PRO PHARMACEUTICALS INC
Form 10-K
March 12, 2010
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

x Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the fiscal year ended December 31, 2009

¨ Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the transition period from to

Commission File No. 000-32877

PRO-PHARMACEUTICALS, INC.

Nevada	**04-3562325**
(State or other jurisdiction of incorporation)	**(I.R.S. Employer Identification No.)**
7 Wells Avenue, Newton, Massachusetts	**02459**
(Address of Principal Executive Offices)	**(Zip Code)**

(617) 559-0033

(Registrant s Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act:

None

Securities registered pursuant to Section 12(g) of the Act:

Common Stock, Par Value $.001

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ¨ NO x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. YES ¨ NO x

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES x NO ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). YES ¨ NO ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ¨

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 ¨ Smaller reporting company x

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ¨ NO x

The aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was sold, or the average bid and asked price of such common equity, as of June 30, 2009 was $13.0 million.

The number of shares outstanding of the registrant s common stock as of March 1, 2010 was 51,742,090.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive Proxy Statement for the 2010 Annual Meeting of Stockholders are incorporated by reference into Part III of this Report.

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FORWARD-LOOKING STATEMENTS

This annual report on Form 10-K contains, 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 project, may, could, expect, anticipate, estimate, c 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. The following are some of the important factors that could cause our actual performance to differ materially from those discussed in the forward-looking statements:

- We have incurred significant operating losses since our inception and cannot assure you that we will generate revenue or profit.
- As a result of our lack of financial liquidity and negative stockholders equity, our auditors have indicated there is uncertainty of our ability to continue as a going concern.
- If we fail to raise additional capital by the end of April 2010, we may need to significantly curtail operations, cease operations or seek federal bankruptcy protection.
- We are subject to extensive and costly regulation by the U.S. Food and Drug Administration, or FDA, which must approve our product candidates in development and could restrict the sales and marketing of such products in development.
- We may be unable to achieve commercial viability and acceptance of our proposed products.
- We may be unable to improve upon, protect and/or enforce our intellectual property.
- We may be unable to enter into strategic partnerships for the development, commercialization, manufacturing and distribution of our proposed product candidates.
- We are subject to significant competition.
- As a public company, we must implement additional and expensive finance and accounting systems, procedures and controls as we grow our business and organization to satisfy new reporting requirements, which will increase our costs and require additional management resources.

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 above and in the Risk Factors section of this annual report on Form 10-K. We cannot assure you that we have identified all the factors that create uncertainties. Moreover, new risks emerge from time to time and it is not possible for our management to predict all risks, nor can we assess the impact of all risks on our business or the extent to which any risk, or combination of risks, may cause actual results to differ from those contained in any forward-looking statements. 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.

PART I

Item 1. ***Business***

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 liver, microbial and inflammatory diseases. All of our products are presently in development, including pre-clinical and clinical trials.

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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 which 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, increases the efficacy while reducing adverse side effects of the chemotherapy. We hold the patent on DAVANAT®, which was invented by company founders David Platt, Ph.D., our former Chief Executive Officer, and Anatole Klyosov, Ph.D., our Chief Scientist.

On February 12, 2009, David Platt, Ph.D. resigned as Chairman of our Board of Directors and as Chief Executive Officer and each of Dale H. Conaway, Dr. Henry J. Esber and Dr. James T. Gourzis resigned from our Board of Directors. Theodore Zucconi, Ph.D. was named our Chief Executive Officer and President. Also, on February 12, 2009, James C. Czirr, Rod Martin, Gilbert Amelio, Ph.D. and Peter Traber, M.D., were elected to our Board of Directors. Mr. Czirr and Mr. Martin were designated as the Series B Directors and Dr. Amelio and Dr. Traber were the Series B Nominees under the terms of our Series B convertible preferred stock agreement announced on February 12, 2009.

In 2002, the Federal 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 FDA-approved and one of the most widely used chemotherapies for treatment of various types of cancer, including colorectal, breast and gastrointestinal. In September 2008, we submitted a clinical and pre-clinical package to the FDA in support of our DAVANAT® New Drug Application (NDA). The FDA reported to us in its minutes for the December 2008 meeting that we will be required to conduct a Phase III trial to demonstrate superiority to the best standard of care for late stage colorectal cancer patients. We believe that using DAVANAT® in combination with 5-FU enables greater absorption of the chemotherapy in cancer cells while reducing its toxic side effects.

We plan to submit an NDA for co-administration of DAVANAT® with 5-FU for the indication of colorectal cancer.

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 own 10% of a Nevada subsidiary that we formed in October 2008 for the development of our technology in cardiovascular treatments.

Our Strengths and Strategies

Focus on novel therapeutic opportunities that target Galectin receptors. We believe our company is one of the pioneers focused on development of therapeutics that target Galectin receptors to treat cancer. Carbohydrate molecules, which are essential to the transmission and recognition of cellular information, have been shown to play an important role in major diseases including cancer, cardiovascular disease, Alzheimer s disease, inflammatory disease and viral infections. We believe this offers a largely untapped area for treatment of disease including chemotherapeutics, infection treatment, vaccines and antibiotics.

Leverage extensive scientific expertise. Our scientists have substantial expertise, developed over decades, in the area of carbohydrates that target Galectin receptors. Our team has conducted research in therapeutic application of carbohydrate-based therapeutics for more than 20 years. Dr. Klyosov, who headed the Carbohydrate Research Laboratory at the USSR Academy of Sciences and was a visiting biochemistry professor at Harvard Medical School, holds more than 20 patents. We believe that his expertise, supplemented by members of our Scientific and Medical Advisory Boards, provides us with a substantial advantage in this relatively new area of drug development.

