CYTODYN INC
Form S-1
September 11, 2015
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As filed with the Securities and Exchange Commission September 11, 2015

File No. 333-

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-1

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

CYTODYN INC.

(Exact name of registrant as specified in its charter)

Delaware	**75-3056237**
(State or other jurisdiction of incorporation or organization)	**(IRS Employer Identification Number)**

1111 Main Street, Suite 660

Vancouver, Washington 98660

(360) 980-8524

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

Nader Pourhassan

President and Chief Executive Officer

CytoDyn Inc.

1111 Main Street, Suite 660

Vancouver, Washington 98660

Telephone: (360) 980-8524

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

With copy to:

Michael J. Lerner, Esq.

Steven M. Skolnick, Esq.

Lowenstein Sandler LLP

1251 Avenue of the Americas

New York, New York 10020

Telephone: (212) 262-6700

Approximate date of commencement of proposed sale to the public: From time to time after the effective date of this Registration Statement.

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 of 1933, check the following box. x

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 of 1933, 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(d) 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. ¨

Indicate by checkmark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in rule 12b-2 of the Exchange Act.

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer ¨	Smaller reporting company x

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered(1)(2)	Proposed Maximum Offering Price Per Share(3)	Proposed Maximum Aggregate Offering Price(3)	Amount of Registration Fee
Common Stock, par value $0.001 per share	18,044,568 shares	$0.715	$12,901,867	$1,499.20

(1) The shares of common stock to be offered for resale by selling shareholders include: (i) 899,999 shares issued in the August 2015 Placement (as defined herein), (ii) 449,999 shares issuable upon exercise of the August 2015 Warrants (as defined herein), (iii) 9,785,621 shares issued in the July 2015 Placement (as defined herein),

(iv) 4,892,791 shares issuable upon exercise of the July 2015 Investor Warrants (as defined herein), (v) 1,272,131 shares issuable upon exercise of the July 2015 Placement Agent Warrants (as defined herein), and (vi) up to 744,027 incremental shares of our common stock, which have not previously registered for resale under a separate registration statement, issuable in connection with the May 2015 Placement (as defined herein), in each case as described in greater detail herein.

(2) Pursuant to Rule 416 under the Securities Act, this registration statement also covers an indeterminate number of shares that may be issued upon stock splits, stock dividends or similar transactions.

(3) Estimated in accordance with Rule 457(c) under the Securities Act of 1933, as amended, solely for the purpose of calculating the registration fee, based on the average of the high and low prices of shares of CytoDyn Common Stock reported on the OTC Bulletin Board on September 10, 2015.

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 of 1933 or until this 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 shareholders may not sell these securities until the registration statement filed with the Securities and Exchange Commission relating to these securities is effective. This prospectus is not an offer to sell these securities and it is not a solicitation of an offer to buy these securities in any jurisdiction where such offer, solicitation or sale is not permitted.

Subject to Completion, dated September 11, 2015

Prospectus

18,044,568 SHARES OF COMMON STOCK

This prospectus relates to the offer and sale of up to 18,044,568 shares of our common stock, par value $0.001 per share, by the selling shareholders identified in this prospectus. The shares being offered include:

- 899,999 shares issued to selling shareholders in certain private placements completed in early August, 2015 (the August 2015 Placement);
- 449,999 shares issuable to selling stockholders upon exercise, at an exercise price of $0.75 per share, of warrants issued in the August 2015 Placement;
- 9,785,621 shares issued to selling shareholders in the private placement completed on July 31, 2015 (the July 2015 Placement);
- 4,892,791 shares issuable to selling stockholders upon exercise, at an exercise price of $0.75 per share, of warrants issued in the July 2015 Placement;
- 1,272,131 shares issuable upon the exercise, at an exercise price of $0.75 per share, of warrants issued to our placement agent in the July 2015 Placement; and
- up to 744,027 incremental shares of common stock issuable to selling shareholders in connection with the private placement completed on May 15, 2015, which have not previously been registered for resale under a separate registration statement, as described in greater detail herein.

The selling shareholders may sell all or a portion of these shares from time to time, in amounts, at prices and on terms determined at the time of sale. The shares may be sold by any means described in the section of this prospectus

entitled Plan of Distribution beginning on page 27 of this prospectus.

We will not receive any proceeds from the sale of these shares. We will, however, receive cash proceeds equal to the total exercise price of warrants that are exercised for cash.

Our common stock is quoted on the OTCQB of the OTC Markets under the symbol CYDY. On September 10, 2015, the closing price of our common stock was $0.75 per share.

Investing in our common stock involves risks. You should read and carefully consider the Risk Factors section beginning on page 5 of this prospectus before investing in our common stock.

Neither the Securities and Exchange Commission nor any state regulatory agency 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 , 2015.

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In making your investment decision, you should rely only on the information contained in this prospectus. We have not authorized anyone to provide you with different or additional information.

We are not making an offer to sell or seeking an offer to buy any shares of common stock in any jurisdiction where the offer or sale is not permitted.

You should not assume that the information contained in this prospectus is complete and accurate as of any date other than the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of securities offered hereby.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains certain forward-looking statements that involve risks, uncertainties and assumptions that are difficult to predict. Words and expressions reflecting optimism, satisfaction or disappointment with current prospects, as well as words such as believes, hopes, intends, estimates, expects, projects, plans, anticipates and va or the use of future tense, identify forward-looking statements, but their absence does not mean that a statement is not forward-looking. Our forward-looking statements are not guarantees of performance and actual results could differ materially from those contained in or expressed by such statements. In evaluating all such statements we urge you to specifically consider various risk factors identified in this prospectus, including the matters set forth under the heading Risk Factors, any of which could cause actual results to differ materially from those indicated by our forward-looking statements.

