKHOLDERS EQUITY		
<i>Current Liabilities:</i>		
Accounts payable	\$ 984,997	\$ 659,906
Accrued expenses and other current liabilities	1,602,806	1,302,567
Deferred revenue	3,070,359	3,264,660
Current maturities of capital lease obligations and convertible note	1,281,997	585,206
Total current liabilities	6,940,159	5,812,339
Long-term capital lease obligations	770,702	1,379,385
Contingent liability		567,722
Deferred income taxes	661,018	
Other liability	108,347	61,561
Total liabilities	8,480,226	7,821,007
Commitments and Contingencies		
<i>Stockholders Equity:</i>		
Common stock - \$.00025 par value; authorized 18,000,000 shares, issued and outstanding 10,710,481 and 8,427,653 shares at December 31, 2003 and 2002, respectively	2,678	2,107
Additional paid-in capital	20,873,968	9,405,412
Accumulated deficit	(3,450,258)	(5,788,111)
Stockholders equity	17,426,388	3,619,408
Total liabilities and stockholders equity	\$ 25,906,614	\$ 11,440,415

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,	
	2003	2002
Service revenues	\$ 21,747,636	\$ 17,189,762
Reimbursement revenues	3,223,548	3,278,319
Total revenues	24,971,184	20,468,081
Cost and expenses:		
Cost of revenues	16,635,643	14,089,801
General and administrative expenses	4,079,419	3,098,388
Sales and marketing expenses	2,057,878	1,728,945
Total cost and expenses	22,772,940	18,917,134
Income from operations	2,198,244	1,550,947
Interest expense net	130,655	122,175
Income before income tax	2,067,589	1,428,772
Income tax (benefit) provision	(270,264)	288,935
Net income	\$ 2,337,853	\$ 1,139,837
Basic earnings per common share	\$ 0.25	\$ 0.14
Weighted average number of common shares	9,275,752	8,361,105
Diluted earnings per common share	\$ 0.22	\$ 0.12
Weighted average number of common shares and dilutive Common equivalent shares	10,848,979	9,827,877

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 Capital</u>	<u>Deficit</u>	<u>Equity</u>
Balance at December 31, 2001	8,278,141	\$ 2,070	\$ 9,286,871	\$ (6,927,948)	\$ 2,360,993
Stock options exercised	149,512	37	118,541		118,578
Net income				1,139,837	1,139,837
Balance at December 31, 2002	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

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,	
	2003	2002
<i>Cash flows from operating activities:</i>		
Net income	\$ 2,337,853	\$ 1,139,837
Adjustments to reconcile net income to net cash provided by Operating activities, net of acquisition:		
Depreciation and amortization	1,075,742	738,440
(Benefit) provision for deferred income taxes	(418,965)	52,681
Bad debt provision	(38,179)	
Non-cash stock based compensation expense	26,266	
Changes in operating assets and liabilities:		
Increase in accounts receivable	(463,168)	(480,615)
Increase in prepaid expenses and other current assets	(175,455)	(124,210)
Decrease (increase) in other assets	91,976	(349,714)
Increase in accounts payable	325,091	54,849
Increase in accrued expenses and other current liabilities	273,973	918,994
(Decrease) increase in deferred revenue	(194,301)	1,552,688
Increase in other liabilities	46,786	
Net cash provided by operating activities	2,887,619	3,502,950
<i>Cash flows used in investing activities:</i>		
Purchases of property and equipment	(1,641,209)	(991,979)
Cash paid for intangible assets	(273,014)	
Net cash used in investing activities	(1,914,223)	(991,979)
<i>Cash flows from financing activities:</i>		
Payments under equipment lease obligations	(505,923)	(399,325)
Payments under promissory note	(166,668)	(166,668)
Proceeds from exercise of stock options	275,388	118,578
Net proceeds from private placement	9,874,250	
Proceeds from sales leaseback	275,744	
Net cash provided by (used in) financing activities	9,752,791	(447,415)
Net increase in cash and cash equivalents	10,726,187	2,063,556
Cash and cash equivalents at beginning of period	2,563,266	499,710
Cash and cash equivalents at end of period	\$ 13,289,453	\$ 2,563,266
Supplemental disclosure of cash flow information:		
Cash paid during the period for interest	\$ 139,942	\$ 125,962

Edgar Filing: BIO IMAGING TECHNOLOGIES INC - Form 10KSB

Cash paid during the period for income taxes	\$	\$ 67,000
Supplemental schedule of noncash investing and financing activities:		
Equipment purchases under capital lease obligations	\$ 760,697	\$ 1,246,400
Contingent liability converted to common stock incurred in connection with acquisition	\$ 567,722	\$
Common stock issued for intangible assets	\$ 338,171	\$
Deferred income taxes related to CapMed acquired assets	\$ 244,400	\$

The accompanying notes are an integral part of these statements.