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Completion of development milestones toward commercialization of DAVANAT® and 5-FU combination cancer therapy. We have completed important milestones in the development of DAVANAT® in combination with 5-FU to treat late-stage cancer patients with solid tumors. These include our submission of the Drug Master File, or DMF, to the FDA in May 2008, which we believe demonstrates our ability to produce commercial quantities of pharmaceutical-grade DAVANAT® under manufacturing standards known as cGMP (current Good Manufacturing Process); our submission in September 2008 of a clinical and pre-clinical package to the FDA in support of our DAVANAT® NDA; and our December 2008 pre-NDA meeting with the FDA which provided guidance as to certain components of a Phase III trial of DAVANAT®/5-FU that would be needed for an NDA demonstrating superiority to the best standard of care for late stage colorectal patients. We also have explored utilizing DAVANAT® with other therapeutics and also as a potential stand-alone therapeutic.

Apply our technology to broad range of applications. Our research indicates that DAVANAT® has the potential for broad application. Following development of DAVANAT® in combination with chemotherapies and biologics, we plan to combine it with other drugs to extend its use to treat other serious diseases. Generally speaking, a biologic is a therapeutic product based on materials derived from living materials, whereas chemotherapies are chemical compounds, typically used in cancer treatment. Pre-clinical studies indicate that DAVANAT®, and other proprietary therapeutics we have in development, may have application for advanced treatment of liver, microbial and inflammatory diseases. This could substantially increase the marketability of our products.

Product Development

We are initially developing a pipeline of compounds that may be combined with chemotherapies, such as 5-FU and biologics, such as Avastin®, so as to improve the clinical benefit to cancer patients. Based on our research, we believe DAVANAT®, when combined with chemotherapies and biologics can significantly increase the clinical benefit to cancer patients by extending survival and increasing quality of life. Our lead product candidate, DAVANAT®, is a patented new chemical entity that has completed Phase II trials for treatment of colorectal cancer in combination with 5-FU.

To date, DAVANAT® has been administered to approximately 100 cancer patients in Phase I and II trials. Data from a Phase II trial for late-stage colorectal cancer patients showed DAVANAT® extended median survival to 6.7 months with significantly reduced side effects, as compared to 4.6 months for best standard of care as determined by the patient s physician. Patients have improved quality of life as result of experiencing fewer adverse side effects of the chemotherapy and requiring less hospitalization.

In addition, results of pre-clinical studies we have conducted in mice show that more 5-FU accumulates in the tumor when co-administered with DAVANAT® than when 5-FU is administered alone in the mice. Our pre-clinical and clinical trial data also show that DAVANAT® is safe and non-toxic.

Our NDA for DAVANAT® will seek FDA approval for co-administration of DAVANAT® with 5-FU for intravenous injection for the treatment of colorectal cancer. We plan additionally to file NDAs for DAVANAT® in combination with other chemotherapeutics and biologics.

According to its published guidance, the FDA initially determines whether an NDA filing is complete for purposes of allowing a review, and, if allowed, then determines whether to approve the NDA, a process that takes six months (typically for a chemotherapy) or ten months (typically for a biologic). Upon approval, an applicant may commence commercial marketing and distribution of the approved products. We have retained Camargo Pharmaceutical Services, LLC (Camargo) for regulatory support of our submission with the FDA. Camargo s expertise in regulatory affairs and submissions includes the preparation and submission of NDAs.

We are also developing other therapeutic compounds for treatment of other serious disease, such as liver and kidney fibrosis. These product candidates are all in the pre-clinical stage of development. We entered into research collaborations with the Mount Sinai School of Medicine to study the anti-fibrotic effects of our

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compounds on liver fibrosis and with Brigham and Women s Hospital to evaluate the anti-fibrotic effects of these compounds to treat acute and chronic kidney disease. Our compound reduced collagen expression and reversed fibrosis in animal models. Whereas previously *in vitro* data indicated a reversal of fibrosis markers, in this proof-of-concept animal study, the compounds clearly reduced collagen expression and reversed liver fibrosis.

DAVANAT®

DAVANAT®, our lead product candidate in development, is a proprietary polysaccharide polymer comprised of mannose and galactose that is derived from plant sources and has a precisely defined chemical structure. More specifically, it is galactomannan which is isolated from seeds of guar and subjected to a controlled partial chemical and physical degradation. Guar is a legume grown in the United States and elsewhere for a wide variety of food and non-food uses.

We believe the mechanism of action for DAVANAT® is based upon interaction with lectins, which are cell surface proteins that bind only to a particular kind of carbohydrate. DAVANAT® is formulated to attach to specific lectins, called galectins, which are abundant on the surface of tumor cells, while selectively avoiding healthy tissue. We believe the structure of DAVANAT® is such that it is attracted to Galectin receptors that are specific and over-expressed on cancer cells. The Galectin receptor effectively interacts with DAVANAT® and the chemotherapy and/or biologic combination and assists in the accumulation of the chemotherapy in the cancer cell. This may allow for administration of higher doses of chemotherapy thereby increasing efficacy while reducing toxicity.