Our forward-looking statements reflect our current views with respect to future events and are based on currently available financial, economic, scientific, and competitive data and information on current business plans. You should not place undue reliance on our forward-looking statements, which are subject to risks and uncertainties relating to, among other things: (i) the sufficiency of our cash position, (ii) our ability to meet our debt obligations, (iii) our ability to achieve approval of a marketable product, (iv) design, implementation and conduct of clinical trials, (v) the results of our clinical trials, including the possibility of unfavorable clinical trial results, (vi) the market for, and marketability of, any product that is approved, (vii) the existence or development of vaccines, drugs, or other treatments for infection with the Human Immunodeficiency Virus that are viewed by medical professionals or patients as superior to our products, (viii) regulatory initiatives, compliance with governmental regulations and the regulatory approval process, (ix) general economic and business conditions, (x) changes in foreign, political, and social conditions, (xi) the specific risk factors discussed under the heading Risk Factors below, and (x) various other matters, many of which are beyond our control. Should one or more of these risks or uncertainties develop, or should underlying assumptions prove to be incorrect, actual results may vary materially and adversely from those anticipated, believed, estimated, or otherwise indicated by our forward-looking statements.

We intend that all forward-looking statements made in this prospectus will be subject to the safe harbor protection of the federal securities laws pursuant to Section 27A of the Securities Act of 1933, as amended, to the extent applicable. Except as required by law, we do not undertake any responsibility to update these forward-looking statements to take into account events or circumstances that occur after the date of this prospectus. Additionally, we do not undertake any responsibility to update you on the occurrence of any unanticipated events which may cause actual results to differ from those expressed or implied by these forward-looking statements.

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PROSPECTUS SUMMARY

The following summary highlights information contained elsewhere in this prospectus. It does not contain all the information that is important to you. You should read the entire prospectus, including the section entitled Risk Factors, before making an investment decision.

Corporate Information

CytoDyn Inc. is a Delaware corporation with its principal business office at 1111 Main Street, Suite 660, Vancouver, Washington 98660. Our website can be found at www.cytodyn.com. We do not intend to incorporate any contents from our website into this prospectus. Effective August 27, 2015, we completed a reincorporation from Colorado to Delaware, upon approval of our shareholders at our annual meeting.

Unless the context otherwise requires, references in this prospectus to CytoDyn, the Company, we, our, or us are CytoDyn Inc. and its subsidiaries.

The Company

We are a publicly traded biotechnology company focused on the clinical development and potential commercialization of humanized monoclonal antibodies to treat Human Immunodeficiency Virus (HIV) infection. Our lead product candidate, PRO 140, belongs to a class of HIV therapies known as entry inhibitors. These therapies block HIV from entering into and infecting certain cells. Although CytoDyn intends to focus its efforts on PRO 140, we also hold certain rights in two proprietary platform technologies: Cytolin®, a humanized monoclonal antibody targeting HIV with a mechanism of action which may prove to be synergistic to that of PRO 140 and other treatments, and CytoFeline , a felinized monoclonal antibody targeting Feline Immunodeficiency Virus.

The Transactions

The shares of our common stock being offered for resale by selling shareholders named herein pursuant to this prospectus were issued or are issuable in connection with private placement transactions described below.

August 2015 Placement

Between August 7, 2015 and August 12, 2015, we issued in private placements to accredited investors (which we refer to as the August 2015 Placement) an aggregate of 899,999 shares of our common stock, together with warrants to purchase an aggregate of 449,999 shares of our common stock (the August 2015 Warrants) at an exercise price of $0.75 per share. The August 2015 Warrants have a five-year term and are immediately exercisable.

We are registering for resale by the selling shareholders named herein the 899,999 shares of our common stock issued in the August 2015 Placement, as well as the 449,999 shares of our common stock issuable upon exercise of the August 2015 Warrants.

July 2015 Placement

On July 31, 2015, we completed a private placement to accredited investors (which we refer to as the July 2015 Placement) of an aggregate of 9,785,621 shares of our common stock, together with warrants (the July 2015 Investor Warrants) to purchase an aggregate of 4,892,791 shares of our common stock at an exercise price of $0.75 per share. We also paid the placement agent in the July 2015 Placement, in addition to certain cash fees, warrants (the July 2015

Placement Agent Warrants and, together with the July 2015 Investor Warrants, the July 2015 Warrants) to purchase an aggregate of 1,272,131 shares of our common stock at an exercise price of $0.75 per share. The July 2015 Warrants have a five-year term and are immediately exercisable. (The August 2015 Warrants and the July 2015 Warrants are referred to herein collectively as the Warrants.)

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We are registering for resale by the selling shareholders named herein the 9,785,621 shares of our common stock issued in the July 2015 Placement, as well as the 4,892,791 shares of our common stock issuable upon exercise of the July 2015 Investor Warrants and the 1,272,131 shares of our common stock issuable upon exercise of the July 2015 Placement Agent Warrants.

May 2015 Placement Incremental Shares

On May 15, 2015, we completed a private placement to accredited investors (the May 2015 Placement) of convertible promissory notes in the aggregate principal of $3,981,050 (the May 2015 Notes), together with warrants (the May 2015 Warrants) to purchase an aggregate of 1,061,586 shares of our common stock. The May 2015 Notes have a conversion price of $0.75 per share and a six month term, bearing interest at 7% per year, with maturity dates ranging from October 30, 2015 to November 15, 2015. The May 2015 Warrants have an exercise price of $0.75 per share and a five-year term and are immediately exercisable.

Following the May 2015 Placement, on August 24, 2015, we commenced an offer (the Exchange Offer) to exchange outstanding May 2015 Notes for (i) the issuance of restricted shares of our common stock for the settlement of principal plus accrued but unpaid interest on the May 2015 Notes at a reduced price of $0.675 per share (the Offer Price) and (ii) the amendment of the 2015 Warrants to reduce the exercise price to the Offer Price. The Offer Price represents a 10.0% discount to the current conversion price of the May 2015 Notes and exercise price of the May 2015 Warrants of $0.75 per share. We currently anticipate that the Exchange Offer will expire on September 21, 2015.

