PRO PHARMACEUTICALS INC
Form POS AM
April 28, 2011
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As filed with the Securities and Exchange Commission on April 28, 2011

Registration No. 333-150898

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Post-Effective Amendment No. 4

on

FORM S-1

to

FORM S-3

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

PRO-PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Nevada	2834	04-3562325
(State or other jurisdiction of incorporation or organization)	**(Primary SIC Number)**	**(I.R.S. Employer Identification No.)**

7 Wells Avenue

Newton, Massachusetts 02459

(617) 559-0033

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

Peter G. Traber, M.D.

Chief Executive Officer and President

Pro-Pharmaceuticals, Inc.

7 Wells Avenue

Newton, Massachusetts 02459

(617) 559-0033

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

With a copy to:

Jonathan C. Guest

McCarter & English, LLP

265 Franklin Street

Boston, Massachusetts 02110

Tel. (617) 449-6500

Fax (617) 449-9200

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, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

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

If 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 check mark 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 ¨ (Do not check if a smaller reporting company)	Smaller reporting company x

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, as amended, or until this Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

Pursuant to Rule 401(b) under the Securities Act of 1933, and in order to comply with Section 10(a)(3) of the Securities Act, the Registrant is filing this Post-Effective Amendment on Form S-1 because it is currently ineligible to file a registration statement on Form S-3. Pursuant to Rule 429 under the Securities Act, the prospectus contained in this Post-Effective Amendment on Form S-1 shall serve as a combined prospectus that also relates to, and this Post-Effective Amendment on Form S-1 shall act, upon effectiveness, as a post-effective amendment to, the Registrant s previous Registration Statement on Form S-3, Registration No. 333-148911.

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EXPLANATORY NOTE

The prospectus contained in this registration statement serves as a combined prospectus relating to two previously filed registration statements. Alternate versions of certain pages of the prospectus relating to registration statement No. 333-150898 appear following page F-43, and serve as replacement pages to form the prospectus relating to registration statement No. 333-148911 as follows: page A-1 replaces the prospectus cover page; page A-2 replaces page 3; and page A-3 replaces pages 11-15.

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

Subject To Completion, Dated April 28, 2011

PROSPECTUS

4,797,500 Shares of Common Stock

This prospectus covers the offer and sale of up to 4,797,500 shares of our common stock from time to time by certain selling stockholders named in this prospectus. The shares of common stock being offered are issuable upon the exercise of outstanding warrants or the conversion of outstanding shares of Series A 12% Convertible Preferred Stock.

We are not offering any shares of common stock.

The selling stockholders will receive all of the net proceeds from sales of the common stock covered by this prospectus and will pay all underwriting discounts and selling commissions, if any, applicable to those sales. We will not receive any proceeds from sales of any of these shares. However, we will receive the exercise price of the warrants to the extent they are not exercised on a net or cashless exercise basis.

The selling stockholders may periodically sell the shares directly or through agents, underwriters or dealers. The shares may be sold:

in the over-the-counter market, in privately negotiated transactions or otherwise;

directly to purchasers or through agents, brokers, dealers or underwriters; and

at market prices prevailing at the time of sale, at prices related to the prevailing market prices, or at negotiated prices.

If required, each time a selling stockholder sells shares of common stock, we will provide a prospectus supplement that will contain specific information about the terms of that transaction. We urge you to carefully read this prospectus and any accompanying prospectus supplement before you make an investment decision.

Investing in our securities involves a high degree of risk. You should purchase these securities only if you can afford a complete loss of your investment. See Risk Factors beginning on page 4 of this prospectus.

Neither the U.S. Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is [ ], 2011

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ABOUT THIS PROSPECTUS

Unless the context otherwise requires, all references to Pro-Pharmaceuticals, we, us, our, our company, or the Company in this prospectus to Pro-Pharmaceuticals, Inc., a Nevada corporation, and its subsidiaries, and their respective predecessor entities for the applicable periods, considered as a single enterprise.

You should rely only on the information contained in this prospectus. We have not authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. For further information, please see the section of this prospectus entitled Where You Can Find More Information. The selling stockholders are not making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted.

You should not assume that the information appearing in this prospectus is accurate as of any date other than the date on the front cover of this prospectus, regardless of the time of delivery of this prospectus or any sale of a security. Our business, financial condition, results of operations and prospects may have changed since those dates.