F-6

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

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. All Intelligent Imaging personnel at the time of the Intelligent Imaging Acquisition became employed by the Company and all of the clinical projects, which were handled by Intelligent Imaging, are now being managed by the Company.

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

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 bears 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 is 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 is previously converted into the Company 's common stock, \$0.00025 par value per

Edgar Filing: BIO IMAGING TECHNOLOGIES INC - Form 10KSB

share (the Common Stock). The Company has recorded \$666,664 as a current liability for this Note at December 31, 2003.

The Note is convertible by Quintiles at any time prior to maturity into shares of the Company's Common Stock. The number of shares of Common Stock into which the Note may be converted is calculated by dividing the outstanding principal balance of the Note, plus all accrued and unpaid interest thereon, by the greater of: (i) 75% of the average closing price of the Company's Common Stock over the ten consecutive trading days ending prior to the date of conversion; or (ii) \$0.906 per share. At December 31, 2003, the Note would have been convertible into approximately 145,068 shares of the Company's Common Stock. This was calculated by dividing the unpaid principal balance (\$666,664 as of December 31, 2003) plus accrued interest (approximately \$5,000 as of December 31, 2003), totaling \$671,664, by \$4.63 (75% of the average closing price of the

F-7

Table of Contents

BIO-IMAGING TECHNOLOGIES, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Company's Common Stock over the ten consecutive trading days ending prior to December 31, 2003). Under the formula contained in the Note, at the minimum price per share of \$0.906, the maximum number of shares of Common Stock to be issued to Quintiles, based upon the outstanding principal amount and accrued interest at December 31, 2003, would be 741,351 shares.

The Asset Purchase Agreement requires the Company to make an additional payment if the Company achieves certain results subsequent to the acquisition (the Earnout). The Earnout was contingent on the Company obtaining cumulative revenues greater than \$1,800,000 for the period beginning on the closing date and ending on December 31, 2002, which were derived from the contracts included within the acquired assets. The Company must satisfy this obligation in shares of its Common Stock. On February 18, 2003, the Company satisfied its obligation to Quintiles under the Earnout through the issuance of 188,549 shares of its restricted Common Stock. At December 31, 2002, the additional consideration of \$567,722 is classified on the Company's balance sheet as a long-term liability. As a result of the Company's issuance of the 188,549 shares of its Common Stock, the long term liability has been satisfied and the Company reflected the issuance of the Common Stock with a \$567,722 increase to stockholders' equity. 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 Corporation (CapMed), located in Wilmington, Delaware, 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.

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

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

F-8

Table of Contents

BIO-IMAGING TECHNOLOGIES, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 and \$115,000 at December 31, 2003 and 2002, respectively. This letter of credit represents an irrevocable guarantee to fulfill the office facilities operating lease obligation. 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.

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.

Edgar Filing: BIO IMAGING TECHNOLOGIES INC - Form 10KSB

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 would immediately expense the deferred costs, which would reduce net income in the period that the customer terminated the relationship, offset by any 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. Accounts receivable includes approximately \$2,140,000 and \$894,000 of unbilled receivables at December 31, 2003 and 2002, respectively. Deferred revenue is recorded for cash received from clients for services that have not yet been earned at the respective balance sheet date.

F-9

Table of Contents

BIO-IMAGING TECHNOLOGIES, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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.

Property and Equipment

Property and equipment is initially 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 approximately \$460,000 and \$437,000 for the year ended December 31, 2003 and 2002, 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.

F-10

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

	For the year ended	
	December 31,	
	2003	2002
Net income basic	\$ 2,337,853	\$ 1,139,837
Interest expense on convertible note	37,454	53,300
Net income diluted	2,375,307	1,193,137
Denominator basic:		
Weighted average number of common shares	9,275,752	8,361,105
Basic earnings per common share	\$ 0.25	\$ 0.14
Denominator diluted:		
Weighted average number of common shares	9,275,752	8,361,105
Common share equivalents of outstanding stock options	1,429,149	721,431
Common share equivalents related to the convertible promissory note	144,078	493,467
Common share equivalents related to the additional consideration from the acquisition		251,874
Weighted average number of common shares and dilutive common equivalent shares	10,848,979	9,827,877
Diluted earnings per common share	\$ 0.22	\$.12

At December 31, 2003, the Company has one stock-based employee compensation plan, which is described more fully in Note 6. The Company accounts for this plan under the recognition and measurement principles of 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

Edgar Filing: BIO IMAGING TECHNOLOGIES INC - Form 10KSB

exercise price equal to the market value of the underlying Common Stock on the date of grant. 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 , to stock-based employee compensation.

