

BIO IMAGING TECHNOLOGIES INC

Form S-3/A

December 22, 2003

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As filed with the Securities and Exchange Commission on December 22, 2003

Registration Statement No. 333-109702

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

AMENDMENT NO. 2
TO
FORM S-3
REGISTRATION STATEMENT
Under
THE SECURITIES ACT OF 1933

BIO-IMAGING TECHNOLOGIES, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

11-2872047
(I.R.S. Employer
Identification Number)

826 Newtown-Yardley Road, Newtown, Pennsylvania 18940

(267) 757-3000

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Mark L. Weinstein, President and Chief Executive Officer

826 Newtown-Yardley Road, Newtown, Pennsylvania 18940

(267) 757-3000

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies of all communications, including all communications sent to the agent for service, should be sent to:

William J. Thomas, Esq.

Hale and Dorr LLP

650 College Road East

Princeton, New Jersey 08540

(609) 750-7600

Approximate date of commencement of proposed sale to the public: From time to time, at the discretion of the selling stockholders, as soon as practicable after this registration statement becomes effective.

If the only securities being registered on this form are being offered pursuant to dividend or interest reinvestment plans, check the following box.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act, check the following box.

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If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. "

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. "

If delivery of the prospectus is expected to be made pursuant to Rule 434, check the following box. "

CALCULATION OF REGISTRATION FEE

| Title of Shares To Be Registered | Amount To Be Registered | Proposed Maximum Aggregate Price Per Share | Proposed Maximum Aggregate Offering Price | Amount Of Registration Fee |
|-----------------------------------|-------------------------|--|---|----------------------------|
| Common Stock, \$0.00025 par value | 4,441,714(1) | \$6.40(2) | \$28,426,969 | \$2,299.74(3) |

- (1) Includes 136,165 shares of common stock issuable upon the conversion of a convertible note.
- (2) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(c). Such price is based upon the average of the high and low prices of the registrant's common stock as reported on the American Stock Exchange on October 10, 2003.
- (3) The registrant previously paid such filing fee on October 15, 2003.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

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The information in this prospectus is not complete and may be changed. The selling stockholders named in this prospectus may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED DECEMBER 22, 2003

PROSPECTUS

BIO-IMAGING TECHNOLOGIES, INC.

4,441,714 Shares of Common Stock

The stockholders of Bio-Imaging listed in this prospectus are offering and selling an aggregate of 4,441,714 shares of our common stock. We will not receive any proceeds from the sale of the shares held by the selling stockholders.

Our common stock is traded on the NASDAQ National Market under the symbol BITI. On December 18, 2003, the last reported sale price of our common stock was \$6.00 per share. You are urged to obtain current market quotations for the common stock.

Investing in our common stock involves a high degree of risk. See Risk Factors beginning on page 5 for a discussion of certain factors that you should consider before you invest in any of the common stock being offered with this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is _____, 2003.

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As used in this prospectus, references to Bio-Imaging, we, us, and our refer to Bio-Imaging Technologies, Inc., unless the context otherwise requires.

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Prospectus Summary

About This Prospectus

This prospectus is a part of a registration statement on Form S-3 filed by us with the Securities and Exchange Commission to register 4,441,714 shares of our common stock. This prospectus does not contain all of the information set forth in the registration statement, certain parts of which are omitted in accordance with the rules and regulations of the SEC. Accordingly, you should refer to the registration statement and its exhibits for further information about us and our common stock. Copies of the registration statement and its exhibits are on file with the SEC. Statements contained in this prospectus concerning the documents we have filed with the SEC are not intended to be comprehensive, and in each instance we refer you to the copy of the actual document filed as an exhibit to the registration statement or otherwise filed with the SEC.

We have not authorized anyone to provide you with information different from that contained or incorporated by reference in this prospectus. The selling stockholders are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of common stock.

About Bio-Imaging

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

We continue to believe that we are at an early stage of market penetration and 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.

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Recent Developments

On December 18, 2003, our common stock began trading on the NASDAQ National Market under the symbol BITI . Our common stock no longer trades on the American Stock Exchange.

Our company was incorporated in Delaware in 1987 under the name Wise Ventures, Inc. Our name was changed to Bio-Imaging Technologies, Inc. in 1991. We are a Delaware corporation, our executive offices are located at 826 Newtown-Yardley Road, Newtown, Pennsylvania 18940, our telephone number is (267) 757-3000 and our Internet address is <http://www.bioimaging.com>. The information on our Internet website is not incorporated by reference in this prospectus and our website address is included in this prospectus as a textual reference only.

The Offering

| | |
|--|--|
| Common Stock offered by selling stockholders | 4,441,714 shares |
| Use of proceeds | Bio-Imaging will not receive any proceeds from the sale of shares in this offering |
| NASDAQ National Market symbol | BITI |

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RISK FACTORS

You should carefully consider the following risk factors, together with all of the other information included in this prospectus, before making an investment decision. 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 could result in a partial or complete loss 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;
- our failure to perform our obligations under the contract; or
- the failure of products to satisfy safety requirements.