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PROSPECTUS SUMMARY

This summary highlights important features of this offering and the information included in this prospectus. This summary does not contain all of the information that you should consider before investing in our securities. You should read this prospectus carefully as it contains important information you should consider when making your investment decision. See Risk Factors beginning on page 4.

About Pro-Pharmaceuticals, Inc.

We are a development-stage company engaged in the discovery and development of therapeutics that target Galectin receptors that we believe enhance existing cancer treatments and could also be used in the treatment of tissue fibrosis, particularly liver fibrosis, inflammatory diseases, and enhancement of tumor vaccines. All of our products are presently in development, including pre-clinical and clinical trials.

Since our inception on July 10, 2000, our primary focus has been the development of a new generation of anti-cancer treatments using polysaccharide polymers that are aimed at increasing survival and improving the quality of life for cancer patients. Our lead product candidate, DAVANAT®, is a patented new chemical entity that we believe, when administered in combination with chemotherapy, biologics and vaccines, increases efficacy while reducing adverse side effects of the chemotherapy. The Company holds composition of matter and method of use patents on DAVANAT®, which were invented by the founders, without any license or royalty encumbrances.

In 2002, the Food and Drug Administration (FDA) granted us an Investigational New Drug application (IND), for use of DAVANAT® in combination with 5-fluorouracil (5-FU), to treat late-stage cancer patients with solid tumors. 5-FU is one of the most widely used chemotherapies for treatment of various types of cancer, including colorectal, breast, head and neck, and other gastrointestinal cancers. In September 2008, we submitted a clinical and pre-clinical package to the FDA in support of our DAVANAT® New Drug Application (NDA). Following a meeting in December 2008, the FDA advised us that we would be required to conduct a Phase III trial to demonstrate superiority to the best standard of care for late stage colorectal cancer patients.

On December 17, 2010, we met with the FDA to present our Phase III clinical development program for DAVANAT®. Agreement was reached on the design of pivotal, randomized, controlled, and blinded Phase III clinical trials of DAVANAT® co-administered with standard chemotherapy for second line treatment of patients with metastatic colorectal cancer.

On March 9th, 2011 we announced that our Board of Directors named Peter G. Traber, M.D., President and Chief Executive Officer, effective March 17, 2011. Dr. Traber was named Interim Chief Medical Officer in June 2010 and appointed to the Board of Directors in February 2009. Dr. Traber succeeds Theodore D. Zucconi, Ph.D., who continues as a member of the Board of Directors. Dr. Zucconi also will direct Company operations with a focus on approvals and expansion of the Latin American business and manufacturing.

We were incorporated under Nevada law on January 26, 2001 and in May of that year acquired a Massachusetts corporation (organized on July 10, 2000) engaged in the business we now undertake. We have a wholly-owned Delaware subsidiary that we formed in 2003 to hold our cash and cash equivalents. We also have a wholly-owned Nevada subsidiary that we formed in August 2010 for the development of our technology in cardiovascular treatments.

Principal Executive Offices

Our principal executive offices are located at 7 Wells Avenue, Newton, Massachusetts 02459. Our telephone number is (617) 559-0033, fax number is (617) 928-3450 and our website address is www.pro-pharmaceuticals.com. The information on our website is not incorporated by reference into this prospectus and should not be relied upon with respect to this offering.

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The Offering

Securities Offered	4,797,500 shares of our common stock offered by selling stockholders
Use of Proceeds	We will not receive any proceeds from the sale of shares by the selling stockholders. To the extent that the warrants are exercised by the selling stockholders for cash, rather than by cashless exercise, we will receive proceeds constituting the exercise price of such warrants. Any such proceeds received by us through warrant exercises will be used for working capital.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated by reference contain, in addition to historical information, forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These statements relate to future events or our future financial performance and can be identified by the use of forward-looking terminology such as may, could, expect, anticipate, estimate, continue or other similar words. These forward-looking statements are based on management s current expectations and are subject to a number of factors and uncertainties which could cause actual results to differ materially from those described in these statements. We caution investors that actual results or business conditions may differ materially from those projected or suggested in forward-looking statements as a result of various factors including, but not limited to, those described in, or incorporated by reference into, the Risk Factors section of this prospectus. We cannot assure you that we have identified all the factors that create uncertainties. Readers should not place undue reliance on forward-looking statements. We undertake no obligation to publicly release the result of any revision of these forward-looking statements to reflect events or circumstances after the date they are made or to reflect the occurrence of unanticipated events.