The 5,308.040 shares of common stock issuable upon conversion of the principal amount of the May 2015 Notes, the 1,061,586 shares of common stock issuable upon exercise of May 2015 Warrants, and the 530,802 shares of common stock issuable upon the exercise of certain additional warrants issued to our placement agent in the May 2015 Placement, were previously registered for resale by the selling stockholders named in the Registration Statement on Form S-1 (File No. 333-204802) (the Prior Registration Statement), which was declared effective by the Securities and Exchange Commission (the SEC) on September 2, 2015.

We are registering for resale by the selling shareholders named herein up to 744,027 incremental shares of our common stock issuable upon either (i) the conversion of principal plus accrued but unpaid interest through September 21, 2015 on the May 2015 Notes, at the reduced Offer Price of $0.675 per share (for investors participating in the Exchange Offer), or (ii) the conversion of accrued but unpaid interest through maturity on the May 2015 Notes, at the original conversion price of $0.75 per share (for investors not participating in the Exchange Offer). Such incremental shares of our common stock have not previously been registered for resale under the Prior Registration Statement.

Our offer and sale of each of the foregoing securities in connection with the August 2015 Placement, the July 2015 Placement and the May 2015 Placement (including, as the case may be, any shares of common stock issuable upon exercise, conversion, or exchange of warrants or convertible promissory notes) were and are intended to be exempt from the registration requirements of the Securities Act of 1933, as amended (the Securities Act), pursuant to Section 4(a)(2) of the Securities Act and the safe harbor provisions of Rule 506(b) of Regulation D thereunder, as applicable to sales of securities exclusively to accredited investors, as that term is defined in Rule 501(a) of Regulation D.

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This Offering

Securities being offered:	Up to 18,044,568 shares of common stock, including (i) 899,999 shares issued in the August 2015 Placement, (ii) 449,999 shares issuable upon exercise of the August 2015 Warrants, (iii) 9,785,621 shares issued in the July 2015 Placement, (iv) 4,892,791 shares issuable upon exercise of the July 2015 Investor Warrants, (v) 1,272,131 shares issuable upon exercise of the July 2015 Placement Agent Warrants, and (vi) up to 744,027 incremental shares of our common stock, which have not previously registered for resale under a separate registration statement, issuable in connection with either (a) the consummation of the Exchange Offer for the May 2015 Notes at a reduced Offer Price of $0.675 per share or (b) the conversion of accrued but unpaid interest through maturity on the May 2015 Notes at the original conversion price of $0.75 per share.
Use of proceeds:	We will not receive any of the proceeds from the sale or other disposition of shares of our common stock by the selling shareholders. We may receive proceeds upon exercise for cash of the Warrants, in which case such proceeds will be used for general working capital purposes. The July 2015 Placement Agent Warrants include a cashless exercise feature, while the other Warrants do not.
Market for common stock:	Our common stock is quoted on the OTCQB of the OTC Markets under the symbol CYDY. On September 10, 2015, the closing price of our common stock was $0.75 per share.
Risk factors:	See Risk Factors beginning on page 5 for risks you should consider before investing in our shares.

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RISK FACTORS

The risks enumerated below are not the only risks we face, and the listed risk factors are not intended to be an all-inclusive discussion of all of the potential risks relating to our business. Any of the risk factors described below could significantly and adversely affect our business, prospects, financial condition and results of operations. Additional risks and uncertainties not currently known or that are currently considered to be immaterial may also materially and adversely affect our business.

Risks Related to Our Business

We are a biotechnology company and have a history of significant operating losses; we expect to continue to incur operating losses, and we may never achieve or maintain profitability.

We have not generated any revenue from product sales, licensing, or other potential sales to date. Since our inception, we have incurred operating losses in each year due to costs incurred in connection with research and development activities and general and administrative expenses associated with our operations. Our current drug candidate is in the later stages of clinical trials, and we expect to commence significant additional clinical trials before we can seek the regulatory approvals necessary to begin commercial sales. During the fiscal years ended May 31, 2015, 2014 and 2013, we have incurred net losses of approximately $25.1 million, $12.4 million and $9.6 million and at May 31, 2015, we had an accumulated deficit of approximately $71.5 million. We expect to incur losses for the foreseeable future as we continue development of, and seek regulatory approvals for, our drug candidate and commercialize any approved product usages. If our current drug candidate fails to gain regulatory approval, or if it or other candidates we own do not achieve approval and market acceptance, we will not be able to generate any revenue, or explore other opportunities to enhance shareholder value, such as through a sale. If we fail to generate revenue and eventually become and remain profitable, or if we are unable to fund our continuing losses, our shareholders could lose all or part of their investments.

We will need substantial additional funding to complete our Phase 3 clinical trial for PRO 140 and to operate our business and such funding may not be available or, if it is available, such financing is likely to substantially dilute our existing shareholders.

The discovery, development, and commercialization of new treatments, such as our PRO 140 product candidate, entail significant costs. We expect the total estimated expenses for our first Phase 3 trial may range from approximately $13 million to $15 million. In addition, to the extent further development and clinical trials of PRO 140 and other products continue to appear promising and we elect to fund its development and commercialization, we will need to raise substantial additional capital, or enter into strategic partnerships, to enable us to:

- fund clinical trials and seek regulatory approvals;
- build or access manufacturing and commercialization capabilities;
- pay required license fees, milestone payments, and maintenance fees to Progenics Pharmaceuticals, Inc. (from which we acquired our PRO 140 product candidate) (Progenics) and other third parties;

develop, test, and, if approved, market our product candidate;

acquire or license additional internal systems and other infrastructure; and

hire and support additional management and scientific personnel.