Pre-clinical Studies of DAVANAT®

Our pre-clinical studies demonstrate that DAVANAT® when used in combination with chemotherapies, such as 5-FU and irinotecan, and biologics, such as Avastin®, may improve the clinical benefit of anti-cancer treatments. Pre-clinical studies also demonstrated delayed tumor growth and tumor shrinkage against a control group of animals when DAVANAT® was used in combination with standard therapies. These studies demonstrated that DAVANAT® could be used effectively with different chemotherapies and biologics.

Clinical Trial Development of DAVANAT®

Results from our Phase II clinical trial data in late-stage cancer patients shows that DAVANAT® extends median survival to 6.7 months from 4.6 months (or a 46% increase) after other treatments were exhausted. The results of this trial also demonstrated reduction of adverse gastrointestinal, hematological and other side effects of chemotherapy treatment.

Phase I Trial for Late-Stage Patients with Solid Tumors. In 2005, we completed a Phase I study to evaluate DAVANAT®, alone and in combination with 5-FU, to treat solid tumors in a trial of 40 end-stage patients with advanced solid tumors who failed chemotherapy, radiation therapy, and/or surgical treatments. The objective of the open label study was to evaluate the safety and tolerability of escalating doses of DAVANAT® (30-280mg/m 2) when administered alone and in combination.

Based on objective tumor assessment using Response Evaluation Criteria in Solid Tumors, or RECIST, the disease was stabilized in 14 of 26 of the evaluable patients with measurable disease. Furthermore, 7 of 10 patients were stabilized at the highest dose level of DAVANAT® administered in the study. Efficacy results are analyzed based on RECIST following completion of the second cycle of treatment. According to RECIST, a stable disease is a disease with neither sufficient shrinkage to qualify for Partial Response (more than 30% shrinkage) nor sufficient increase to qualify for Progressive Disease (greater than 20% increase) taking as reference the smallest sum longest diameter since the treatment started.

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The Phase I data also indicate that DAVANAT® was well tolerated by patients. The maximum tolerated dose was not reached indicating DAVANAT® is safe and has the potential for further dose escalation. Adverse side effects were primarily disease related. Additionally, the results showed that the DAVANAT®/5-FU combination remained in the bloodstream up to eight times longer, which we believe increases the efficacy of the treatment.

Phase II Trial for Late Stage Patients with Metastatic Colorectal Cancer. In 2004, we initiated a Phase II clinical trial to further evaluate DAVANAT® for late-stage patients with metastatic colorectal cancer. The multi-center, open label, single-dose level study was designed to evaluate up to 15 patients in stage one, and up to 18 patients in stage two. The study, which was designed to evaluate the efficacy and safety of DAVANAT® in combination with chemotherapy when administered in monthly cycles, had two objectives: (1) to document the rate of response and stabilization of patients with advanced colorectal cancer; and (2) to continue evaluating the safety of the DAVANAT® in combination 5-FU. Dosing of patients began in May 2005. We stopped recruiting for the study in May 2006 because we achieved our objective. The data for the study indicates that based on objective tumor assessment one patient experienced a partial tumor response and the disease was stabilized in 6 of 20 patients. Data on 20 patients from this trial showed that DAVANAT® extended median survival. We tracked these patients and gathered data after they left the trial. The patients entered the trial with disease that progressed despite previously being treated with standard chemotherapies and biologics.

Phase II Trial for First-line Treatment of Patients with Biliary Cancer. In 2007, we initiated a Phase II trial for the first-line treatment of patients with biliary (gall bladder) cancer. Biliary cancer may represent an opportunity for orphan drug status approval. See FDA Orphan Drug Designation below under Government Regulation. The multi-center, open label, single-dose level study is designed to evaluate up to 42 patients. The study was designed to evaluate the efficacy and safety of DAVANAT® when administered for at least two monthly cycles or until disease progression. The trial had two objectives: (1) complete/partial tumor response in 20% of patients (17% in the first stage); and (2) the safety of DAVANAT® regimen in this patient population. We stopped the trial due to financial constraints in the second quarter of 2008 and do not expect to resume it.

Phase II Trial for First-line Treatment of Patients with Colorectal Cancer. In 2006, we initiated a Phase II trial for initial treatment of colorectal cancer patients. The multi-center, open label, single-dose level study was designed to evaluate up to 50 patients who are unable to sustain the high toxicity of current intensive combination chemotherapy. The study was expected to evaluate the efficacy and safety of DAVANAT® when administered in combination with the current standard of care in two monthly cycles or until disease progression or toxicity. The primary objectives of the study were a complete or partial response in 33% of the patients and a secondary measurement of progression free survival at 6 and 12 months. We stopped the trial due to financial constraints in the second quarter of 2008 and do not expect to resume it.

See Risk Factors Risks Related to our Company We have one drug candidate in clinical trials and results are uncertain for additional discussion of risks related to clinical trials.

Patents and Proprietary Rights

Our development and commercial viability, and ultimately our competitiveness, depend on our ability to develop and maintain the proprietary aspects of our technology and operate without infringing on the proprietary rights of others. We rely on a combination of patent, trademark, trade secret and copyright law and contract restrictions to protect the proprietary aspects of our technologies. We seek to limit disclosure of our intellectual property by requiring employees, consultants, and any third parties with access to our proprietary information to execute confidentiality agreements and by restricting access to that information.