RISK FACTORS

An investment in our common stock involves a high degree of risk. You should carefully consider the risks described below and the other information before deciding to invest in our common stock. The risks described below are not the only ones facing our company. Additional risks not presently known to us or that we currently consider immaterial may also adversely affect our business. We have attempted to identify below the major factors that could cause differences between actual and planned or expected results, but we cannot assure you that we have identified all of those factors.

If any of the following risks actually happen, our business, financial condition and operating results could be materially adversely affected. In this case, the trading price of our common stock could decline, and you could lose all or part of your investment.

Risks Related to Our Company

We have incurred net losses to date and must raise additional capital by the end of the second quarter of 2012 in order to continue to operate.

We have incurred net losses in each year of operation since our inception in July 2000. Our accumulated deficit as of December 31, 2010 was $56.4 million and our cumulative net loss applicable to common stockholders as of December 31, 2010 was $56.7 million. Based on $5.9 million of unrestricted cash as of December 31, 2010 and $2.6 million received subsequent to year end through March 15, 2011, we believe that we have sufficient cash to meet our financial and operating obligations through 2012. We will require more cash to fund our operations and believe that we will be able to obtain additional financing. However, there can be no assurance that we will be successful in obtaining such new financing or, if available, that such financing will be obtainable on terms favorable to us. We have taken steps to reduce our administrative and clinical spending; however, we must raise additional cash by the end of the fourth quarter of 2012, or we may not be able to continue operations and may be forced to seek bankruptcy protection.

We may raise capital through public or private equity financings, partnerships, debt financings, bank borrowings, or other sources. Additional funding may not be available on favorable terms or at all. If adequate funds are not otherwise available, we may need to significantly curtail operations. To obtain additional funding, we may need to enter into arrangements that require us to relinquish rights to certain technologies, products and/or potential markets. To the extent that additional capital is raised through the sale of equity, or securities convertible into equity, our equity holders may experience dilution of their proportionate ownership of the company.

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We are a development stage company and have not yet generated any revenue.

We are a development stage company and have not generated any revenues to date. We granted PROCAPS, S.A. exclusive rights to market and sell DAVANAT® to treat cancer patients in Colombia, South America, which we refer to as the PROCAPS Channel. In addition, there is no assurance that we will obtain FDA approval of DAVANAT® or any other of our products in development and, even if we do so, that we will generate revenue sufficient to become profitable. Our failure to generate revenue and profit would likely lead to loss of your investment.

We have one drug candidate in clinical trials and results are uncertain.

DAVANAT®, our lead product candidate, is in human clinical trials. Clinical trials are expensive, time-consuming and may not be successful. They involve the testing of potential therapeutic agents, or effective treatments, in humans, typically in three phases, to determine the safety and efficacy of the product candidates necessary for an approved drug. Many products in human clinical trials fail to demonstrate the desired safety and efficacy characteristics. Even though DAVANAT® progressed successfully through Phase I and Phase II human trials, it may fail in Phase III trials or in later stages of development. We will engage others to conduct our clinical trials, including clinical research organizations and, possibly, government-sponsored agencies. These trials may not start or be completed as we forecast, or may not achieve desired results.

We may be unable to commercialize our product candidates.

Even if DAVANAT® and other anticipated product candidates achieve positive results in clinical trials, we may be unable to commercialize them. Although we anticipate receipt of regulatory approvals in connection with the PROCAPS Channel, there is no assurance that such approvals will be obtained. Our general inability to commercialize our products would substantially impair the viability of the Company.

Performance milestones may not occur as contemplated by the agreement with PROCAPS S.A.

As our arrangement with PROCAPS is a collaboration, and because collaborations take place over time, milestone and performance risks are inherent and so performance milestones may not occur as contemplated by our agreement.

There are risks associated with our reliance on third parties to design trial protocols, arrange for and monitor the clinical trials, and collect and analyze data.