Until we can generate a sufficient amount of product revenue to finance our cash requirements, which we may never achieve, we expect to finance our cash needs primarily through public or private equity offerings, debt financings or through strategic alliances. We cannot be certain that additional funding will be available on acceptable terms or at all. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of, or

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eliminate one or more of our clinical trials, collaborative development programs or future commercialization initiatives. In addition, any additional funding that we do obtain will dilute the ownership held by our existing security holders. The amount of this dilution may be substantially increased if the trading price of our common stock is lower at the time of any financing. Regardless, the economic dilution to shareholders will be significant if our stock price does not increase significantly, or if the effective price of any sale is below the price paid by a particular shareholder. Any debt financing could involve substantial restrictions on activities and creditors could seek a pledge of some or all of our assets. We have not identified potential sources for the additional financing that we will require, and we do not have commitments from any third parties to provide any future financing. If we fail to obtain additional funding as needed, we may be forced to cease or scale back operations, and our results, financial condition and stock price would be adversely affected.

The amount of financing we require will depend on a number of factors, many of which are beyond our control. Our results of operations, financial condition and stock price are likely to be adversely affected if our funding requirements increase or are otherwise greater than we expect.

Our future funding requirements will depend on many factors, including, but not limited to:

- our stock price, which, if it declines, would serve as a disincentive to holders of our convertible promissory notes, totaling approximately $4.0 million in face amount at June 30, 2015, to exercise their conversion rights, thereby prolonging our interest expense burden and increasing the probability that repayment of all of the outstanding principal of $4.0 million will be required in fiscal 2016;

- the costs of our Phase 3 clinical trial for PRO 140 and other clinical trials and development activities conducted by us directly, and our ability to successfully conclude the studies and achieve favorable results;

- the rate of progress and commercial benefits to us, if any, related to clinical trials of PRO 140 being conducted at Drexel University College of Medicine (Drexel);

- our ability to attract strategic partners to pay for or share costs related to our product development efforts;

- the costs and timing of seeking and obtaining regulatory approvals and making related milestone payments due to Progenics and other third parties.

- the costs of filing, prosecuting, maintaining and enforcing patents and other intellectual property rights and defending against potential claims of infringement;

- decisions to hire additional scientific or administrative personnel or consultants;

- our ability to manage administrative and other costs of our operations; and

the presence or absence of adverse developments in our research program.

If any of these factors cause our funding needs to be greater than expected, our operations, financial condition, ability to continue operations and stock price may be adversely affected.

Our future cash requirements may differ significantly from our current estimates.

Our cash requirements may differ significantly from our estimates from time to time, depending on a number of factors, including:

the costs and results of our Phase 3 clinical trial and other clinical trials we are undertaking or may in the future pursue with PRO 140;

the time and costs involved in obtaining regulatory approvals;

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whether our outstanding convertible notes are converted into equity or we receive additional cash upon the exercise of our outstanding common stock warrants;

whether we are able to obtain funding under future licensing agreements, strategic partnerships, or other collaborative relationships, if any;

the costs of compliance with laws, regulations, or judicial decisions applicable to us;

the costs of general and administrative infrastructure required to manage our business and protect corporate assets and shareholder interests; and

the ability to maintain and benefit from our clinical trial agreement with Drexel.

If we fail to raise additional funds on a timely basis we will need to scale back our business plans, which would adversely affect our business, financial condition, and stock price, and we may even be forced to discontinue our operations and liquidate our assets.

We have significant debt as a result of prior financings, all of which is scheduled to mature at various dates over the next two years. Our substantial indebtedness could adversely affect our business, financial condition and results of operations.

Our level of debt, which includes convertible promissory notes totaling approximately $4.0 million in face amount at June 30, 2015, could have significant consequences for our future operations, including, among others:

making it more difficult for us to meet our other obligations or raise additional capital;

resulting in an event of default, if we fail to comply with our payment obligations;

reducing the availability of any financing proceeds to fund operating expenses, other debt repayment, and working capital requirements; and

limiting our financial flexibility and hindering our ability to obtain additional financing.

Any of the above-listed factors could have a material adverse effect on our business, financial condition, results of operations, and ability to continue as a going concern.

Our ability to make interest and principal payments on our outstanding promissory notes will depend entirely on our ability to raise sufficient funds to satisfy our debt service obligations and our note holders willingness to convert their notes to common shares, which will likely depend on our stock price from time to time. If note holders do not elect to convert, it is likely that we will need to borrow or raise additional funds to make required principal and interest payments, as such payments become due and payable, or undertake alternative financing plans, such as refinancing or

restructuring our debt, selling additional shares of capital stock, selling assets or reducing or delaying investments in our business. Any inability to obtain additional funds or alternative financing on acceptable terms would likely cause us to be unable to meet our payment obligations, which could have a material adverse effect on our business, financial condition and results of operations and our ability to continue to operate.

Certain agreements and related license agreements require us to make significant milestone, royalty, and other payments, which will require additional financing and, in the event we do commercialize our PRO 140 product, decrease the revenues we may ultimately receive on sales.

Under the Progenics Agreement (see Our Business PRO 140 for a description), we must pay to Progenics and third-party licensors significant milestone payments, license fees for system know-how technology and royalties. For more information, see Business PRO 140 Acquisition and the Progenics Agreement, which is attached as

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Exhibit 10.1 to our Current Report on Form 8-K filed with the SEC on July 30, 2012, and the PDL License Agreement, which is filed as Exhibit 10.21 to our Annual Report on Form 10-K for the fiscal year ended May 31, 2013, filed with the SEC on August 29, 2013. In order to make the various milestone and license payments that are required, we will need to raise additional funds. In addition, our royalty obligations will reduce the economic benefits to us of any future sales if we do receive regulatory approval and seek to commercialize PRO 140.

