

CYTODYN INC
Form S-1
June 08, 2015
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As filed with the Securities and Exchange Commission June 8, 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)

Colorado
(State or other jurisdiction of
incorporation or organization)

75-3056237
(IRS Employer
Identification Number)

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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.

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Lowenstein Sandler LLP

1251 Avenue of the Americas

New York, New York 10020

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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	Proposed	Proposed	Amount of Registration Fee
		Maximum Offering Price Per Share ⁽³⁾	Maximum Aggregate Offering Price ⁽³⁾	
Common Stock, no par value	30,754,131 shares ⁽¹⁾⁽²⁾	\$0.98	\$30,139,048	\$3,502

(1) The shares of common stock to be offered for resale by selling shareholders include: (a) 11,233,666 shares issuable upon exercise, at an exercise price of \$0.75 per share, of warrants issued in private placement transactions, (b) 923,072 shares issuable upon exercise, at an exercise price of \$0.50 per share, of warrants issued in a bridge financing transaction, (c) 4,860,092 shares issuable upon exercise, at an exercise price of \$0.75 per share, of warrants issued to our placement agent and its employees, (d) 6,311,232 shares issuable upon exercise, at an exercise price of \$1.00 per share, of warrants issued in connection with an offer to induce the conversion of outstanding promissory notes, (e) 525,641 shares issued upon the inducement to exercise warrants related to previously converted or repaid promissory notes, (f) 5,308,040 shares issuable upon the conversion of promissory

notes issued in a private placement transaction, (g) 1,061,586 shares issuable upon exercise, at an exercise price of \$0.75 per share, of warrants issued in such private placement transaction, and (h) 530,802 shares issuable upon exercise, at an exercise price of \$0.75 per share, of a warrant issued to our placement agent for such private placement transaction.

- (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 June 3, 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 June 8, 2015

Prospectus

30,754,131 SHARES OF COMMON STOCK

This prospectus relates to the offer and sale of up to 30,754,131 shares of our common stock by the selling shareholders identified in this prospectus. The shares being offered include:

11,233,666 shares issuable upon exercise, at an exercise price of \$0.75 per share, of warrants issued in connection with private placement transactions;

923,072 shares issuable upon exercise, at an exercise price of \$0.50 per share, of warrants issued in a privately placed bridge financing transaction;

a total of 4,860,092 shares issuable upon exercise, at an exercise price of \$0.75 per share, of warrants issued to our placement agent and its employees for such private placement transaction;

6,311,232 shares issuable upon exercise, at an exercise price of \$1.00 per share, of warrants issued in connection with an offer to induce conversion of outstanding promissory notes;

525,641 shares issued upon the inducement to exercise warrants related to previously converted or repaid promissory notes;

5,308,040 shares issuable upon the conversion of promissory notes issued in a private placement transaction;

1,061,586 shares issuable upon exercise, at an exercise price of \$0.75 per share, of warrants issued in such private placement transaction; and

530,802 shares issuable upon exercise, at an exercise price of \$0.75 per share, of a warrant issued to our placement agent for such private placement transaction.

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 22.

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 June 3, 2015, the closing price of our common stock was \$0.98 per share.

Investing in our common stock involves risks. You should read and carefully consider the Risk Factors section beginning on page 4 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) general economic and business conditions, (ii) changes in foreign, political, and social conditions, (iii) regulatory initiatives, compliance with governmental regulations and the regulatory approval process, (iv) our ability to achieve approval of a marketable product, (v) design, implementation and conduct of clinical trials, (vi) the results of our clinical trials, including the possibility of unfavorable clinical trial results, (vii) the market for, and marketability of, any product that is approved, (viii) 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, (ix) 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 Colorado 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.

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 for the treatment and prevention of Human Immunodeficiency Virus (HIV) infection. Our lead product candidate, PRO 140, belongs to a class of HIV therapies known as entry inhibitors. These therapies potentially 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 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 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 primarily issued in connection with private placement transactions and the inducement of the exercise of certain warrants.

On March 7, 2013 and May 31, 2013, we issued warrants to an individual to purchase 333,334 and 192,307, respectively, shares of common stock at an exercise price of \$0.75 and \$2.00 per share in connection with a private placement. Such warrants were exercised on January 20, 2015 at \$0.55 per share in connection with an offer to induce the exercise of such warrants. A total of 525,641 shares of our Common Stock (the Shares) were issued in connection with such exercise.

On July 31, 2013, we issued to seven individuals and one entity a total of \$1.2 million in unsecured convertible promissory notes bearing interest at a rate of 5% per year and convertible into shares of our common stock at a price of \$0.65 per share (the Bridge Notes). We paid our placement agent, Paulson Investment Company, Inc. (Paulson), a 10% cash commission on the gross sale proceeds of the Bridge Notes. In connection with the sale of the Bridge Notes, we issued to the purchasers, warrants (the Bridge Warrants) to purchase a total of 923,072 shares of common stock exercisable at a price of \$0.50 per share, expiring on July 31, 2016. Each holder of a Bridge Note had the right to convert all, but not less than all, of the principal amount of such notes, plus accrued but unpaid interest, into Units in our private placement, as described below. A total of \$850,000 in principal amount of Bridge Notes was converted to Units in our private placement, \$250,000 was repaid, and \$100,000 plus accrued interest was later converted to 157,154 shares of common stock.

On October 23, 2013, we completed a private placement of 11,234,241 units (Units) for total gross proceeds of approximately \$14.5 million (including Bridge Notes converted into Units). Each Unit was comprised of two shares of our common stock plus a warrant to purchase one additional share of common stock exercisable at an exercise price of \$0.75 per share, expiring five years from the date of issuance. A total of 22,465,620 shares of common stock were issued, together with warrants (Unit Warrants) to purchase a total of 11,234,241 additional shares of our common stock.