As we develop products eligible for clinical trials, including DAVANAT®, we will contract with independent parties to assist us in the design of the trial protocols, arrange for and monitor the clinical trials, collect data and analyze data. In addition, certain clinical trials for our products may be conducted by government-sponsored agencies and will be dependent on governmental participation and funding. Our dependence on independent parties and clinical sites involves risks including reduced control over the timing and other aspects of our clinical trials.

There are risks associated with our reliance on third parties for manufacturing, marketing, sales, managed care and distribution infrastructure and channels.

We do not have, and do not now intend to develop, facilities for the manufacture of any of our products for clinical or commercial production. At this time, we are not a party to any long-term agreement with any of our suppliers, and accordingly, we have our products manufactured on a purchase-order basis from one of two primary suppliers. We are developing relationships with manufacturers and will enter into collaborative arrangements with licensees or have others manufacture our products on a contract basis. We expect to depend on such collaborators to supply us with products manufactured in compliance with standards imposed by the FDA and foreign regulators.

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We have limited experience in marketing, sales or distribution, and we do not intend to develop a sales and marketing infrastructure to commercialize our pharmaceutical products. If we develop commercial products, we will need to rely on licensees, collaborators, joint venture partners or independent distributors to market and sell those products. Thus, we expect that we will be required to enter into agreements with commercial partners to engage in sales, marketing and distribution efforts around our products in development. We may be unable to establish or maintain third-party relationships on a commercially reasonable basis, if at all. In addition, these third parties may have similar or more established relationships with our competitors. If we do not enter into relationships with third parties for the sales and marketing of our proposed products, we will need to develop our own sales and marketing capabilities.

Even if engaged, these distributors may:

- fail to satisfy financial or contractual obligations to us;
- fail to adequately market our products;
- cease operations with little or no notice to us; or
- offer, design, manufacture or promote competing formulations or products.

If we fail to develop sales, managed care, marketing and distribution channels, we would experience delays in generating sales and incur increased costs, which would harm our financial results.

Our lack of operating experience may cause us difficulty in managing our growth.

We have limited experience in manufacturing or procuring products in commercial quantities, conducting other later-stage phases of the regulatory approval process, selling pharmaceutical products, or negotiating, establishing and maintaining strategic relationships. Although we have engaged a number of consultants to assist us, any additional growth may require us to expand our management, operational and financial systems and controls. If we are unable to do so, our business and financial condition would be materially harmed. If rapid growth occurs, it may strain our managerial, operational and financial resources.

We are exposed to product liability, pre-clinical and clinical liability risks which could place a financial burden upon us, should we be sued, because we do not currently have product liability insurance above and beyond our general insurance coverage.

Our business exposes us to potential product liability and other liability risks that are inherent in the testing, manufacturing and marketing of pharmaceutical formulations and products. Claims may be asserted against us. In addition, the use in our clinical trials of pharmaceutical formulations and products that our potential collaborators may develop and the subsequent sale of these formulations or products by us or our potential collaborators may cause us to bear a portion of or all product liability risks. A successful liability claim or series of claims brought against us could have a material adverse effect on our business, financial condition and results of operations.

Because we do not currently have any FDA-approved products or formulations, we do not currently have any product liability insurance covering commercialized products. We may not be able to obtain or maintain adequate product liability insurance on acceptable terms, if at all, or such insurance may not provide adequate coverage against our potential liabilities. Furthermore, our current and potential partners with whom we have collaborative agreements or our future licensees may not be willing to indemnify us against these types of liabilities and may not themselves be sufficiently insured or have sufficient liquidity to satisfy any product liability claims. Claims or losses in excess of any product liability insurance coverage that may be obtained by us could have a material adverse effect on our business, financial condition and results of operations.

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If users of our proposed products are unable to obtain adequate reimbursement from third-party payers, market acceptance of our proposed products may be limited and we may not achieve revenues.

The continuing efforts of governments, insurance companies, health maintenance organizations and other payers of healthcare costs to contain or reduce costs of health care may affect our future revenues and profitability, and the future revenues and profitability of our potential customers, suppliers and collaborative partners and the availability of capital. In other words, our ability to commercialize our proposed products will depend in large part on the extent to which appropriate reimbursement levels for the cost of our proposed formulations, products and related treatments are obtained by the health care providers of these products and treatments. At this time we cannot predict the precise impact of the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Affordability Act of 2010, the comprehensive health care reform legislation passed by Congress in March 2010. It is possible that the adoption of this legislation could harm our business, financial condition and results of operations.