F-11

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

	For the year ended	
	December 31,	
	2003	2002
Net income, as reported	\$ 2,337,853	\$ 1,139,837
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	\$ (804,086)	\$ (204,477)
Pro forma net income	\$ 1,533,767	\$ 935,360
Earnings per share:		
Basic as reported	\$ 0.25	\$ 0.14
Basic pro forma	\$ 0.17	\$ 0.11
Diluted as reported	\$ 0.22	\$ 0.12
Diluted pro forma	\$ 0.14	\$ 0.10

The weighted average fair value of options granted for the year ended December 31, 2003 and 2002 was \$2.91 and \$1.17, 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:

	2003	2002
Risk-free interest rate	3.01%	2.73%
Expected dividend yield	0.00%	0.00%
Expected volatility	105.00%	109.00%
Expected life in years	6.00	6.00

Reclassifications

Certain reclassifications have been made to the 2002 financial statements to conform with the 2003 presentation.

3. Property and Equipment

Edgar Filing: BIO IMAGING TECHNOLOGIES INC - Form 10KSB

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

	December 31,		Estimated Useful Life
	2003	2002	
Equipment	\$ 4,255,224	\$ 3,841,488	5 years
Equipment under capital leases	2,807,467	2,046,770	5 years
Furniture and fixtures	477,314	294,996	7 years
Leasehold improvements	365,918	151,111	5 years
Computer software costs	1,140,298	585,693	5 years
	<u>9,046,221</u>	<u>6,920,058</u>	
Less: Accumulated depreciation and amortization	(4,384,501)	(3,308,759)	
	<u>\$ 4,661,720</u>	<u>\$ 3,611,299</u>	

Accumulated depreciation related to equipment acquired under capital leases amounted to approximately \$1,124,000 and \$725,000 at December 31, 2003 and 2002, respectively. Accumulated amortization related to capitalized computer software costs amounted to approximately \$47,000 and \$0 at December 31, 2003 and 2002, respectively. Depreciation expense for the year ended December 31, 2003 and 2002 approximated \$1,029,000 and \$738,000, respectively.

Table of Contents**BIO-IMAGING TECHNOLOGIES, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****4. Acquired Intangible Assets**

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

	<u>December 31,</u>		<u>Estimated</u>
	<u>2003</u>	<u>2002</u>	
Amortized intangible assets:			
Technology	\$ 406,502		5 years
Trademarks	372,130		5 years
Non-competition agreement	76,953		2 years
	<u>855,585</u>		
Accumulated amortization			
	<u>855,585</u>		
Unamortized intangible assets:			
Goodwill	\$ 83,009	\$ 83,009	

The Company has evaluated the intangible assets and has determined that there is no impairment of the values at December 31, 2003.

5. Accrued Expenses

Accrued expenses and other current liabilities at December 31, 2003 and 2002 consists of the following:

	<u>December 31,</u>	
	<u>2003</u>	<u>2002</u>
Accrued compensation	\$ 891,608	\$ 645,947

Edgar Filing: BIO IMAGING TECHNOLOGIES INC - Form 10KSB

Accrued consulting fees	239,912	155,500
Accrued income taxes	294,526	264,638
Accrued other	176,760	236,482
	\$ 1,602,806	\$ 1,302,567
	\$ 1,602,806	\$ 1,302,567

6. Long-term Debt and Capital Lease Obligations

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 \$7,310, including interest at rates ranging from 6.77% to 11.5%, through June 2007, and are collateralized by the related equipment. In connection with the Intelligent Imaging Acquisition, beginning February 1, 2002, the Company is 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 is previously converted into the Company's common stock, \$0.00025 par value per share (the Common Stock). The Company has recorded \$666,664 and \$833,332 for the total obligation of this Note at December 31, 2003 and 2002, respectively. The current portion of the obligation is \$666,664 and \$166,668 at December 31, 2003 and 2002, respectively. \$666,664 was recorded as long-term debt of the Note at December 31, 2002. The Note bears 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 LIBOR Rate as published from time to time in the Wall Street Journal plus 3%, compounded annually based on a 365-day year. The Note is convertible by Quintiles at any time prior to maturity into shares of the Company's Common Stock. The number of shares of