Effective July 29, 2015, the Company entered into a License Agreement with Lonza Sales AG (Lonza) covering Lonza s system know-how technology with respect to the Company s use of proprietary cell lines to manufacture new PRO 140 material. The license requires payment of £600,000 (approximately US$930,000) by December 31, 2015, and a contingent payment of up to an additional £600,000 (approximately US$930,000) on June 30, 2016. The amount of the contingent payment depends on the outcome of pending litigation between Lonza and the company that sold PRO 140 to CytoDyn. The Company has accrued an expense for the payment of US$930,000, as of May 31, 2015, for the amount due by December 31, 2015, but has not accrued the contingent payment due on June 30, 2016, as of May 31, 2015, as the amount and probability of payment cannot be reasonably estimated. Future annual license fees and royalty rate will vary depending on whether CytoDyn manufactures PRO 140 itself, utilizes Lonza as a contract manufacturer, or utilizes an independent party as a contract manufacturer. Lonza does not charge an annual license fee of £300,000 when it serves as the manufacturer.

Certain proposed clinical trials of PRO 140 depend on funding from National Institute of Health (NIH) grants awarded to Drexel and its principal investigator, Dr. Jeffrey M. Jacobson.

Prior to our acquisition of PRO 140, Progenics and Drexel and its principal investigator, Dr. Jeffrey M. Jacobson, were awarded various grants from the NIH to fund clinical trials of PRO 140, including two grants that remain open. Our ability to benefit commercially from this continued funding will depend on whether Dr. Jacobson s protocols are structured in a manner that facilitates efforts to maintain PRO 140 s fast track drug candidate designation by the United States Food and Drug Administration (FDA) and obtain regulatory approval of commercially viable uses of PRO 140 in HIV-infected patients. We believe these clinical trials may constitute a Phase 2 study of PRO 140, but there can be no assurance that will be the case. If study protocols are not designed in a manner that provides commercial and regulatory benefits for us or if NIH funding is not maintained, is withdrawn, or proves insufficient, we may not derive any benefit from these clinical trials.

Clinical trials are expensive, time-consuming and subject to delay.

Clinical trials are subject to rigorous regulatory requirements and are expensive and time-consuming to design and implement. The length of time and number of trial sites and patients required for clinical trials vary substantially based on the type, complexity, novelty, intended use and any safety concerns relating to a drug candidate. We estimate that it may take at least two years to complete the necessary clinical trials, obtain regulatory approval from the FDA or other non-U.S. regulatory agency, and begin to commercialize PRO 140, even if trials are successful, of which there can be no assurance. Clinical trials for our other drug candidates, including Cytolin, may take significantly longer to complete, if they are pursued at all.

The commencement and completion of clinical trials which we are undertaking ourselves or are being conducted by Drexel could be delayed or prevented by many factors, including, but not limited to:

- our ability to obtain regulatory or other approvals to commence and conduct clinical trials in the manner we or our partners consider appropriate for timely development;

our ability to identify and reach agreement on acceptable terms with prospective clinical trial sites and entities involved in the conduct of our clinical trials;

slower than expected rates of patient recruitment and enrollment, including as a result of competition with other clinical trials for patients, limited numbers of patients that meet the enrollment criteria, or the introduction of alternative therapies or drugs by others;

unforeseen issues with our relationship with our contract clinical management services provider;

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delays in paying third-party vendors of biopharmaceutical services;

lack of effectiveness of our drug candidates during clinical trials; or

unforeseen safety issues.

Testing of our primary product candidate, PRO 140, is ongoing and our clinical trial results may not ultimately confirm initial positive indications, which would materially and adversely affect our business, financial condition and stock price.

Our efforts to commercialize PRO 140 are dependent on obtaining FDA or other non-U.S. regulatory agency approval of its use in HIV-infected patients. Although test results have been positive thus far, the process of obtaining approval of a drug product for use in humans is extremely lengthy and time-consuming, and numerous factors may prevent our successful development of PRO 140, including negative results in future clinical trials, the development by competitors of other products with equal or better results, or inability to obtain sufficient additional funding to continue to pursue development. Failure to successfully develop PRO 140 would have a material and adverse effect on our business, financial condition and stock price, and would threaten our ability to continue to operate our business, particularly since PRO 140 is the only product candidate we are actively pursuing at this time.

Although PRO 140 has been designated as a candidate for fast track approval by the FDA, our ability to obtain accelerated approval may be lost.

The FDA designated PRO 140 as a candidate for fast track consideration in 2006. The letter ascribing this designation stated that, if the clinical development program pursued for PRO 140 did not continue to meet the criteria for fast track designation, the Investigational New Drug (IND) application would not be reviewed under the fast track program. There is no assurance that the FDA will ultimately consider PRO 140 for approval on an accelerated basis. Failure to maintain eligibility for fast track review will likely result in requirements for longer or additional clinical trials and a slower approval process, resulting in additional costs and further delay in the potential realization of revenues from commercialization of PRO 140.

Any failure to attract and retain skilled directors, executives, employees and consultants could impair our drug development and commercialization activities.

Our business depends on the skills, performance, and dedication of our directors, executive officers and key scientific and technical advisors. All of our current scientific advisors are independent contractors and are either self-employed or employed by other organizations. As a result, they may have conflicts of interest or other commitments, such as consulting or advisory contracts with other organizations, which may affect their ability to provide services to us in a timely manner. We may need to recruit additional directors, executive management employees, and advisers, particularly scientific and technical personnel, which will require additional financial resources. In addition, there is currently intense competition for skilled directors, executives and employees with relevant scientific and technical expertise, and this competition is likely to continue. If we are unable to attract and retain persons with sufficient scientific, technical and managerial experience, we may be forced to limit or delay our product development activities or may experience difficulties in successfully conducting our business, which would adversely affect our operations and financial condition.

We do not have internal research and development personnel, making us dependent on consulting relationships and strategic alliances with industry partners.

We currently have no research and development staff or coordinators. We rely and intend to continue to rely on third parties for many of these functions. We engaged Amarex Clinical Research, LLC (Amarex), a full service clinical research organization, to manage our clinical trials and chemistry and manufacturing control (CMC) endeavors. As a result, we will be dependent on consultants and strategic partners in our development and commercialization activities, and it may be administratively challenging to monitor and coordinate these relationships. If we do not appropriately manage our relationships with third parties, we may not be able to successfully manage development, testing, and approval of our PRO 140 drug candidate or other products or commercialize any products that are approved, which would have a material and adverse effect on our business, financial condition and stock price.