As of December 31, 2009, we held five U.S. patents and have patent applications pending from the U.S. Patent and Trademark Office. Many of our patents and patent applications cover methods and composition for

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reducing toxicity and enhancing chemotherapeutic drugs by co-administering a polysaccharide with a chemotherapeutic agent. We have corresponding patent applications pending in Europe, Canada, Israel, Brazil, Japan, China and Australia. Additionally, we have patent applications in other areas to utilize our carbohydrate-based compounds to treat disease other than cancer. See Risk Factors Risks Related to the Drug Development Industry Our competitive position depends on protection of our intellectual property.

Research

Our initial focus is on the design and analysis of Galectin targeting therapeutics to improve the clinical benefit of chemotherapeutic agents and biologics. We contract with independent laboratories and other facilities to conduct our research, which is designed, evaluated and managed by our scientists. We do not anticipate building in-house research or development facilities or hiring staff other than for purposes of designing and managing our out-sourced research.

As we develop products eligible for clinical trials, we contract with independent parties to design 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.

Our research and development expenditures totaled $18.5 million for the cumulative period from inception (July 10, 2000) through December 31, 2009. During the years ended December 31, 2009 and 2008, our expenditures for research and development were $1.1 million and $1.8 million, respectively.

Manufacturing and Marketing

We are a development stage company at this time and do not intend to establish internal facilities for the manufacture of our products for clinical or commercial production. To have our products manufactured, we have developed and will continue to develop relationships with third-parties that have established manufacturing capabilities. 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.

Because our products are in the development stage, we have not created a sales and marketing staff to commercialize pharmaceutical products. If we develop products eligible for commercial sale, we will need to develop a sales and marketing capability or rely on third parties such as licensees, collaborators, joint venture partners or independent distributors to market and sell those products. Our dependence on third-party manufacturers and marketers will involve risks relating to our reduced control, and other risks including those discussed in Risk Factors Risks Related to our Company We will depend on third parties to manufacture and market our products and to design trial protocols, arrange for and monitor the clinical trials, and collect and analyze data.

Competition

Many biotechnology and pharmaceutical companies are developing new technologies for the treatment of cancer and other diseases. Technologies such as monoclonal antibodies, developed by Genentech, Inc., could be competitive with our Galectin therapeutic platforms. Companies, such as Momenta Pharmaceuticals Inc., are developing technologies to improve or develop new or existing drugs. Other companies, such as ImClone Systems Incorporated, are trying to improve the therapeutic profile of widely used protein-based drugs. While these companies may broaden the market for our products they may also provide competitive alternatives to our products.

See Risk Factors Risks Related to the Drug Development Industry We face intense competition in the biotechnology and pharmaceutical industries for additional discussion related to our current and potential competition.

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Government Regulation

The research, development, testing, manufacture, labeling, promotion, advertising, distribution, and marketing, among other things, of our products are extensively regulated by governmental authorities in the United States and other countries. The FDA regulates drugs under the federal Food, Drug, and Cosmetic Act and its implementing regulations. Failure to comply with the applicable U.S. requirements may subject us to administrative or judicial sanctions, such as FDA refusal to approve pending NDAs, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, and/or criminal prosecution.

Drug Approval Process

Drugs may not be marketed in the U.S. until the FDA has approved them. The steps required before a drug may be marketed in the U.S. include (similar rules apply in other countries):

1. Pre-clinical laboratory tests, animal studies, and formulation studies,

2. Submission to the FDA of an IND for human clinical testing, which must become effective before human clinical trials may begin,

3. Adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug for each indication,

4. Submission to the FDA of an NDA,

5. Satisfactory completion of an FDA inspection of the manufacturing facility or facilities, at which the drug is produced to assess compliance with cGMP established by the FDA,

6. FDA review and approval of the NDA, and

7. FDA review and approval of a trademark used in connection with a pharmaceutical.

Pre-clinical tests include laboratory evaluation of product chemistry, toxicity, and formulation, as well as animal studies. The results of the pre-clinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND, which must become effective before human clinical trials may begin. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about issues such as the conduct of the trials as outlined in the IND. In such a case, the IND sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed. There is no certainty that submission of an IND will result in the FDA allowing clinical trials to begin.

Clinical trials involve the administration of the investigational drug to human subjects under the supervision of qualified investigators. Clinical trials are conducted under protocols detailing the objectives of the study, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND.

Clinical trials typically are conducted in three sequential phases, but the phases may overlap or be combined. Each trial must be reviewed and approved by an independent Institutional Review Board, IRB, before it can begin. Study subjects must sign an informed consent form before participating in a clinical trial. Phase I usually involves the initial introduction of the investigational drug into patients to evaluate its safety, dosage tolerance, pharmacodynamics, and, if possible, to gain an early indication of its effectiveness. Phase II usually involves trials in a limited patient population to (i) evaluate dosage tolerance and appropriate dosage; (ii) identify possible adverse effects and safety risks; and (iii) evaluate preliminarily the efficacy of the drug for specific indications. Phase III trials usually further evaluate clinical efficacy and test further for safety by using the drug in its final form in an expanded patient population. There is no assurance that these trials will be completed within a specified period of time, if at all.