We depend on key individuals to develop our products and pursue collaborations.

We are highly dependent on Anatole Klyosov, Ph.D., D.Sc. and Peter G. Traber, M.D. Dr. Klyosov is our Chief Scientist and has scientific technical or other business expertise and experience that is critical to our success. Dr. Traber is our Chief Medical Officer who, among other things, leads our FDA Phase III colorectal cancer trial for DAVANAT® as well as our overall FDA approval process. Effective March 17, 2011 Dr. Traber will become our Chief Executive Officer as well as our Chief Medical Officer. The loss of Dr. Klyosov or Dr. Traber, or failure to attract or retain other key personnel, could prevent us from pursuing collaborations or developing our products and core technologies.

We are involved in litigation with Summer Street Research Partners.

On January 30, 2008, Custom Equity Research, Incorporated (d/b/a Summer Street Research Partners), or Summer Street, filed a lawsuit against us, alleging claims for breach of contract, declaratory judgment and unjust enrichment arising out of an engagement letter under which Summer Street agreed to provide institutional investment placement services. Discovery is currently underway. A trial date has been set for November 8, 2011. We believe the lawsuit is without merit and intends to contest it vigorously.

We received a letter dated January 12, 2011 from Maxim Group, or Maxim, which has acted as our placement agent. The letter advises that Maxim has been named as a respondent in a FINRA arbitration matter commenced by Summer Street arising out of the Company s termination of its relationship with Summer Street and its engagement of Maxim as its placement agent. Our placement agent agreement with Maxim contains an indemnification provision that requires us to indemnify Maxim in connection with FINRA arbitration. We believe the claims asserted by Summer Street in the arbitration are without merit.

Risks Related to the Drug Development Industry

We will need regulatory approvals to commercialize our products.

We are required to obtain approval (i) from the FDA in order to sell our products in the U.S. and (ii) from foreign regulatory authorities in order to sell our products in other countries. The FDA s review and approval process is lengthy, expensive and uncertain. Extensive pre-clinical and clinical data and supporting information must be submitted to the FDA for each indication for each product candidate in order to secure FDA approval. Before receiving FDA clearance to market our proposed products, we will have to demonstrate that our products are safe on the patient population and effective for the diseases that are to be treated. Clinical trials, manufacturing and marketing of drugs are subject to the rigorous testing and approval process of the FDA and equivalent foreign regulatory authorities. The Federal Food, Drug and Cosmetic Act and other federal, state and foreign statutes and regulations govern and influence the testing, manufacture, labeling, advertising, distribution and promotion of drugs and medical devices. As a result, regulatory approvals can take a number of years or

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longer to accomplish and require the expenditure of substantial financial, managerial and other resources. The FDA could reject an application or require us to conduct additional clinical or other studies as part of the regulatory review process. Delays in obtaining or failure to obtain FDA approvals would delay or prevent the commercialization of our product candidates, which would prevent, defer or decrease our receipt of revenues. In addition, if we receive initial regulatory approval, our product candidates will be subject to extensive and rigorous ongoing domestic and foreign government regulation.

Data obtained from clinical trials are susceptible to varying interpretations, which could delay, limit or prevent regulatory clearances.

Data already obtained, or in the future obtained, from pre-clinical studies and clinical trials do not necessarily predict the results that will be obtained from later pre-clinical studies and clinical trials. Moreover, pre-clinical and clinical data is susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. The failure to adequately demonstrate the safety and effectiveness of a proposed formulation or product under development could delay or prevent regulatory clearance of the potential drug. The resulting delays to commercialization could materially harm our business. Our clinical trials may not demonstrate sufficient levels of safety and efficacy necessary to obtain the requisite regulatory approvals for our drugs, and thus our proposed drugs may not be approved for marketing.

Our competitive position depends on protection of our intellectual property.

Development and protection of our intellectual property are critical to our business. All of our intellectual property, patented or otherwise, has been invented and/or developed by employees of the Company. If we do not adequately protect our intellectual property, competitors may be able to practice our technologies. Our success depends in part on our ability to obtain patent protection for our products or processes in the U.S. and other countries, protect trade secrets, and prevent others from infringing on our proprietary rights.