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

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

For the year ended December 31, 2002, revenues from one client, NPS Pharmaceuticals, Inc., encompassing four distinct projects, amounted to 13% of service revenues. For the nine months ended September 30, 2003, revenues from

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one client, NPS Pharmaceuticals, Inc., encompassing four distinct projects, amounted to 12.7% of service revenues. 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 \$40.2 million at September 30, 2003 is based on anticipated net service revenue from uncompleted projects with clients. Backlog is the amount of revenue that remains to be earned and recognized on signed and verbally agreed to contracts. Contracts included in backlog are subject to termination by our clients at any time. In the event that the client cancels a contract, we would be entitled to receive payment for all services performed up to the cancellation date. The duration of the projects included in our backlog range from less than three months to seven years. We cannot assure that this backlog will be indicative of future results. A number of factors may affect backlog, including:

- the variable size and duration of the projects (some are performed over several years);
- the loss or delay of projects;
- the change in the scope of work during the course of a project; and
- the cancellation of such contracts by our clients.

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

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 the nine months ended September 30, 2003 were \$15,922,710, an increase of 26.1% over service revenues for the nine months ended September 30, 2002 of \$12,625,857. Service revenues for the twelve months ended December 31, 2002 were \$17,189,762, an increase of 66.9% over service revenues for the twelve months ended December 31, 2001 of \$10,301,921. Our continuing sales and marketing efforts have increased the number of projects under management from 141 in 2001 to 186 in 2002 and 167 in the nine months ended September 30, 2003. We had 137 employees in 2001, 175 employees in 2002 and 205 employees in 2003. 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.

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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, Vice President Operations, Colin G. Miller, Ph.D., Vice President Business Development and Ted Kaminer, Senior Vice President and Chief Financial Officer. Although we have employment agreements with Mr. Weinstein and Mr. Kaminer, this does not mean Mr. Weinstein or Mr. Kaminer 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 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 2002 and the nine-month period ended September 30, 2003, we derived a small portion of service revenues from international operations. Our financial statements are denominated in U.S. 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 increase the operating costs of our facility in the Netherlands.

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.

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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.

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

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

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

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

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

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.

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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

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reduce the need for our services. If these changes in regulations were to occur, our business, results of operations and financial condition could be materially adversely affected. These and other changes in regulation could have a material adverse impact on our available business opportunities.

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

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

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

We may be exposed to liability claims as a result of our involvement in clinical trials. There can be no assurance 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, there can be no assurance 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 this Offering

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 September 30, 2003, we had the following capital structure:

| | |
|--|------------|
| Common stock outstanding | 10,632,852 |
| Common stock issuable upon: | |
| Exercise of options which are outstanding | 1,856,957 |
| Exercise of options which have not been granted | 1,493,043 |
| Conversion of outstanding convertible note | 136,165 |
| Total common stock outstanding assuming exercise or conversion of all of the above | 14,119,017 |

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As of September 30, 2003, we had outstanding options to purchase approximately 1,856,957 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 1,399,026 options were then exercisable. In addition, at September 30, 2003, we had outstanding a convertible promissory note in the principal amount of \$708,333. 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. 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. Exercise of our outstanding options, or conversion of the convertible note, 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. As of September 30, 2003, the note was convertible into 136,165 shares of our common stock.

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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 September 30, 2003, we had 10,632,852 shares of our common stock issued and outstanding. Of this amount, 6,191,138 shares are freely tradable and 4,441,714 shares are being registered hereunder. Of the shares being registered hereunder, 2,491,165 shares may already be traded upon reliance of SEC Rule 144.

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.

Your percentage ownership will be reduced upon conversion of the convertible promissory note, and the number of shares issuable upon conversion will increase if the market price of our common stock decreases.

At September 30, 2003, we had outstanding a convertible promissory note in the principal amount of \$708,333, which was convertible into 136,165 shares of our common stock as of that date. 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. 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, based upon the outstanding principal amount and accrued interest at September 30, 2003, would be 788,815 shares. Therefore, the number of shares issuable upon conversion will increase if the market price of our common stock decreases.

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 36% of the outstanding shares of common stock on a fully diluted as-converted to common stock basis at September 30, 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.

We previously used Arthur Andersen LLP as our independent public accountants, and you may not have an effective remedy against them.

Our audited consolidated statements of income, stockholders' equity and cash flows and our subsidiaries as of September 30, 2001 included in this prospectus were audited by Arthur Andersen LLP, our independent public accountants, as stated in their report dated as of October 31, 2001. On March 14, 2002, Arthur Andersen LLP was indicted on federal obstruction of justice charges arising from the federal government's investigation of Enron Corporation. On April 15, 2002, upon the recommendation of the Audit Committee of our board of directors, our board of directors approved the dismissal of Arthur Andersen LLP as our independent public accountants and the appointment of PricewaterhouseCoopers LLP to serve as our independent public accountants for the fiscal year ending December 31, 2002 and for the transition period ending December 31, 2001.