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We will need to outsource and rely on third parties for the clinical development and manufacture, sales and marketing of product candidates, and our future success will be dependent on the timeliness and effectiveness of the efforts of these third parties.

We are dependent on third parties for important aspects of our product development strategy. We do not have the required financial and human resources to carry out independently the pre-clinical and clinical development for our product candidate, and do not have the capability or resources to manufacture, market or sell our current product candidate. As a result, we contract with and rely on third parties for important functions, including testing, storing, and manufacturing our products and managing and conducting clinical trials from which we may obtain a benefit. We have recently entered into several agreements with third parties for such services. If problems develop in our relationships with third parties, or if such parties fail to perform as expected, it could lead to delays or lack of progress, significant cost increases, changes in our strategies, and even failure of our product initiatives.

We may not be able to identify, negotiate and maintain the strategic alliances necessary to develop and commercialize our products and technologies, and we will be dependent on our corporate partners if we do.

We may seek to enter into a strategic alliance with a pharmaceutical company for the further development and approval of one or more of our product candidates. Strategic alliances potentially provide us with additional funds, expertise, access, and other resources in exchange for exclusive or non-exclusive licenses or other rights to the technologies and products that we are currently developing or may explore in the future. We cannot give any assurance that we will be able to enter into additional strategic relationships with a pharmaceutical company or others in the near future or at all, or maintain our current relationships. In addition, we cannot assure you that any agreements we do reach will achieve our goals or be on terms that prove to be economically beneficial to us. When we do enter into strategic or contractual relationships, we become dependent on the successful performance of our partners or counter-parties. If they fail to perform as expected, such failure could adversely affect our financial condition, lead to increases in our capital needs, or hinder or delay our development efforts.

Clinical trials may fail to demonstrate the desired safety and efficacy of our product candidates, which could prevent or significantly delay completion of clinical development and regulatory approval.

Prior to receiving approval to commercialize PRO 140 or any other product candidates, we must adequately demonstrate to the FDA and any foreign regulatory authorities in jurisdictions in which we seek approval that it or any other product candidate is sufficiently safe and effective with substantial evidence from well-controlled clinical trials. In clinical trials, we will need to demonstrate efficacy for the treatment of specific indications and monitor safety throughout the clinical development process and following approval. If clinical work by us or others leads to undesirable adverse effects in patients, it could delay or prevent us from furthering the regulatory approval process or cause us to cease clinical trials with respect to any drug candidate. If our current or future preclinical studies or clinical trials are unsuccessful, our business will be significantly harmed and our stock price would be negatively affected.

Our product candidates are subject to the risks of failure inherent in drug-related product development. Preclinical studies may not yield results that adequately support our regulatory applications. Even if these applications are filed with respect to our product candidates, the results of preclinical studies do not necessarily predict the results of clinical trials. In addition, even if we believe the data collected from clinical trials of our product candidates are promising, these data may not be sufficient to support approval by the FDA or foreign regulatory authorities. If regulatory authorities do not approve our products or if we fail to maintain regulatory compliance, we would be unable to commercialize our products, and our business, results of operations and financial condition would be harmed.

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Our competitors may develop drugs that are more effective, safer and less expensive than ours.

We are engaged in the HIV treatment sector of the biopharmaceutical industry, which is intensely competitive. There are current treatments that are quite effective at controlling the effects of HIV, and we expect that new developments by other companies and academic institutions in the areas of HIV treatment will continue. If approved for marketing by the FDA, depending on the approved clinical indication, our product candidates may be competing with existing and future antiviral treatments for HIV.

Our competitors may:

- develop drug candidates and market drugs that increase the levels of safety or efficacy that our product candidates will need to show in order to obtain regulatory approval;
- develop drug candidates and market drugs that are less expensive or more effective than ours;
- commercialize competing drugs before we or our partners can launch any products we are working to develop;
- hold or obtain proprietary rights that could prevent us from commercializing our products; or
- introduce therapies or market drugs that render our potential product candidates obsolete.

We expect to compete against large pharmaceutical and biotechnology companies and smaller companies that are collaborating with larger pharmaceutical companies, new companies, academic institutions, government agencies and other public and private research organizations. These competitors, in nearly all cases, operate research and development programs that have substantially greater financial resources than we do. Our competitors also have significantly greater experience in:

- developing drug and other product candidates;
- undertaking preclinical testing and clinical trials;
- building relationships with key customers and opinion-leading physicians;
- obtaining and maintaining FDA and other regulatory approvals;
- formulating and manufacturing drugs;

launching, marketing and selling drugs; and

providing management oversight for all of the above-listed operational functions.

If we fail to achieve superiority over other existing or newly developed treatments, we may be unable to obtain regulatory approval. If our competitors market drugs that are less expensive, safer or more effective than our potential product candidates, or that gain or maintain greater market acceptance, we may not be able to compete effectively.

We expect to rely on third party manufacturers and will be dependent on their quality and effectiveness.

Our primary product candidate and potential drug candidates require precise, high-quality manufacturing. The failure to achieve and maintain high manufacturing standards, including failure to detect or control anticipated or unanticipated manufacturing errors or the frequent occurrence of such errors, could result in patient injury or death, discontinuance or delay of ongoing or planned clinical trials, delays or failures in product testing or delivery, cost overruns, product recalls or withdrawals and other problems that could seriously hurt our business. Contract drug manufacturers often encounter difficulties involving production yields, quality control and quality assurance and

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shortages of qualified personnel. These manufacturers are subject to stringent regulatory requirements, including the FDA s current good-manufacturing-practices regulations and similar foreign laws and standards. If our contract manufacturers fail to maintain ongoing compliance at any time, the production of our product candidates could be interrupted, resulting in delays or discontinuance of our clinical trials, additional costs and loss of potential revenues.