Since patent applications in the U.S. are maintained in secrecy for at least portions of their pendency periods (published on U.S. patent issuance or, if earlier, 18 months from earliest filing date for most applications) and since other publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain that we are the first to make the inventions to be covered by our patent applications. The patent position of biopharmaceutical firms generally is highly uncertain and involves complex legal and factual questions. The U.S. Patent and Trademark Office has not established a consistent policy regarding the breadth of claims that it will allow in biotechnology patents.

Some or all of our patent applications may not issue as patents, or the claims of any issued patents may not afford meaningful protection for our technologies or products. In addition, patents issued to us or our licensors may be challenged and subsequently narrowed, invalidated or circumvented. Patent litigation is widespread in the biotechnology industry and could harm our business. Litigation might be necessary to protect our patent position or to determine the scope and validity of third-party proprietary rights, and we may not have the required resources to pursue such litigation or to protect our patent rights.

Although we require our scientific and technical employees and consultants to enter into broad assignment of inventions agreements, and all of our employees, consultants and corporate partners with access to proprietary information to enter into confidentiality agreements, these agreements may not be honored.

Products we develop could be subject to infringement claims asserted by others.

We cannot assure that products based on our patents or intellectual property will not be challenged by a third party claiming infringement of its proprietary rights. If we were not able to successfully defend our patents or other intellectual property, we may have to pay substantial damages, possibly including treble damages, for past infringement.

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We face intense competition in the biotechnology and pharmaceutical industries.

The biotechnology and pharmaceutical industries are intensely competitive. We face direct competition from U.S. and foreign companies focusing on pharmaceutical products, which are rapidly evolving. Our competitors include major multinational pharmaceutical and chemical companies, specialized biotechnology firms and universities and other research institutions. Many of these competitors have greater financial and other resources, larger research and development staffs and more effective marketing and manufacturing organizations, than we do. In addition, academic and government institutions are increasingly likely to enter into exclusive licensing agreements with commercial enterprises, including our competitors, to market commercial products based on technology developed at such institutions. Our competitors may succeed in developing or licensing technologies and products that are more effective, or succeed in obtaining FDA or other regulatory approvals for product candidates before we do. Acquisitions of, or investments in, competing pharmaceutical or biotechnology companies by large corporations could increase such competitors financial, marketing, manufacturing and other resources.

The market for our proposed products is rapidly changing and competitive, and new drugs and new treatments which may be developed by others could impair our ability to maintain and grow our business and remain competitive.

The pharmaceutical and biotechnology industries are subject to rapid and substantial technological change. Developments by others may render our proposed products noncompetitive or obsolete, or we may be unable to keep pace with technological developments or other market factors. Technological competition from pharmaceutical and biotechnology companies, universities, governmental entities and others diversifying into the field is intense and is expected to increase.

As a pre-revenue company engaged in the development of drug technologies, our resources are limited and we may experience technical challenges inherent in such technologies. Competitors have developed or are in the process of developing technologies that are, or in the future may be, the basis for competition. Some of these technologies may have an entirely different approach or means of accomplishing similar therapeutic effects compared to our proposed products. Our competitors may develop drugs that are safer, more effective or less costly than our proposed products and, therefore, present a serious competitive threat to us.

The potential widespread acceptance of therapies that are alternatives to ours may limit market acceptance of our proposed products, even if commercialized. Many of our targeted diseases and conditions can also be treated by other medication. These treatments may be widely accepted in medical communities and have a longer history of use. The established use of these competitive drugs may limit the potential for our technologies, formulations and products to receive widespread acceptance if commercialized.

Risks Related to Our Common Stock

Stock prices for pharmaceutical and biotechnology companies are volatile.

The market price for securities of pharmaceutical and biotechnology companies historically has been highly volatile, and the market from time to time has experienced significant price and volume fluctuations that are unrelated to the operating performance of such companies. Fluctuations in the trading price or liquidity of our common stock may adversely affect, among other things, the interest in our stock by purchasers on the open market and, generally, our ability to raise capital.

Our Board of Directors has the power to designate, without shareholder approval, a series of preferred stock the shares of which could be senior to the common stock and be entitled to conversion or voting rights that adversely affect the holders of our common stock.