Arthur Andersen LLP was convicted on federal obstruction of justice charges on June 15, 2002, ceased practicing before the SEC on August 31, 2002, and was sentenced to five years probation on October 16, 2002. Arthur Andersen LLP has not consented to the inclusion of their audit report dated as of October 31, 2001 in this prospectus. Rule 437a under the Securities Act of 1933, as amended, permits us to dispense with the requirement to file their consent. As a result, you may not have an effective remedy against Arthur Andersen LLP in connection with a material misstatement or omission with respect to our audited consolidated financial statements that are included in this prospectus or any other filing we may make with the SEC, including, with respect to this offering or any other offering registered under the Securities Act, any claim under Section 11 of the Securities Act. In addition, even if you were able to assert such a claim, as a result of its conviction and other lawsuits, Arthur Andersen LLP may fail or otherwise have insufficient assets to satisfy claims made by investors or by us that might arise under federal securities laws or otherwise relating to any material misstatement or omission with respect to our audited consolidated financial statements.

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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 the three months ended September 30, 2003 would have been \$325,237, as compared to the reported net income of \$526,874, and our net income for the nine months ended September 30, 2003 would have been \$523,052, as compared to the reported net income of \$1,127,962.

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

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

- operating results;
- analysts' reports;
- market conditions in the industry;
- changes in governmental regulations; and
- changes in general conditions in the economy or the financial markets.

The 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 31, 2002 and September 30, 2003, our common stock has traded at a low of \$1.12 per share and a high of \$7.98 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.

Special Note Regarding Forward-Looking Statements

This prospectus includes and incorporates forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended, based upon the beliefs of our management, as well as assumptions made by, and the information currently available to, our management. All statements, other than statements of historical facts, included or incorporated in this prospectus regarding our strategy,

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future operations, financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. The words anticipates, believes, estimates, expects, intends, may, plans, projects, will, would and similar expressions identify forward-looking statements, although not all forward-looking statements contain these identifying words. We cannot guarantee that we actually will achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included or incorporated in this prospectus, particularly under the heading Risk Factors, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this prospectus. Except for special circumstances in which a duty to update arises when prior disclosure becomes materially misleading in light of subsequent circumstances, we do not intend to update any of these forward-looking statements to reflect events or circumstances after the date of this prospectus or to reflect the occurrence of unanticipated events.

Use of Proceeds

We will not receive any proceeds from the sale of common stock by the selling stockholders. The selling stockholders will pay any underwriting discounts and commissions and expenses incurred by the selling stockholders in disposing of the shares. We will bear all other costs, fees and expenses incurred in effecting the registration of the shares covered by this prospectus, including, without limitation, all registration and filing fees, American Stock Exchange listing fees and fees and expenses of our counsel and our accountants.

Selling Stockholders

The following table sets forth the common stock ownership of the selling stockholders, as of September 30, 2003, as adjusted to reflect the sale of the common stock in this offering. Except as described in this prospectus, the selling stockholders have not held any position or office or had any other material relationship with us or any of our predecessors or affiliates within the past three years.

The 4,441,714 shares covered by this prospectus represented approximately 41.8% of our outstanding shares of common stock as of September 30, 2003. The 4,441,714 shares covered by this prospectus consist of the following:

1,762,000 shares are being registered on behalf of certain institutional investors who purchased such shares in a private placement of our common stock, which closed on September 15, 2003;

2,355,000 shares represent previously issued and outstanding shares, which are being registered pursuant to piggyback registration rights granted in 1994 to a certain holder of our common stock;

188,549 shares represent previously issued and outstanding shares, which are being registered pursuant to piggyback registration rights granted in 2001 to a certain holder of our common stock; and

136,165 shares represent shares of our common stock issuable but not outstanding under a convertible note, which are being registered pursuant to piggyback registration rights granted in 2001.

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The shares of our common stock may be offered and sold from time to time by the selling stockholders identified in this prospectus, or their pledgees, donees, transferees or other successors-in-interest through public or private transactions at prevailing market prices, at prices related to prevailing market prices or at privately negotiated prices. The selling stockholders will pay all underwriting discounts and selling commissions, if any, applicable to the sale of the shares.

The following table sets forth the aggregate number of shares of common stock beneficially owned by the selling stockholders as of September 30, 2003, and the percentage of all shares of common stock held by such selling stockholders prior to and after giving effect to the offering based on 10,632,852 shares of common stock outstanding as of September 30, 2003. We considered the following factors and made the following assumptions regarding the table:

beneficial ownership is determined under Section 13(d) of the Exchange Act and generally includes voting or investment power with respect to securities and including any securities that grant the selling stockholder the right to acquire common stock within 60 days of September 30, 2003; and
the selling stockholders may sell all of the securities offered by this prospectus under certain circumstances.

Notwithstanding these assumptions, the selling stockholders may sell less than all of the shares listed on the table. In addition, the shares listed below may be sold pursuant to this prospectus or in privately negotiated transactions. Accordingly, we cannot estimate the number of shares of common stock that the selling stockholders will sell under this prospectus.