We may not be able to successfully scale-up manufacturing of our product candidates in sufficient quality and quantity, which would delay or prevent us from developing our product candidates and commercializing approved products, if any.

In order to conduct larger-scale or late-stage clinical trials and for commercialization of any resulting product, if that candidate is approved for sale, we will need to manufacture it in larger quantities. We may not be able to successfully increase the manufacturing capacity for any of our product candidates in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities. If we are unable to successfully scale up the manufacture of our product candidates in sufficient quality and quantity, the development and testing of that product candidate and regulatory approval or commercial launch of any resulting product may be delayed, which could significantly harm our business.

There is uncertainty relating to our product candidate Cytolin, and our business may be adversely affected if it later proves not to have the novel and beneficial characteristics we currently believe it to possess.

Until late 2012, the primary focus of our business was on the development of Cytolin, a monoclonal antibody that has, what we believe are, novel mechanisms of action directed against the replication of HIV. We do not understand all of the biomechanical mechanisms of Cytolin and we are not actively pursuing its development and review at this time. If we cannot determine how Cytolin acts to reduce the viral load of HIV infection, we may not seek or be able to obtain regulatory approval of its use in human patients.

We may be subject to potential product liability and other claims that could materially impact our business and financial condition.

The development and sale of medical products exposes us to the risk of significant damages from product liability and other claims, and the use of our product candidates in clinical trials may result in adverse effects. We cannot predict all the possible harms or adverse effects that may result. We maintain a modest amount of product liability insurance to provide some protections from claims. Nonetheless, we may not have sufficient resources to pay for any liabilities resulting from a personal injury or other claim, even if it is partially covered by insurance. In addition to the possibility of direct claims, we may be required to indemnify third parties against damages and other liabilities arising out of our development, commercialization and other business activities, which would increase our liability exposure. If third parties that have agreed to indemnify us fail to do so, we may be held responsible for those damages and other liabilities as well.

Legislative, regulatory, or medical cost reimbursement changes may adversely impact our business.

New laws, regulations and judicial decisions, or new interpretations of existing laws, regulations and decisions, that relate to the health care system in the U.S. and in other jurisdictions may change the nature of and regulatory requirements relating to drug discovery, clinical testing and regulatory approvals, limit or eliminate payments for medical procedures and treatments, or subject the pricing of pharmaceuticals to government control. Outside the U.S., and particularly in the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In addition, third-party payers in the U.S. are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement of new drug products. Consequently, significant uncertainty exists as to the

reimbursement status of newly approved health care products. Significant changes in the health care system in the U.S. or elsewhere, including changes resulting from adverse trends in third-party reimbursement programs, could have a material adverse effect on our projected future operating results and our ability to raise capital, commercialize products, and remain in business.

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If we are unable to effectively implement or maintain a system of internal control over financial reporting, we may not be able to accurately or timely report our financial results and our stock price could be adversely affected.

Section 404 of the Sarbanes-Oxley Act of 2002 and related regulations require us to evaluate the effectiveness of our internal control over financial reporting as of the end of each fiscal year, and to include a management report assessing the effectiveness of our internal control over financial reporting in our Annual Report on Form 10-K for that fiscal year. Management determined that as of both May 31, 2015, and May 31, 2014, our disclosure controls and procedures and internal control over financial reporting were not effective due to material weaknesses in our internal control over financial reporting related to inadequate segregation of duties over authorization, review and recording of transactions, as well as the financial reporting of such transactions. Any failure to implement new or improved controls necessary to remedy the material weaknesses described above, or difficulties encountered in the implementation or operation of these controls, could harm our operations, decrease the reliability of our financial reporting, and cause us to fail to meet our financial reporting obligations, which could adversely affect our business and reduce our stock price.

Our success depends substantially upon our ability to obtain and maintain intellectual property protection relating to our product candidates and research technologies.

Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering pharmaceutical inventions and the claim scope of patents, our ability to enforce our existing patents and to obtain and enforce patents that may issue from any pending or future patent applications is uncertain and involves complex legal, scientific and factual questions. To date, no consistent policy has emerged regarding the breadth of claims allowed in biotechnology and pharmaceutical patents. Thus, we cannot be sure that any patents will issue from any pending or future patent applications owned by or licensed to us. Even if patents do issue, we cannot be sure that the claims of these patents will be held valid or enforceable by a court of law, will provide us with any significant protection against competing products, or will afford us a commercial advantage over competitive products. If one or more products resulting from our product candidates is approved for sale by the FDA and we do not have adequate intellectual property protection for those products, competitors could duplicate them for approval and sale in the United States without repeating the extensive testing required of us or our partners to obtain FDA approval.

Known third party patent rights could delay or otherwise adversely affect our planned development and sale of PRO 140. We have identified but not exhaustively analyzed other patents that could relate to our proposed products.

We are aware of patent rights held by a third party that may cover certain compositions within our PRO 140 candidate. The patent holder has the right to prevent others from making, using, or selling a drug that incorporates the patented compositions, while the patent remains in force. While we believe that the third party s patent rights will not affect our planned development, regulatory clearance, and eventual marketing, commercial production, and sale of PRO 140, there can be no assurance that this will be the case. The relevant patent expires before we expect to commercially introduce PRO 140. In addition, the Hatch-Waxman exemption to U.S. patent law permits all uses of compounds in clinical trials and for other purposes reasonably related to obtaining FDA clearance of drugs that will be sold only after patent expiration, so our use of PRO 140 in those FDA-related activities does not infringe the patent holder s rights. However, were the patent holder to assert its rights against us before expiration of the patent for activities unrelated to FDA clearance, the development and ultimate sale of a PRO 140 product could be significantly delayed, and we could incur the expense of defending a patent infringement suit and potential liability for damages for periods prior to the patent s expiration.