Our Articles of Incorporation authorizes issuance of capital stock including 20,000,000 undesignated shares, and empowers our Board of Directors to prescribe by resolution and without shareholder approval a class or series of undesignated shares, including the number of shares in the class or series and the voting powers,

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designations, rights, preferences, restrictions and the relative rights in each such class or series. Accordingly, we may authorize the issuance of additional shares or series of preferred stock that would rank senior to the shares of common stock as to dividend rights or rights upon our liquidation, winding-up, or dissolution.

We could issue additional common stock, which might dilute the book value of our common stock.

Our Board of Directors has authority, without action or vote of our shareholders, to issue all or a part of our authorized but unissued shares. Such stock issuances could be made at a price that reflects a discount or a premium from the then-current trading price of our common stock. In addition, in order to raise capital, we may need to issue securities that are convertible into or exchangeable for a significant amount of our common stock. These issuances would dilute the percentage ownership interest, which would have the effect of reducing your influence on matters on which our shareholders vote, and might dilute the book value of our common stock. You may incur additional dilution if holders of stock options, whether currently outstanding or subsequently granted, exercise their options, or if warrant holders exercise their warrants to purchase shares of our common stock.

One investor, by virtue of ownership of our securities and related rights, may be able to control the Company.

The 10X Fund, L.P., or 10X Fund, owns all of our issued and outstanding Series B-1 Convertible Preferred Stock and Series B-2 Convertible Preferred Stock, collectively the Series B Preferred Stock, which are convertible into 12 million shares of our common stock. The 10X Fund owns related warrants exercisable to purchase an aggregate of 36 million shares of our common stock. We have issued approximately 2.1 million shares of our common stock as dividends on the Series B Preferred Stock. In addition, James C. Czirr, a general partner of the 10X Fund and Executive Chairman of our Board of Directors, owns or controls approximately 5 million shares of our common stock. As of December 31, 2010, on a fully diluted basis, assuming conversion of all Series B Preferred Stock and exercise of all the related warrants, the 10X Fund would own approximately 44.8% of our then outstanding shares of common stock, which together with Mr. Czirr s shares of our common stock, would constitute approximately 49.2% of the then outstanding shares. As holder of Series B Preferred Stock, the 10X Fund is entitled to elect two directors in a separate class vote, nominate three directors for election by all shares entitled to vote, and provide or withhold consent to a range of fundamental corporate action we may wish to undertake, such as recapitalization, sale of the company, and other matters. Such concentration of stock ownership and related rights could have the effect of delaying, deterring or preventing corporate events that our other security holders may desire or consider beneficial to the company.

As a thinly-traded stock, large sales can place downward pressure on our stock price.

Our common stock, despite certain increases of trading volume from time to time, experiences periods when it could be considered thinly-traded. Finance transactions resulting in a large amount of newly issued shares that become readily tradable, or other events that cause current shareholders to sell shares, could place downward pressure on the trading price of our stock. In addition, the lack of a robust resale market may require a shareholder who desires to sell a large number of shares of common stock to sell the shares in increments over time to mitigate any adverse impact of the sales on the market price of our stock.

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USE OF PROCEEDS

We will not receive any proceeds from the sale of the shares by the selling stockholders. To the extent that the warrants are exercised by the selling stockholders for cash, rather than by cashless exercise, we will receive proceeds constituting the exercise price of such warrants. Any such proceeds received by us through warrant exercises will be used for working capital.

SELLING STOCKHOLDERS

In February 2008, we completed a private placement of 1,742,500 units to investors, with each unit consisting of (1) one share of our Series A 12% Convertible Preferred Stock, which is convertible into one share of common stock, (2) a five-year warrant to purchase one share of common stock at an exercise price of $1.50, and (3) a five-year warrant to purchase one share of common stock at an exercise price of $2.00.

This prospectus covers the sale by the selling stockholders from time to time of:

- 1,562,500 shares of common stock issuable upon the conversion of shares of our Series A 12% Convertible Preferred Stock sold in the February 2008 private placement; and
- 3,235,000 shares of common stock issuable upon the exercise of the warrants sold in the February 2008 private placement.