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The selling stockholders have advised us that they are the beneficial owners of the shares being offered.

| Name of Selling Stockholder | Beneficial Ownership of Selling Stockholders Prior to Offering | | Number of Shares Offered Hereby | Beneficial Ownership of Shares After Offering | |
|--|--|----------------------------|---------------------------------------|--|-------------------------------|
| | Number | Percent (%) ⁽¹⁾ | Number ⁽²⁾ | Number ⁽²⁾ | Percent (%) ⁽¹⁾⁽²⁾ |
| Atlas Capital Master Fund, Ltd. | 150,000 | 1.4% | 150,000 | | * |
| Atlas Capital (Q.P.) L.P. | 50,000 | * | 50,000 | | * |
| Bonanza Master Fund Ltd. | 91,018 | * | 91,018 | | * |
| CDC Derivatives Inc. | 134,051 | 1.3% | 134,051 | | * |
| Covance Inc. ⁽³⁾ | 2,355,000 | 22.15% | 2,355,000 | | * |
| Eller Financial Corp | 30,000 | * | 30,000 | | * |
| Hathaway Partners Investment Limited Partnership | 45,000 | * | 28,000 | 17,000 | * |
| Merlin Biomed Long Term Appreciation Fund, L.P. | 67,000 | * | 34,000 | 33,000 | * |
| Merlin Biomed Offshore Fund, L.P. | 183,000 | 1.7% | 66,000 | 117,000 | 1.1% |
| Oppenheimer Emerging Growth Fund | 123,800 | 1.2% | 123,800 | | * |
| OppenheimerFunds plc U.S. Emerging Growth Fund | 11,500 | * | 11,500 | | * |
| Pequot Navigator Onshore Fund, L.P. | 60,000 | * | 60,000 | | * |
| Pequot Scout Fund, L.P. | 90,000 | * | 90,000 | | * |
| The Pinnacle Fund, L.P. | 521,500 | 4.9% | 243,798 | 277,702 | 2.6% |
| Precept Capital Master Fund, G.P. | 192,000 | 1.8% | 50,000 | 142,000 | 1.3% |
| Quintiles, Inc. | 324,714 | 3.1% | 324,714 | | * |
| Sandor Capital Master Fund, L.P. | 15,000 | * | 15,000 | | * |
| SDS Merchant Fund, LP | 20,133 | * | 20,133 | | * |
| SF Capital Partners Ltd. | 75,000 | * | 75,000 | | * |
| Southwell Partners, L.P. | 157,700 | 1.5% | 65,000 | 92,700 | * |
| Tarpon Partners LP | 20,500 | * | 20,000 | 500 | * |
| USAZ Oppenheimer Emerging Growth Fund | 64,700 | * | 64,700 | | * |
| Valor Capital Management, LP | 184,800 | 1.7% | 125,000 | 59,800 | * |
| Walker Smith Capital Master Fund | 38,550 | * | 38,550 | | * |
| Walker Smith International Fund, Ltd. | 36,450 | * | 36,450 | | * |
| WS Opportunity Master Fund | 51,000 | * | 51,000 | | * |
| WS Opportunity Fund International, Ltd. | 24,000 | * | 24,000 | | * |
| Westpark Capital, L.P. | 70,000 | * | 65,000 | 5,000 | * |

* Less than one percent.

⁽¹⁾ Does not include 1,729,457 shares of common stock that could be issued upon exercise of options granted under our stock option plan as of September 30, 2003.

⁽²⁾ We do not know when or in what amounts a selling stockholder may offer shares for sale. The selling stockholders might not sell any or all of the shares offered by this prospectus. Because the selling stockholders may offer all or some of the shares pursuant to this offering and because there are currently no agreements, arrangements or understandings with respect to the sale of any of the shares, we cannot estimate the number of the shares that will be held by the selling stockholders after completion of the offering. However, for purposes of this table, we have assumed that, after completion of the offering, none of the shares covered by this prospectus will be held by the selling stockholders.

- ⁽³⁾ Pursuant to a stock purchase agreement, we agreed to take all actions necessary to nominate and cause the election to our board of directors of up to three designees of Covance, Inc. Such obligation terminates at such time as Covance owns less than 200,000 shares of our common stock. James Bannon, Pharm.D., has served as Covance's designee on our board of directors since 2002. Covance has reserved all of its rights under such stock purchase agreement for subsequent years.

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Plan of Distribution

We are registering the shares of common stock on behalf of the selling stockholders. Sales of shares may be made by selling stockholders, including their respective donees, transferees, pledgees or other successors-in-interest directly to purchasers or to or through underwriters, broker-dealers or through agents. Sales may be made from time to time on the NASDAQ National Market, any other exchange upon which our shares may trade in the future, in the over-the-counter market or otherwise, at market prices prevailing at the time of sale, at prices related to market prices, or at negotiated or fixed prices. The shares may be sold by one or more of, or a combination of, the following:

- a block trade in which the broker-dealer so engaged will attempt to sell the shares as agent, but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by such broker-dealer, including resales for its account, pursuant to this prospectus;
- ordinary brokerage transactions and transactions in which the broker solicits purchases;
- through options, swaps or derivatives;
- in privately negotiated transactions;
- in making short sales or in transactions to cover short sales; and
- put or call option transactions relating to the shares.