From October 2012 to January 2013, we issued to 14 individuals and three entities a total of approximately \$6.0 million in unsecured convertible promissory notes bearing interest at a rate of 5% or 10% per year and convertible into shares of our common stock at a price of \$0.75 per share (the Convertible Notes). In connection with an offer to induce the conversion of the remaining principal balance of the Convertible Notes of approximately \$3.0 million in March 2015, we issued to the purchasers warrants (the Conversion Warrants) to purchase a total of 6,311,232 shares of common stock exercisable at a price of \$1.00 per share. All but three of the Conversion Warrants are exercisable through October 2015, one Conversion Warrant, for the purchase of 530,641 shares of Common Stock, is exercisable through November 2015, one Conversion Warrant, for the purchase of 186,667 shares of Common Stock, is exercisable through December 2015, and one Conversion Warrant, for the purchase of 160,000 shares of Common Stock, is exercisable through January 2016.

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On October 23, 2013, we paid Paulson a 10% cash commission and a 3% nonaccountable, administrative fee on the gross sale proceeds of the Units (other than Units issued upon conversion of the Bridge Notes). With respect to the converted Bridge Notes, the placement agent received a 5% cash commission on the converted amount. We also issued to Paulson assignable warrants (the Placement Agent Warrants) to purchase 4,860,092 shares of our Common Stock at an exercise price of \$0.75 per share. The Placement Agent Warrants expire seven years from the date of issuance. In addition, warrants to purchase 80,000 shares of common stock originally issuable to Paulson were instead issued to an assignee as Unit Warrants pursuant to a settlement between us and Paulson. If Unit Warrants are exercised in the future, Paulson will be entitled to an additional cash fee of 6% of the gross exercise proceeds realized by us.

On May 15, 2015, we completed a private placement of convertible promissory notes (the Private Placement Notes) in the aggregate principal of \$3,981,050, convertible into an aggregate of 5,308,040 shares of Common Stock, together with warrants (the Private Placement Warrants) to purchase an aggregate of 1,061,586 shares of Common Stock at an exercise price of \$0.75 per share. We issued to, Paulson, as placement agent in this offering, a Private Placement Warrant to purchase an aggregate of 530,802 shares of Common Stock, with an exercise price of \$0.75 per share. This warrant expires five years from the date of issuance.

The offer and sale of the Shares, Convertible Notes, Bridge Notes, Bridge Warrants, Units, Unit Warrants, Conversion Warrants, Placement Agent Warrants, Private Placement Notes and Private Placement Warrants were 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 promulgated thereunder applicable to sales of securities exclusively to accredited investors, as that term is defined in Rule 501(a) of Regulation D.

This Offering

Securities being offered: 30,754,131 shares of common stock, including 11,234,666 shares that may be issued upon exercise of the Unit Warrants, 923,072 shares that may be issued upon exercise of the Bridge Warrants, 4,860,092 shares that may be issued upon exercise of the Placement Agent Warrants, 6,311,232 shares that may be issued upon the exercise of the Conversion Warrants, 525,641 shares issued upon the exercise of previously issued warrants, 5,308,040 shares that may be issued upon the conversion of the Private Placement Notes, and 1,592,390 shares that may be issued upon the exercise of the Private Placement Warrants.

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 Unit Warrants, the Placement Agent Warrants, the Bridge Warrants and the Conversion Warrants, in which case such proceeds will be used for general working capital purposes. The 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 June 3, 2015, the closing price of our common stock was \$0.98 per share.

Risk factors:

See Risk Factors beginning on page 4 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. We expect to incur losses for the foreseeable futures 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, which may not be available or, if it is available, such financing may substantially dilute our existing shareholders.

The discovery, development, and commercialization of new treatments, such as our PRO 140 product candidate, entail significant costs. See **Our Business** below. As a result, to the extent further development and clinical trials of PRO 140 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;
- 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 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 \$7.5 million in face amount at May 28, 2015, to exercise their conversion rights, thereby prolonging our interest expense burden and increasing the probability that repayment of principal of \$5.5 million will be required in fiscal 2016;

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the costs of clinical trials of PRO 140 and other 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 Pharmaceuticals, Inc. (from which we acquired our PRO 140 product candidate) 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 clinical trials we are undertaking or may in the future pursue with PRO 140;

the time and costs involved in obtaining regulatory approvals;

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 \$7.5 million in face amount at May 28, 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 noteholders' willingness to convert their notes to common

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shares, which will likely depend on our stock price from time to time. If noteholders 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.

The agreement with Progenics pursuant to which we acquired our PRO 140 product candidate, and related license agreements assumed in the PRO 140 acquisition, 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 and royalties. For more information, please see the Progenics Agreement, which is attached as Exhibit 10.1 to our Current Report on Form 8-K filed with the Securities and Exchange Commission (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 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.

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;

delays in paying third-party vendors of biopharmaceutical services;

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

unforeseen safety issues.

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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.

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.

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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.

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;

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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 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

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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.

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, 2014, and May 31, 2013, 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.

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

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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.

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, 2014. A going concern opinion means that there is doubt that the company can continue as an ongoing business for the next 12 months. There is no assurance that we will be able to adequately fund our operations in the future.

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Risks Relating to Our Common Stock

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

Conversion of outstanding convertible notes into common shares and the sale of such shares into the trading market of common shares or exercise of our warrants and sale of the underlying common stock could depress the market price of our shares.

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 financing proceeds and earnings, if any, to fund operating expenses. Consequently, shareholders' only opportunity to achieve a return on their investment is if the price of our stock appreciates and they sell their shares at a profit.