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Assuming successful completion of the required clinical testing, the results of the pre-clinical studies and of the clinical studies, together with other detailed information, including information on the manufacture and composition of the drug, are submitted to the FDA in an NDA requesting approval to market the product for one or more indications. Before approving an NDA, the FDA usually will inspect the facilities at which the drug is manufactured, and will not approve the product unless compliance with cGMP is satisfactory. If the FDA evaluates the NDA and the manufacturing facilities as acceptable, the FDA will issue an approval letter. If the FDA evaluates the NDA submission or the manufacturing facilities as not acceptable, the FDA will outline the deficiencies in the submission and often will request additional testing or information. Even if an applicant submits the requested additional information, the FDA ultimately may decide that the NDA does not satisfy the regulatory criteria for approval. The testing and approval process requires substantial time, effort, and financial resources, and there is no assurance that any approval will be granted on a timely basis, if at all. After approval, certain changes to the approved product, such as adding new indications, manufacturing changes, or additional labeling claims are subject to further FDA review and approval.

See Risk Factors Risks Related to the Drug Development Industry We will need regulatory approvals to commercialize our products for additional discussion of regulatory risks related to our drug development program.

FDA Priority Review

FDA procedures provide for priority review of an NDA submitted for drugs that, compared to currently marketed products, offer a significant improvement in the treatment, diagnosis, or prevention of a disease. NDAs that are granted priority review are acted upon more quickly than NDAs given standard review. If we were to seek priority review, there can be no guarantee that the FDA will grant priority review status, that priority review status will affect the time of review, or that the FDA will approve the NDA submitted for any of our product candidates, whether or not priority review status is granted.

Post-Approval Requirements

If FDA approval of one or more of our products is obtained, we will be required to comply with a number of post-approval requirements. For example, holders of an approved NDA are required to report certain adverse reactions to the FDA and to comply with certain requirements concerning advertising and promotional labeling for their products. Also, quality control and manufacturing procedures must continue to conform to cGMP after approval, and the FDA periodically inspects manufacturing facilities to assess compliance with cGMP. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. In addition, discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved NDA, including withdrawal of the product from the market. Also, new government requirements may be established that could delay or prevent regulatory approval of our products under development.

FDA Orphan Drug Designation

The FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition, which generally is a disease or condition that affects fewer than 200,000 individuals in the United States. Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are publicly disclosed by the FDA. Orphan drug designation does not convey an advantage in, or shorten the duration of, the regulatory review and approval process. If a product which has an orphan drug designation subsequently receives the first FDA approval for the indication for which it has such designation, the product is entitled to orphan exclusivity, meaning that the FDA may not approve any other applications to market the same drug for the same indication, except in certain very limited circumstances, for a period of seven years. As well, orphan drugs usually receive ten years of marketing exclusivity in the European Union. We currently are not seeking orphan drug designation.

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Regulation Outside the United States

Before our products can be marketed outside of the United States, they are subject to regulatory approval similar to that required in the United States, although the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary widely from country to country. No action can be taken to market any product in a country until an appropriate application has been approved by the regulatory authorities in that country. The current approval process varies from country to country, and the time spent in gaining approval varies from that required for FDA approval. In certain countries, the sales price of a product must also be approved. The pricing review period often begins after market approval is granted. No assurance can be given that even if a product is approved by a regulatory authority, satisfactory prices will be approved for such product.

Environmental Regulation

Pharmaceutical research and development involves the controlled use of hazardous materials. Biotechnology and pharmaceutical companies must comply with laws and regulations governing the use, generation, manufacture, storage, air emission, effluent discharge, handling and disposal of certain materials, biological specimens and wastes. We do not anticipate building in-house research, development or manufacturing facilities, and, accordingly, do not expect to have to comply directly with environmental regulation. However, our contractors and others conducting research, development or manufacturing activities for us may be required to incur significant compliance cost, and this could in turn could increase our expense or delay our completion of research or manufacturing programs.

Employees

As of December 31, 2009, we had six full-time employees, two of whom were involved primarily in management of our pre-clinical research and development and clinical trials and four who were involved primarily in financial management and administration of our company. We also had one part-time contractor who provides manufacture and clinical trial support and two part-time contractors, one of whom provides financial management services and the other of whom serves as our medical director.

Item 1A. ***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 are at an early stage of development and have not generated any revenue.

We are a development-stage company with a limited operating history, and we have not generated any revenues to date. We have no products available for sale, and none are expected to be commercially available for several years, if at all. We may never obtain FDA approval of our products in development and, even if we do so and are also able to commercialize our products, we may never generate revenue sufficient to become profitable. Our failure to generate revenue and profit would likely lead to loss of your investment in our company.

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We have incurred net losses to date and must raise additional capital by the end of April 2010 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, 2009 was $47.7 million. We will need to continue to conduct significant research, development, testing and regulatory compliance activities that, together with projected general and administrative expenses, we expect will result in substantial operating losses for the next several years. Accordingly, we do not expect to be generating sales or other revenue and will remain dependent on outside sources of financing during that time. If we are unable to raise funds from outside sources for our continuing operations, we may be adversely affected.

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.

Based on $251,000 of unrestricted cash as of December 31, 2009, combined with $308,000 and $322,000, net, respectively, received from offerings of our Series B-2 financings on January 29 and March 8, 2010, we believe that we have sufficient cash to meet our financial and operating obligations into April 2010. 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 April 2010, or we may not be able to continue operations and may be forced to seek bankruptcy protection.

We were a counterclaim defendant in a lawsuit instituted by our former Chief Executive Officer that relates to certain of our intellectual property.