The selling stockholders may consummate these transactions by selling shares directly to purchasers or to or through broker-dealers, which may act as agents or principals. These broker-dealers may receive compensation in the form of discounts, concessions or commissions from the selling stockholders and/or the purchasers of shares for whom such broker-dealers may act as agents or to whom they sell as principals, or both (which compensation as to a particular broker-dealer might be in excess of customary commissions). The selling stockholders may also sell shares of common stock short and deliver shares covered by this prospectus to close out short positions, provided that the short sale is made after the registration statement is declared effective and a copy of this prospectus is delivered in connection with the short sale. The selling stockholders have advised us that they have not entered into any agreements, understandings or arrangements with any underwriters or broker-dealers regarding the sale of their securities.

The selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions. In connection with those transactions, the broker-dealers or other financial institutions may engage in short sales of the shares or of securities convertible into or exchangeable for the shares in the course of hedging positions they assume with the selling stockholders. The selling stockholders may also enter into options or other transactions with broker-dealers or other financial institutions that require the delivery of shares offered by this prospectus to those broker-dealers or other financial institutions. The broker-dealer or other financial institution may then resell the shares pursuant to this prospectus (as amended or supplemented, if required by applicable law, to reflect those transactions).

The selling stockholders and any broker-dealers that act in connection with the sale of shares may be deemed to be underwriters within the meaning of Section 2(11) of the Securities Act, and any commissions received by broker-dealers or any profit on the resale of the shares sold by them while acting as principals may be deemed to be underwriting discounts or commissions under the Securities Act. The selling stockholders may agree to indemnify any agent, dealer or broker-dealer that participates in transactions involving sales of the shares against liabilities, including liabilities arising under the Securities Act. The Company has agreed to indemnify each of the selling stockholders and each selling stockholder has agreed, severally and not jointly, to indemnify the Company against some liabilities in connection with the offering of the shares, including liabilities arising under the Securities Act.

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The selling stockholders will be subject to the prospectus delivery requirements of the Securities Act. We have informed the selling stockholders that the anti-manipulative provisions of Regulation M promulgated under the Exchange Act may apply to their sales in the market.

Selling stockholders also may resell all or a portion of the shares in open market transactions in reliance upon Rule 144 under the Securities Act, provided they meet the criteria and conform to the requirements of Rule 144.

Upon being notified by a selling stockholder that a material arrangement has been entered into with a broker-dealer for the sale of shares through a block trade, special offering, exchange distribution or secondary distribution or a purchase by a broker or dealer, we will file a supplement to this prospectus, if required pursuant to Rule 424(b) under the Securities Act, disclosing:

- the name of each such selling stockholder and of the participating broker-dealer(s);
- the number of shares involved;
- the initial price at which the shares were sold;
- the commissions paid or discounts or concessions allowed to the broker-dealer(s), where applicable;
- that such broker-dealer(s) did not conduct any investigation to verify the information set out or incorporated by reference in this prospectus; and
- other facts material to the transactions.

In addition, we will file a supplement to this prospectus when a selling stockholder notifies us that a donee or pledgee intends to sell more than 500 shares of common stock.

We are paying all expenses and fees in connection with the registration of the shares. The selling stockholders will bear all brokerage or underwriting discounts or commissions paid to broker-dealers in connection with the sale of the shares.

We have agreed with the selling stockholders to keep the registration statement of which this prospectus constitutes a part effective until the earlier of:

- such time as all of the shares covered by this prospectus have been disposed of pursuant to and in accordance with the registration statement; or
- September 15, 2005.

Legal Matters

The validity of the shares of common stock offered by this prospectus have been passed upon for us by Hale and Dorr LLP, Princeton, New Jersey.

Experts

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The audited consolidated financial statements as of December 31, 2002 and 2001 and for the year ended December 31, 2002 and the three months ended December 31, 2001 incorporated in this Registration Statement by reference to the Annual Report on Form 10-KSB for the year ended December 31, 2002 have been so incorporated in reliance on the report of PricewaterhouseCoopers LLP, independent accountants, given on the authority of said firm as experts in auditing and accounting.

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The balance sheet of Bio-Imaging Technologies, Inc. as of September 30, 2001, and the related statements of income, stockholders' equity and cash flows for the year then ended, have been incorporated by reference herein and in the registration statement in reliance upon the report of Arthur Andersen LLP, independent accountants, incorporated by reference herein, and upon the authority of said firm as experts in accounting and auditing. Arthur Andersen LLP has not consented to the inclusion of their report in this prospectus, and we have not obtained their consent to do so in reliance upon Rule 437a of the Securities Act. The absence of this consent may limit recovery against Arthur Andersen LLP under Section 11 of the Securities Act for any untrue statement of a material fact, or any omission to state a material fact required to be stated, in the financial statements audited by Arthur Andersen LLP. Also, as a practical matter, Arthur Andersen LLP's ability to satisfy any claims may be limited due to events arising out of their conviction on federal obstruction of justice charges.

Where You Can Find More Information

We file reports, proxy statements and other documents with the SEC. You may read and copy any document we file at the SEC's public reference room at Judiciary Plaza Building, 450 Fifth Street, N.W., Room 1024, Washington, D.C. 20549. You should call 1-800-SEC-0330 for more information on the public reference room. Our SEC filings are also available to you on the SEC's Internet website at <http://www.sec.gov>.