We issued the securities to the selling stockholders without registration under the Securities Act of 1933 (the Securities Act) in reliance upon the exemption provided by Section 4(2) of the Securities Act for transactions not involving a public offering. Prior to issuance, each selling stockholder represented to us that it was an accredited investor, as defined in Rule 501 of Regulation D under the Securities Act, and that it was acquiring the securities for investment purposes only and not with a view to, or sale in connection with, any distribution thereof.

The term selling stockholder includes (i) each person and entity that is identified in the table below (as such table may be amended from time to time by means of an amendment to the registration statement of which this prospectus forms a part) and (ii) any transferee, donee, pledgee or other successor of any person or entity named in the table that acquires any of the shares of common stock covered by this prospectus in a transaction exempt from the registration requirements of the Securities Act and that is identified in a supplement or amendment to this prospectus.

We have listed below:

- the name of each selling stockholder;
- the number of shares of common stock known to be beneficially owned by the selling stockholder based on beneficial ownership information available to us as of the date of this prospectus;
- the maximum number of shares of common stock being offered by each of them in this offering; and
- the number of shares of common stock to be owned by the selling stockholder after this offering (assuming sale of such maximum number of shares) and the percentage of the class which such number constitutes (if one percent or more).

The footnotes to the table identify each selling stockholder that is a registered broker-dealer or an affiliate of a registered broker-dealer.

Except as otherwise noted below, during the last three years, no selling stockholder has been an officer, director or affiliate of our company, nor has any selling stockholder had any material relationship with our company or affiliates during that period. Each selling stockholder represented at the closing of the private

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placement that it did not have any contract, undertaking, agreement or arrangement with any person to sell, transfer, pledge, hypothecate, grant any option to purchase or otherwise dispose of any of the securities. Based on information provided to us by the selling stockholders, the selling stockholders purchased the securities in the ordinary course of business.

The shares of common stock being offered hereby are being registered to permit public secondary trading, and the selling stockholders are under no obligation to sell all or any portion of their shares included in this prospectus. The information contained in the following table is derived from information provided to us by selling stockholders, our books and records, as well as from our transfer agent. Where we were unable to obtain information from a selling stockholder with respect to the total number of shares beneficially owned by such holder, we have included only the shares underlying warrants held by such holder.

Unless otherwise indicated, each person has sole investment and voting power with respect to the shares indicated. For purposes of this table, a person or group of persons is deemed to have beneficial ownership of any shares as of a given date which such person has the right to acquire within 60 days after such date.

We do not know when or in what amounts a selling stockholder may offer shares for sale. The selling stockholders may not sell any or all of the shares offered by this prospectus. Because the selling stockholders may offer some or all of the shares pursuant to this prospectus, and because there are currently no agreements, arrangements or understandings with respect to 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. The numbers of shares shown under the column Common Stock Owned Upon Completion of this Offering reflect the assumption solely for purpose of this table that such shares are still owned upon completion of the offering, which assumption is not intended to override the selling stockholder table in, as applicable, any other prospectus covering the resale of any other of our securities by the selling stockholders.

Name of Selling Stockholder	Common Stock Beneficially Owned Prior to the Offering	Common Stock Offered Pursuant to this Prospectus(1)	Common Stock Owned Upon Completion of this Offering	Percentage of Common Stock Owned Upon Completion of this Offering
William & Karen Belcher	75,000	75,000		*
Roy Brown	75,000	75,000		*
Clark Capraro	30,000	30,000		*
Estate of Mildred Christian	620,500	75,000	545,500	*
Dale Conaway(2)	302,000	30,000	272,000	*
Howard Crosby	150,000	150,000		*
James Czirr Trust(3)	346,232	300,000	46,232	*
Cynthia Dimmette	75,000	75,000		*
Fivex LLC(4)	300,000	300,000		*
Peter Fox	75,000	75,000		*
Gayle Galan Living Trust	75,000	75,000		*
Harvey & Sandra Gertsch	75,000	75,000		*
Irwin Goldstein	30,000	30,000		*
Richard & Mary Gumaer	37,500	37,500		*
James Hart	60,000	60,000(8)		*
Preston & Carrie Hawkins	225,000	225,000		*
Robert Jacobs	165,000	165,000		*
JAM Capital Associates, LLC(5)	60,000	60,000		*
Kendler Family Trust	75,000	75,000		*
Anatole Klyosov(6)	1,731,567			