In connection with our acquisition of rights to PRO 140, our patent counsel conducted a freedom-to-operate search that identified other patents that could relate to our proposed PRO 140 candidate. Sufficient research and analysis was conducted to enable us to reach the conclusion that PRO 140 likely does not infringe those patent rights. However, we did not have an exhaustive analysis conducted as to the identified patent rights, because doing so would have been more costly than appeared to be justified. If any of the holders of the identified patents were to assert patent rights against us, the development and sale of PRO 140 could be delayed, we could be required to spend time and money defending patent litigation, and we could incur liability for infringement or be enjoined from producing our products if the patent holders prevailed in an infringement suit.

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If we are sued for infringing on third-party intellectual property rights, it will be costly and time-consuming, and an unfavorable outcome would have a significant adverse effect on our business.

Our ability to commercialize our product candidates depends on our ability to use, manufacture and sell those products without infringing the patents or other proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the monoclonal antibody therapeutic area in which we are developing product candidates and seeking new potential product candidates. There may be existing patents, unknown to us, on which our activities with our product candidates could infringe.

If a third party claims that our actions infringe on its patents or other proprietary rights, we could face a number of issues that could seriously harm our competitive position, including, but not limited to:

- infringement and other intellectual property claims that, even if meritless, can be costly and time-consuming, delay the regulatory approval process and divert management s attention from our core business operations;
- substantial damages for infringement, if a court determines that our products or technologies infringe a third party s patent or other proprietary rights;
- a court prohibiting us from selling or licensing our products or technologies unless the holder licenses the patent or other proprietary rights to us, which it is not required to do; and
- even if a license is available from a holder, we may have to pay substantial royalties or grant cross-licenses to our patents or other proprietary rights.

If any of these events occur, it could significantly harm our operations and financial condition and negatively affect our stock price.

We may undertake infringement or other legal proceedings against third parties, causing us to spend substantial resources on litigation and exposing our own intellectual property portfolio to challenge.

We may come to believe that third parties are infringing on our patents or other proprietary rights. To prevent infringement or unauthorized use, we may need to file infringement and/or misappropriation suits, which are very expensive and time-consuming and would distract management s attention. Also, in an infringement or misappropriation proceeding a court may decide that one or more of our patents is invalid, unenforceable, or both, in which case third parties may be able to use our technology without paying license fees or royalties. Even if the validity of our patents is upheld, a court may refuse to stop the other party from using the technology at issue on the ground that the other party s activities are not covered by our patents.

We may become involved in disputes with our present or future contract partners over intellectual property ownership or other matters, which would have a significant effect on our business.

Inventions discovered in the course of performance of contracts with third parties may become jointly owned by our strategic partners and us, in some cases, and the exclusive property of one of us, in other cases. Under some circumstances, it may be difficult to determine who owns a particular invention or whether it is jointly owned, and

disputes could arise regarding ownership or use of those inventions. Other disputes may also arise relating to the performance or alleged breach of our agreements with third parties. Any disputes could be costly and time-consuming, and an unfavorable outcome could have a significant adverse effect on our business.

We are subject to the oversight of the SEC and other regulatory agencies. Investigations by those agencies could divert management s focus and could have a material adverse effect on our reputation and financial condition.

We are subject to the regulation and oversight of the SEC and state regulatory agencies, in addition to the FDA. As a result, we may face legal or administrative proceedings by these agencies. We are unable to predict the effect of any investigations on our business, financial condition or reputation. In addition, publicity surrounding any investigation, even if ultimately resolved in our favor, could have a material adverse effect on our business.

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Our auditors have issued a going concern opinion, and we will not be able to achieve our objectives and will have to cease operations if we cannot adequately fund our operations.

Our auditors issued a going concern opinion in connection with the audit of our annual financial statements for the fiscal year ended May 31, 2015. A going concern opinion means that there is substantial doubt that the company can continue as an ongoing business for the next 12 months. If we are unable to continue as a going concern, we might have to liquidate our assets and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements. In addition, the inclusion of an explanatory paragraph regarding substantial doubt about our ability to continue as a going concern and our lack of cash resources may materially adversely affect our share price and our ability to raise new capital or to enter into critical contractual relations with third parties. There is no assurance that we will be able to adequately fund our operations in the future.

Risks Relating to Our Common Stock

The significant number of common shares issuable upon conversion of outstanding notes and exercise of outstanding common stock options and warrants could adversely affect the trading price of our common shares.

If our existing stockholders sell, or indicate an intent to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline significantly. In addition, as of August 31, 2015, we have 5,981,158 shares subject to outstanding options under our stock option plans, 1,754,930 shares reserved for future issuance under our equity compensation plan, 34,022,778 shares issuable upon exercise of outstanding warrants and 5,374,706 shares issuable upon conversion of our outstanding notes. If our existing stockholders sell substantial amounts of our common stock in the public market, or if the public perceives that such sales could occur, this could have an adverse impact on the market price of our common stock, even if there is no relationship between such sales and the performance of our business.

The market price for our common shares has been and is likely to continue to be volatile.

The market price for our common shares has been and is likely to continue to be volatile. The volatile nature of our common share price may cause investment losses for our shareholders. In addition, the market price of stock in small capitalization biotech companies is often driven by investor sentiment, expectation and perception, all of which may be independent of fundamental valuation metrics or traditional financial performance metrics, thereby exacerbating volatility. In addition, our common shares are quoted on the OTCQB of the OTC Markets marketplace, which may increase price quotation volatility and could limit liquidity, all of which may adversely affect the market price of our shares.

We do not expect any cash dividends to be paid on our shares in the foreseeable future.

We have never declared or paid a cash dividend and we do not anticipate declaring or paying dividends for the foreseeable future. We expect to use future finALIGN="bottom" ALIGN="right" WIDTH="7%">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

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.

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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:

	Amount
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.

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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Signatures

Pursuant to the requirements of the Securities Act, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this amendment to the registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Newtown, Commonwealth of Pennsylvania, on December 22, 2003.

BIO-IMAGING TECHNOLOGIES, INC.

(Registrant)

By: /s/ MARK L. WEINSTEIN

Mark L. Weinstein

President and Chief Executive Officer

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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.

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