This prospectus is part of a registration statement that we filed with the SEC. The registration statement contains more information than this prospectus regarding us and our common stock, including certain exhibits and schedules. You can obtain a copy of the registration statement from the SEC at the address listed above or from the SEC's Internet website.

Incorporation of Certain Documents By Reference

The SEC allows us to incorporate by reference much of the information we file with them under Commission File No. 001-11182, which means that we can disclose important information to you by referring you to those publicly available documents. All of the information that we incorporate by reference is considered to be part of this prospectus, and any of our subsequent filings with the SEC will automatically update and supersede this information. This prospectus incorporates by reference the documents listed below and any future filings made by Bio-Imaging with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act, until the filing of a post-effective amendment to this prospectus which indicates that all securities registered have been sold or which deregisters all securities then remaining unsold:

- our registration statement on Form 8-A, filed on December 16, 2003;
- our annual report on Form 10-KSB for the year ended December 31, 2002, filed on March 28, 2003;
- our proxy statement for our annual meeting of stockholders, filed on April 28, 2003;
- our quarterly report on Form 10-QSB and Form 10-QSB/A for the quarter ended March 31, 2003, filed on May 14, 2003 and May 23, 2003, respectively;
- our quarterly report on Form 10-QSB for the quarter ended June 30, 2003, filed on August 14, 2003;
- our quarterly report on Form 10-QSB for the quarter ended September 30, 2003, filed on November 14, 2003;
- our current report on Form 8-K, filed on September 18, 2003;
- our current report on Form 8-K, filed on December 12, 2003; and
- all of our filings pursuant to the Exchange Act after the date of filing the initial registration statement and prior to effectiveness of the registration statement.

You may request a copy of any or all of these filings, at no cost, by writing or telephoning us at: Bio-Imaging Technologies, Inc., 826 Newtown-Yardley Road, Newtown, Pennsylvania 18940; telephone (267) 757-3000, Attention: Ted Kaminer.

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You should rely only on the information incorporated by reference or provided in this prospectus or any supplement. We have not authorized anyone else to provide you with different information. The selling stockholders will not make an offer of these shares in any jurisdiction where the offer is not permitted. You should not assume that information in this prospectus or any supplement is accurate as of any date other than the date on the front of these documents.

Indemnification of Directors and Officers

Section 145 of the Delaware General Corporation Law, or the DGCL, empowers a Delaware corporation to indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of such corporation) by reason of the fact that such person is or was a director, officer, employee or agent of such corporation, or is or was serving at the request of such corporation as a director, officer, employee or agent of another corporation or enterprise. A corporation may, in advance of the final disposition of any civil, criminal, administrative or investigative action, suit or proceeding, pay the expenses (including attorneys' fees) incurred by any officer, director, employee or agent in defending such action, provided that the director or officer undertakes to repay such amount if it shall ultimately be determined that he is not entitled to be indemnified by the corporation. A corporation may indemnify such person against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding if he acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful.

A Delaware corporation may indemnify officers and directors in an action by or in the right of the corporation to procure a judgment in its favor under the same conditions, except that no indemnification is permitted without judicial approval if the officer or director is adjudged to be liable to the corporation. Where an officer or director is successful on the merits or otherwise in the defense of any action referred to above, the corporation must indemnify him against the expenses (including attorneys' fees) which he actually and reasonably incurred in connection therewith. The indemnification provided is not deemed to be exclusive of any other rights to which an officer or director may be entitled under any corporation's by-law, agreement, vote or otherwise.

Our certificate of incorporation includes a provision that eliminates the personal liability of our directors to us or our stockholders for monetary damages for breach of their fiduciary duty to the maximum extent permitted by Section 102 of the DGCL. The DGCL does not permit liability to be eliminated (i) for any breach of a director's duty of loyalty to us or our stockholders, (ii) for acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law, (iii) for unlawful payments of dividends or unlawful stock repurchases or redemptions, as provided in Section 174 of the DGCL, or (iv) for any transaction from which the director derived an improper personal benefit. In addition, as permitted in Section 145 of the DGCL, our certificate of incorporation and by-laws provide that we shall indemnify our directors and officers to the fullest extent permitted by the DGCL, including those circumstances in which indemnification would otherwise be discretionary, subject to certain exceptions. Our by-laws also provide that we shall advance expenses to directors and officers incurred in connection with an action or proceeding as to which they may be entitled to indemnification, subject to certain exceptions.

Each of our indemnification agreements with each of our executive officers and directors provides for indemnification to the maximum extent permitted by applicable law. We also indemnify each of our directors and executive officers with the maximum indemnification allowed to directors and executive officers by the DGCL, subject to certain exceptions, as well as certain additional procedural protections. In addition, we will generally advance expenses incurred by directors and executive officers in any action or proceeding as to which they may be entitled to indemnification, subject to certain exceptions.