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

Common Stock into which the Note may be converted is calculated by dividing the outstanding principal balance of the Note, plus all accrued and unpaid interest thereon, by the greater of: (i) 75% of the average closing price of the Company's Common Stock over the ten consecutive trading days ending prior to the date of conversion; or (ii) \$0.906 per share. At December 31, 2003, the Note would have been convertible into approximately 145,068 shares of the Company's Common Stock. This was calculated by dividing the unpaid principal balance (\$666,664 as of December 31, 2003) plus accrued interest (approximately \$5,000 as of December 31, 2003), totaling \$671,664, by \$4.63 (75% of the average closing price of the Company's Common Stock over the ten consecutive trading days ending prior to December 31, 2003). Under the formula contained in the Note, at the minimum price per share of \$0.906, the maximum number of shares of Common Stock to be issued to Quintiles, based upon the outstanding principal amount and accrued interest at December 31, 2003, would be 741,351 shares.

On May 9, 2003, the Company renewed and amended an agreement with Wachovia Bank, National Association. The renewed and amended agreement is for a committed line of credit of \$2,000,000, collateralized by the Company's assets. Interest is payable at Wachovia Bank's prime rate. The agreement requires the Company, among other things, to maintain a debt service coverage ratio not less than 1.25 to 1.00, measured annually and a liquidity ratio of not less than 2.00 to 1.00 at all times. The committed line of credit matures June 30, 2004 and may be renewed on an annual basis. At December 31, 2003, the Company had no borrowings under the committed line of credit and is compliant with the covenants of the agreement.

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%.

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, 2003:

2004	\$ 707,360
2005	540,580
2006	268,621
2007	11,311
2008 and thereafter	
	<hr/>
Total minimum capital lease payments	1,527,872
Less amount representing interest	(141,837)
	<hr/>
Total present value of minimum payment	1,386,035
Less current portion of such obligations	(615,333)
	<hr/>
Long-term capital lease obligations	770,702
	<hr/>

7. Stockholders Equity

In December 1991 and June 1992, the Company's Board of Directors and stockholders, respectively, approved the adoption of the Bio-Imaging Technologies, Inc. Stock Option Plan. In January 1995 and 1997, the Company amended this plan to provide for the granting of options to key employees, directors and consultants to purchase an aggregate of not more than 1,800,000 and 2,400,000 shares, respectively, of the Company's Common Stock. The 1991 Bio-Imaging Technologies, Inc. Stock Option Plan expired in 2001, therefore, 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.

F-14

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

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.

The following table summarizes the transactions pursuant to the Company's stock option plan for the year ended December 31, 2003 and 2002:

	Number of Options	Weighted Average Exercise Price
Options outstanding at December 31, 2001	1,986,031	\$ 1.17
Options granted	115,000	1.17
Options exercised	(149,512)	0.79
Options cancelled	(208,312)	3.62
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

Approximately 1,543,000 and 1,442,000 options are exercisable at December 31, 2003 and 2002, respectively, at a weighted average exercise price of \$1.22 and \$0.89, respectively.

At December 31, 2003, 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:

Options Outstanding				Options Exercisable	
Range of	Number	Weighted Average	Weighted	Number	Weighted
Exercise	Outstanding	Remaining	Average	Exercisable	Average
	<u> </u>	<u>Contractual Life</u>	<u> </u>	<u> </u>	<u> </u>

Edgar Filing: BIO IMAGING TECHNOLOGIES INC - Form 10KSB

<u>Prices</u>			<u>Exercise Price</u>		<u>Exercise Price</u>
\$0.63-\$0.88	883,927	5.52 years	\$ 0.71	864,677	\$ 0.71
\$1.00-\$1.16	313,500	7.18 years	\$ 1.10	258,208	\$ 1.10
\$1.25-\$1.31	262,500	4.45 years	\$ 1.27	249,583	\$ 1.27
\$1.85-\$2.80	120,500	9.10 years	\$ 2.76	27,333	\$ 2.76
\$3.05-\$4.74	227,500	9.28 years	\$ 4.00	142,778	\$ 4.12
<u>\$0.63-\$4.74</u>	<u>1,807,927</u>	<u>6.37 years</u>	<u>\$ 1.41</u>	<u>1,542,579</u>	<u>\$ 1.22</u>

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 expects to use the net proceeds received from this financing of \$9,874,250 for general corporate purposes, including working capital and capital expenditures, and for possible acquisitions. These securities have been registered with the Securities and Exchange Commission.

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

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.