In January 2004, David Platt, Ph.D., our former Chairman and Chief Executive Officer, filed a lawsuit in Massachusetts Superior Court against GlycoGenesys, Inc., which asserted counterclaims against us related to our intellectual property. Prospect Therapeutics, Inc. subsequently purchased certain assets including this lawsuit from the GlycoGenesys bankruptcy estate. Before the Court could issue a decision after the lawsuit went to trial in March 2009, Prospect Therapeutics announced on May 15, 2009, that it had assigned all of its assets for the benefit of creditors and would liquidate. In response, we moved to dismiss the lawsuit on various grounds, including failure to prosecute. Prospect s assets, including the lawsuit, were sold at auction on June 29, 2009, and the new owner of the assets elected not to prosecute. After a post-trial hearing, the Court issued a judgment dated July 17, 2009, dismissing the lawsuit against us and Dr. Platt.

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) filed a lawsuit against us in the Superior Court of the Commonwealth of Massachusetts, 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 to us. Summer Street claims it is entitled to a placement fee for each placement made during the term of the agreement and for each issuance of securities made or agreed to be made by us from October 17, 2007 through November 16, 2008. We initially responded to the lawsuit with a motion to dismiss, which the Court denied on June 23, 2008, finding that the letter agreement was ambiguous with respect to Summer Street s entitlement to compensation. The Court also denied Summer Street s motion for a pre-judgment attachment and trustee process, preliminarily finding that Summer Street was

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not likely to prevail on any of its claims. On July 3, 2008, we filed our answer, denying Summer Street s material allegations. The parties are currently engaged in discovery and no trial date has been set for this matter. We believe the lawsuit is without merit and intend to contest it vigorously. However, if we were to receive an adverse decision, we might be required to pay cash damages to Summer Street which could have a material adverse effect on our financial position.

Our drug candidates are based on novel unproven technologies.

Our drug candidates in development are based on novel unproven technologies using proprietary compounds in combination with FDA approved drugs currently used in the treatment of cancer and other diseases. Therapeutics that target Galectin receptors are difficult to synthesize and we may not be able to synthesize them in a way that would make them usable as target delivery vehicles for the anti-cancer drugs.

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

We have one product candidate in human clinical trials. Pre-clinical results in animal studies are not necessarily predictive of outcomes 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 if our products progress successfully through initial human testing, they may fail in later stages of development. We may 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 our current and anticipated product candidates achieve positive results in clinical trials, we may be unable to commercialize them. Potential products may fail to receive necessary regulatory approvals, be difficult to manufacture on a large scale, be uneconomical to produce, fail to achieve market acceptance, or be precluded from commercialization by proprietary rights of third parties. Our inability to commercialize out products would substantially impair the viability of our company.

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. Any growth of our company will require us to expand our management and our 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 operational, managerial and financial resources.

We will depend on third parties to manufacture and market our products and to design trial protocols, arrange for and monitor the clinical trials, and collect and analyze data.

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. In addition, 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 will need to develop relationships with manufacturers and 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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In addition, 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.

Moreover, as we develop products eligible for clinical trials, we may contract with independent parties to design 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.

We are exposed to product liability, pre-clinical and clinical liability risks which could place a substantial 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, as a result of which 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.

Since 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.

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

The continuing efforts of government and 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. For example, in certain foreign markets, pricing or profitability of prescription pharmaceuticals is subject to government control. In the U.S., given recent federal and state government initiatives directed at lowering the total cost of health care, the U.S. Congress and state legislatures will likely continue to focus on health care reform, the cost of prescription pharmaceuticals and on the reform of the Medicare and Medicaid systems. While we cannot predict whether any such legislative or regulatory proposals will be adopted, the announcement or adoption of such proposals could materially harm our business, financial condition and results of operations.

Our ability to commercialize our proposed products will depend in part on the extent to which appropriate reimbursement levels for the cost of our proposed formulations and products and related treatments are obtained by governmental authorities, private health insurers and other organizations, such as health management organizations, or HMOs. Third-party payers are increasingly challenging the prices charged for medical drugs and services. Also, the trend toward managed health care in the U.S. and the concurrent growth of organizations

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such as HMOs, which could control or significantly influence the purchase of health care services and drugs, as well as legislative proposals to reform health care or reduce government insurance programs, may all result in lower prices for or rejection of our products.

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

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.

We may be unable to engage qualified distributors. 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.

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

We are highly dependent on Anatole Klyosov, Ph.D., our Chief Scientist who has scientific technical or other business expertise and experience that is critical to our success. The loss of Dr. Klyosov, or failure to attract or retain other key personnel, could prevent us from pursuing collaborations or developing our products and core technologies.

Risks Related to the Drug Development Industry

We will need regulatory approvals to commercialize our products.

We are required to obtain approval from the FDA in order to sell our products in the U.S. and 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 and effective on the patient population and 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 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 prevent or delay 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.

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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, resulting in delays to commercialization, and 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 our 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. We are a counterclaim defendant in a lawsuit instituted by our chief executive officer that relates to our intellectual property as described under Risks Related to Our Company above.

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 that we license from others 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 licensed rights, we may have to pay substantial damages, possibly including treble damages, for past infringement.

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

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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 less costly than ours, 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.

Health care cost containment initiatives and the growth of managed care may limit our returns.

Our ability to commercialize our products successfully may be affected by the ongoing efforts of governmental and third-party payers to contain the cost of health care. These entities are challenging prices of health care products and services, denying or limiting coverage and reimbursement amounts for new therapeutic products, and for FDA-approved products considered experimental or investigational, or which are used for disease indications without FDA marketing approval.