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The indemnification provisions in our certificate of incorporation and by-laws also permit indemnification for liabilities arising under the Securities Act. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

We currently carry director and officer liability insurance in the amount of \$5,000,000.

Table of Contents**PART II****INFORMATION NOT REQUIRED IN PROSPECTUS****Item 14. Other Expenses of Issuance and Distribution.**

The expenses payable by the registrant in connection with the issuance and distribution of the securities being registered hereby are as follows:

| | <u>Amount</u> |
|------------------------|----------------------|
| SEC Registration Fee | \$ 2,299.74 |
| Legal Expenses | 25,000.00* |
| Accounting Expenses | 5,000.00* |
| Printing Expenses | 1,000.00* |
| Miscellaneous Expenses | 1,700.26* |
| Total | \$ 35,000.00* |

*Estimated

Item 15. Indemnification of Directors and Officers.

Section 145 of the Delaware General Corporation Law empowers a Delaware corporation to indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of such corporation) by reason of the fact that such person is or was a director, officer, employee or agent of such corporation, or is or was serving at the request of such corporation as a director, officer, employee or agent of another corporation or enterprise. A corporation may, in advance of the final disposition of any civil, criminal, administrative or investigative action, suit or proceeding, pay the expenses (including attorneys' fees) incurred by any officer, director, employee or agent in defending such action, provided that the director or officer undertakes to repay such amount if it shall ultimately be determined that he is not entitled to be indemnified by the corporation. A corporation may indemnify such person against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding if he acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful.

A Delaware corporation may indemnify officers and directors in an action by or in the right of the corporation to procure a judgment in its favor under the same conditions, except that no indemnification is permitted without judicial approval if the officer or director is adjudged to be liable to the corporation. Where an officer or director is successful on the merits or otherwise in the defense of any action referred to above, the corporation must indemnify him against the expenses (including attorneys' fees) which he actually and reasonably incurred in connection therewith. The indemnification provided is not deemed to be exclusive of any other rights to which an officer or director may be entitled under any corporation's by-law, agreement, vote or otherwise.

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Our certificate of incorporation includes a provision that eliminates the personal liability of our directors to us or our stockholders for monetary damages for breach of their fiduciary duty to the maximum extent permitted by Section 102 of the DGCL. The DGCL does not permit liability to be eliminated (i) for any breach of a director's duty of loyalty to us or our stockholders, (ii) for acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law, (iii) for

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unlawful payments of dividends or unlawful stock repurchases or redemptions, as provided in Section 174 of the DGCL, or (iv) for any transaction from which the director derived an improper personal benefit. In addition, as permitted in Section 145 of the DGCL, our certificate of incorporation and by-laws provide that we shall indemnify our directors and officers to the fullest extent permitted by the DGCL, including those circumstances in which indemnification would otherwise be discretionary, subject to certain exceptions. Our by-laws also provide that we shall advance expenses to directors and officers incurred in connection with an action or proceeding as to which they may be entitled to indemnification, subject to certain exceptions.

Each of our indemnification agreements with each of our executive officers and directors provides for indemnification to the maximum extent permitted by applicable law. We also indemnify each of our directors and executive officers with the maximum indemnification allowed to directors and executive officers by the DGCL, subject to certain exceptions, as well as certain additional procedural protections. In addition, we will generally advance expenses incurred by directors and executive officers in any action or proceeding as to which they may be entitled to indemnification, subject to certain exceptions.

The indemnification provisions in our certificate of incorporation and by-laws also permit indemnification for liabilities arising under the Securities Act. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

We currently carry director and officer liability insurance in the amount of \$5,000,000.

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Item 16. Exhibits.

- 2.1 Asset Purchase Agreement dated October 25, 2001, by and between the Company and Quintiles, Inc. (Incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K dated October 25, 2001.)
- 3.1 Restated Certificate of Incorporation of the Company. (Incorporated by reference to Exhibit 3.1 to the Company's 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 to the Company's Annual Report on Form 10-K for the year ended September 30, 1993 and to Exhibit 3.1 to the Company's Quarterly Report on Form 10-QSB for the quarter ended March 31, 1995.)
- 3.2 Amended and Restated By-Laws of the Company. (Incorporated by reference to Exhibit 3.1 to the Company's Form 10-QSB for the quarter ended June 30, 2001.)
- 4.1 Specimen Common Stock Certificate. (Incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1 (File Number 33-47471) which became effective on June 18, 1992.)
- 4.2 Stock Purchase Agreement dated October 13, 1994 between the Company and Corning Pharmaceuticals Services Inc., now Covance, Inc. (Incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K dated October 13, 1994.)
- 4.3 Registration Agreement, dated October 13, 1994, between the Company and Corning Pharmaceuticals Services Inc., now Covance, Inc. (Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K dated October 13, 1994.)
- 4.4 Registration Rights Agreement, dated as of October 25, 2001, by and between the Company and Quintiles, Inc. (Incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K/A dated October 25, 2001.)
- 4.5 Securities Purchase Agreement dated September 15, 2003, by and among the Company and the Purchasers listed therein. (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K dated September 18, 2003.)
- 4.6 Registration Rights Agreement dated September 15, 2003, by and among the Company and the Investors listed therein. (Incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K dated September 18, 2003.)
- 5.1* Opinion of Hale and Dorr LLP.
- 23.1 Consent of PricewaterhouseCoopers LLP.
- 23.2* Consent of Hale and Dorr LLP (included in Exhibit 5.1).
- 24.1* Power of Attorney (included on signature page).