8. Commitments

The Company has entered into noncancelable 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:

	Year Ending December 31, 2003
2004	\$ 966,866
2005	926,868
2006	907,575
2007	923,158
2008	773,324
Thereafter	1,063,194
	\$ 5,560,985

Rent expense charged to operations for the year ended December 31, 2003 and 2002 approximated \$1,238,000 and \$940,000, 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, 2005. The aggregate amount due from January 1, 2004 through the expiration under these agreements is approximately \$487,000. One agreement provided for the granting of 30,000 restricted shares of Common Stock to the executive officer on January 31, 2005.

9. Employee Benefit Plan

Edgar Filing: BIO IMAGING TECHNOLOGIES INC - Form 10KSB

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 \$43,091 and \$50,000 for the year ended December 31, 2003 and 2002, respectively.

10. Major Customers

Revenue from one major customer, encompassing four projects, accounted for approximately 14% and 13% of service revenues for the year ended December 31, 2003 and 2002, respectively. No other customers accounted for more than 10% of service revenues.

Two customers accounted for approximately 23% of accounts receivable at December 31, 2003 and two customers accounted for approximately 27% of accounts receivable at December 31, 2002. No other customers accounted for more than 10% of accounts receivable.

F-16

Table of Contents**BIO-IMAGING TECHNOLOGIES, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****11. Income Taxes**

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

	For the year ended	
	December 31,	
	2003	2002
	<u> </u>	<u> </u>
Current:		
Federal	\$ 23,908	
State and local	58,315	236,254
Foreign	66,478	
	<u> </u>	<u> </u>
	\$ 148,701	\$ 236,254
	<u> </u>	<u> </u>
Deferred:		
Federal	(55,246)	\$ 555,176
State and local	94,911	934
Foreign	670,661	(120,324)
Change in valuation allowance	(1,129,291)	(383,105)
	<u> </u>	<u> </u>
	(418,965)	52,681
	<u> </u>	<u> </u>
Income tax (benefit) provision	\$ (270,264)	\$ 288,935
	<u> </u>	<u> </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,	
	2003	2002
	<u> </u>	<u> </u>

Edgar Filing: BIO IMAGING TECHNOLOGIES INC - Form 10KSB

Tax provision at statutory rate	34.0%	34.0%
State and local income taxes, net of federal benefit	4.9%	11.0%
Permanent differences	0.7%	1.1%
Foreign losses for which no benefit is available		8.3%
Change in the valuation allowance (federal)	(54.6)%	(35.2)%
Other	1.9%	1.1%
	<u> </u>	<u> </u>
Effective income tax rate	(13.1)%	20.3%
	<u> </u>	<u> </u>

F-17

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,	
	2003	2002
	<u> </u>	<u> </u>
Deferred tax assets:		
Allowance for doubtful accounts	\$ 26,386	\$ 25,961
Amortization of goodwill		14,159
AMT credit	23,908	
Federal net operating loss carryforwards	2,068,387	1,342,079
Foreign net operating loss carryforwards		670,661
	<u> </u>	<u> </u>
Total deferred tax assets	2,118,681	2,052,860
	<u> </u>	<u> </u>
Deferred tax liabilities:		
Excess of tax over book depreciation	(640,426)	(65,561)
Amortization of goodwill	(20,593)	
Prepaid expenses	(97,182)	(85,689)
	<u> </u>	<u> </u>
Total deferred tax liabilities	(758,201)	(151,250)
	<u> </u>	<u> </u>
Valuation Allowance	(408,000)	(1,537,291)
	<u> </u>	<u> </u>
Net deferred tax assets	\$ 952,480	\$ 364,319
	<u> </u>	<u> </u>

The Company has a U.S. Federal net operating loss carryforward of \$5,716,135 and \$3,947,291 at December 31, 2003 and December 31, 2002, respectively. These losses will expire, if unused, in the years 2009 through 2022. Due to ownership changes that have occurred, management has estimated that approximately \$1,100,000 of these losses will likely expire unused due to Internal Revenue Code Section 382 limitations. The Company has a net operating loss carryforward in its Dutch subsidiary of \$0 and \$1,943,945 at December 31, 2003 and December 31, 2002, respectively. Management has determined that there is sufficient future taxable income to utilize the unlimited net operating loss carryforward of approximately \$4,600,000.

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.

Edgar Filing: BIO IMAGING TECHNOLOGIES INC - Form 10KSB

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, 2003 and 2002, since they are not believed to be probable of occurring.

12. Foreign Operations

Foreign customers accounted for approximately 12% and 6% of service revenues for the year ended December 31, 2003 and 2002, respectively.

F-18