Even if we succeed in bringing any products to the market, they may not be considered cost-effective and third-party reimbursement might not be available or sufficient. If adequate third-party coverage is not available, we may not be able to maintain price levels sufficient to realize an appropriate return on our investment in research and product development. In addition, legislation and regulations affecting the pricing of pharmaceuticals may change in ways adverse to us before or after any of our proposed products are approved for marketing.

Our insurance coverage may not be adequate in all circumstances.

If we commercialize our products, their use by patients could expose us to potential product liability and other claims resulting from alleged injury. This liability may result from claims made directly by consumers or by pharmaceutical companies or others selling such products. Although we currently have clinical trial insurance

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and directors and officers insurance, we may be unable to maintain such insurance on acceptable terms, if at all. Moreover, we have no product or professional liability insurance due to our stage of development, and we may be unable to obtain such insurance at the appropriate time on acceptable terms, if at all. Any inability to obtain and/or maintain insurance coverage on acceptable terms could prevent or limit the commercialization of any products we develop.

Risks Related to Our 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 our ability to raise capital.

Our common stock was delisted from trading on the NYSE Alternext US is now quoted on the OTC Bulletin Board.

Our common stock was delisted from trading on the NYSE Alternext US as of January 9, 2009 and as of January 21, 2009, began to be quoted on OTC Bulletin Board. Companies whose stock is quoted on the OTC Bulletin are not required to comply with the more extensive corporate governance and other listing requirements needed to meet the listing qualifications of the national securities exchanges. Investors in such companies may encounter greater compliance required by broker-dealers in trading their shares.

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 stockholders, 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 your percentage ownership interest, which would have the effect of reducing your influence on matters on which our stockholders 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.

Our board of directors has the power to designate a series of preferred stock without shareholder approval that could contain conversion or voting rights that adversely affect the voting power of 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, designations, rights, preferences, restrictions and the relative rights in each such class or series. The Board previously authorized a series of preferred stock comprised of 5,000,000 shares designated as Series A 12% preferred stock, of which 1,642,500 shares are issued and outstanding, in which each share has one vote and votes on an as-converted basis with our common stock. The Board on February 12, 2009, authorized and designated two series of preferred stock comprised Series B-1 preferred stock, of which 900,000 shares are authorized, issued and outstanding, and Series B-2 preferred stock, comprised of 2,100,000 authorized shares, of which 1,330,000 are outstanding at December 31, 2009. Each share of Series B-1 preferred stock and Series B-2 preferred stock is convertible into four shares of our common stock and, in addition to a separate class vote with respect to certain matters, votes on an as-converted basis as a class with our common stock.

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We may need to request our shareholders to authorize additional shares of common stock in connection with subsequent equity finance transactions.

We are authorized to issue 300,000,000 shares of common stock, of which 51,742,090 shares were issued and outstanding on December 31, 2009. We have reserved 13,642,500 shares of common stock for issuance upon conversion of our Series A 12% preferred stock and Series B-1 and Series B-2 preferred stock, 60,647,505 shares for issuance upon exercise of our outstanding stock options and warrants and 10,090,000 shares for issuance for warrants related to additional Series B-2 offerings and for the achievement of consultant milestones. If all of these securities were converted or exercised, a total of approximately 136,122,000 shares of our common stock would be outstanding. In addition, certain dilutive finance transactions could require us to reserve additional shares if certain of our warrants become exercisable for additional shares as a result of anti-dilution protection provisions. As a result, we may have insufficient shares of common stock available to issue in connection with a future equity finance transaction, and accordingly may be required at an annual or special meeting of shareholders to seek approval of an increase in the number of our authorized shares of common stock before undertaking or as a condition to completing an offering. We cannot assure you that our shareholders would authorize an increase in the number of shares of our common stock.

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 stockholders 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 stockholder who desires to sell a large number of shares to sell the shares in increments over time to mitigate any adverse impact of the sales on the market price of our stock.

Item 1B. ***Unresolved Staff Comments***

None.

Item 2. ***Properties***

We lease 9,400 square feet for our executive offices located at 7 Wells Avenue, Newton, Massachusetts. We have a five year lease that commenced in August 2006 with an option to extend for an additional five years. We believe this space is suitable for our present operations and adequate for foreseeable expansion of our business.

Item 3. ***Legal Proceedings***

Other than claims and legal proceedings that arise from time to time in the ordinary course of business which are not material, the Company has no pending legal proceedings except as follows:

In January 2004, David Platt, Ph.D., our former Chairman and Chief Executive Officer, filed a lawsuit in Massachusetts Superior Court against GlycoGenesys, Inc., which asserted counterclaims against us related to our intellectual property. Prospect Therapeutics, Inc. subsequently purchased certain assets including this lawsuit from the GlycoGenesys bankruptcy estate. Before the Court could issue a decision after the lawsuit went to trial in March 2009, Prospect Therapeutics announced on May 15, 2009, that it had assigned all of its assets for the benefit of creditors and would liquidate. In response, we moved to dismiss the lawsuit on various grounds, including failure to prosecute. Prospect s assets, including the lawsuit, were sold at auction on June 29, 2009, and the new owner of the assets elected not to prosecute. After a post-trial hearing, the Court issued a judgment dated July 17, 2009, dismissing the lawsuit against us and Dr. Platt.