* Previously filed.

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Item 17. Undertakings.

(a) The undersigned registrant hereby undertakes:

- (1) to file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:
 - (i) to include any prospectus required by Section 10(a)(3) of the Securities Act;
 - (ii) to reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or together, represent a fundamental change in the information in the registration statement. Notwithstanding the foregoing, any increase or decrease in the volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the SEC pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than twenty percent change in the maximum aggregate offering price set forth in the Calculation of Registration Fee table in the effective registration statement; and
 - (iii) to include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement; provided, however, that paragraphs (a)(1)(i) and (a)(1)(ii) do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in periodic reports filed by the registrant pursuant to Section 13 or 15(d) of the Exchange Act that are incorporated by reference in the registration statement;
- (2) that, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof; and
- (3) to remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(b) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act, each filing of the registrant's annual report pursuant to Section 13(a) or 15(d) of the Exchange Act (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Exchange Act) that is incorporated by reference in this registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(c) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the provisions described under Item 15 above, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

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Pursuant to the requirements of the Securities Act, this registration statement has been signed below by the following persons in the capacities and on the dates indicated.

| <u>Signature</u> | <u>Title</u> | <u>Date</u> |
|---------------------------------|---|-------------------|
| <u>/s/ MARK L. WEINSTEIN</u> | | |
| Mark L. Weinstein | President, Chief Executive Officer and Director (Principal Executive Officer) | December 22, 2003 |
| <u>/s/ TED KAMINER</u> | | |
| Ted Kaminer | Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer) | December 22, 2003 |
| * | | |
| <u>James Bannon, Pharm.D.</u> | | |
| James Bannon, Pharm.D. | Director | December 22, 2003 |
| * | | |
| <u>Jeffrey H. Berg, Ph.D.</u> | | |
| Jeffrey H. Berg, Ph.D. | Director | December 22, 2003 |
| * | | |
| <u>David E. Nowicki, D.M.D.</u> | | |
| David E. Nowicki, D.M.D. | Director | December 22, 2003 |
| * | | |
| <u>Allan Rubenstein, M.D.</u> | | |
| Allan Rubenstein, M.D. | Director | December 22, 2003 |
| * | | |
| <u>David Stack</u> | | |
| David Stack | Director | December 22, 2003 |
| * | | |
| <u>Paula B. Stafford</u> | | |
| Paula B. Stafford | Director | December 22, 2003 |
| * | | |
| <u>James A. Taylor, Ph.D.</u> | | |
| James A. Taylor, Ph.D. | Director | December 22, 2003 |

* By the signature set forth below, the undersigned, pursuant to the duly authorized powers of attorney filed with the Securities and Exchange Commission has signed this Amendment to the Registration Statement on behalf of the person indicated.

/s/ Mark L. Weinstein

Mark L. Weinstein

(Attorney-in-fact)

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Index of Exhibits

- 2.1 Asset Purchase Agreement dated October 25, 2001, by and between the Company and Quintiles, Inc. (Incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K dated October 25, 2001.)
- 3.1 Restated Certificate of Incorporation of the Company. (Incorporated by reference to Exhibit 3.1 to the Company's 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 to the Company's Annual Report on Form 10-K for the year ended September 30, 1993 and to Exhibit 3.1 to the Company's Quarterly Report on Form 10-QSB for the quarter ended March 31, 1995.)
- 3.2 Amended and Restated By-Laws of the Company. (Incorporated by reference to Exhibit 3.1 to the Company's Form 10-QSB for the quarter ended June 30, 2001.)
- 4.1 Specimen Common Stock Certificate. (Incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1 (File Number 33-47471) which became effective on June 18, 1992.)
- 4.2 Stock Purchase Agreement dated October 13, 1994 between the Company and Corning Pharmaceuticals Services Inc., now Covance, Inc. (Incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K dated October 13, 1994.)
- 4.3 Registration Agreement, dated October 13, 1994, between the Company and Corning Pharmaceuticals Services Inc., now Covance, Inc. (Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K dated October 13, 1994.)
- 4.4 Registration Rights Agreement, dated as of October 25, 2001, by and between the Company and Quintiles, Inc. (Incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K/A dated October 25, 2001.)
- 4.5 Securities Purchase Agreement dated September 15, 2003, by and among the Company and the Purchasers listed therein. (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K dated September 18, 2003.)
- 4.6 Registration Rights Agreement dated September 15, 2003, by and among the Company and the Investors listed therein. (Incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K dated September 18, 2003.)
- 5.1* Opinion of Hale and Dorr LLP.
- 23.1 Consent of PricewaterhouseCoopers LLP.
- 23.2* Consent of Hale and Dorr LLP (included in Exhibit 5.1).
- 24.1* Power of Attorney (included on signature page).

* Previously filed.