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On January 30, 2008, Custom Equity Research, Incorporated (d/b/a Summer Street Research Partners) filed a lawsuit against us in the Superior Court of the Commonwealth of Massachusetts, 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 to us. Summer Street claims it is entitled to a placement fee for each placement made during the term of the agreement and for each issuance of securities made or agreed to be made by us from October 17, 2007 through November 16, 2008. We initially responded to the lawsuit with a motion to dismiss, which the Court denied on June 23, 2008, finding that the letter agreement was ambiguous with respect to Summer Street s entitlement to compensation. The Court also denied Summer Street s motion for a prejudgment attachment and trustee process, preliminarily finding that Summer Street was not likely to prevail on any of its claims. On July 3, 2008, we filed our answer, denying Summer Street s material allegations. The parties are currently engaged in discovery and no trial date has been set for this matter. We believe the lawsuit is without merit and intend to contest it vigorously.

Item 4. ***Reserved***

No matter was submitted to a vote of our stockholders during the fourth quarter of the fiscal year covered by this report.

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PART II

Item 5. ***Market for Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities***

Price Range of Common Stock

Following the delisting of our common stock from the NYSE Alternext US as of the close of trading on January 9, 2009, our common stock has been quoted on the OTC Bulletin Board since January 21, 2009 under the symbol PRWP.OB . The high and low sale prices for our common stock as reported on the NYSE Alternext US and OTC Bulletin Board, for the periods indicated below were as follows:

	High	Low
Fiscal Year Ended December 31, 2009		
First Quarter	$ 0.42	$ 0.05
Second Quarter	$ 0.59	$ 0.20
Third Quarter	$ 0.50	$ 0.27
Fourth Quarter	$ 0.44	$ 0.24
Fiscal Year Ended December 31, 2008		
First Quarter	$ 0.70	$ 0.26
Second Quarter	$ 0.48	$ 0.25
Third Quarter	$ 0.39	$ 0.17
Fourth Quarter	$ 0.30	$ 0.05

Holders of Common Stock

As of February 16, 2010, there were 279 shareholders of record of our common stock. Because shares of our common stock are held by depositaries, brokers and other nominees, the number of beneficial holders of our shares is substantially larger than the number of record holders. Based on information available to us, we believe there are 3,923 non-objecting beneficial owners of our shares of our common stock in addition to the record holders.

Dividends

There have been no cash dividends declared on our common stock since our company was formed. Dividends are declared at the sole discretion of our Board of Directors. Our intention is not to declare cash dividends and retain all cash for our operations. In February 2008, we issued 1,742,500 shares of Series A 12% Convertible Preferred Stock which pay dividends at the rate of 12% per share per annum payable, at our option, in cash or shares of common stock valued at the higher of $1.00 or 100% of the value weighted average price of our share price for the twenty consecutive trading dates prior to the dividend payment date. It is our intent to make the dividend payments with shares of common stock.

During 2009, we issued 900,000 shares of Series B-1 Convertible Preferred Stock and 1,330,000 shares of Series B-2 Convertible Preferred Stock, which pay dividends at the rate of 12% per share per annum payable, at our option, in cash or Common Stock valued at $0.50 as amended in August 2009. It is our intent to make the dividend payments with shares of common stock.

Item 6. ***Selected Consolidated Financial Data***

The information called for by this Item is not applicable to us because we are a smaller reporting company.

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Item 7. ***Management s Discussion and Analysis of Financial Condition and Results of Operations***

In addition to historical information, the following Management s Discussion and Analysis of Financial Condition and Results of Operations contains forward-looking statements as defined under federal securities laws and is subject to the safe harbor created therein for forward-looking statements. Such statements include, but are not limited to, statements concerning our anticipated operating results, research and development, clinical trials, regulatory proceedings, and financial resources, and can be identified by use of words such as, for example, anticipate, estimate, expect, project, intend, plan, believe and would, should, could or may. Forward-looking statements are based on current expecta and projections about the industry and markets in which Pro-Pharmaceuticals operates, and management s beliefs and assumptions. These statements are not guarantees of future performance and involve certain known and unknown risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Such risks and uncertainties are related to, without limitation, our early stage of development, our dependence on outside capital, uncertainties of our technology and clinical trials, intellectual property litigation, uncertainties of regulatory approval requirements for our products, competition and stock price volatility in the biotechnology industry, limited trading volume for our stock, concentration of ownership of our stock, and other risks detailed herein and from time to time in our SEC reports. The following discussion should be read in conjunction with the accompanying consolidated financial statements and notes thereto of Pro-Pharmaceuticals appearing elsewhere herein.

Overview

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. We believe our therapeutics could also be used in the treatment of liver, microbial and inflammatory diseases. 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 which are designed to increase survival and improve 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 or biolgics, increases efficacy while reducing adverse side effects of the chemotherapy. We hold the patent on DAVANAT®, which was invented by company founders David Platt, Ph.D., our former Chief Executive Officer, and Anatole Klyosov, Ph.D., our Chief Scientist.

On January 29, 2010 and March 8, 2010, we completed closings for gross proceeds of $325,000 and $335,000, respectively, (net cash proceeds of $308,00 and $322,000, respectively) of Series B-2 redeemable convertible preferred stock (Series B-2) for a total of 162,500 and 167,500 shares, respectively, of Series B-2 and warrants to purchase shares of common stock. We believe that with the funds from the January 29 and March 8, 2010 closings of the Series B-2 and unrestricted cash on hand of $251,000 at December 31, 2009, there is sufficient cash to fund operations into April 2010. We will require more cash to fund our operations and believe 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 on terms favorable to us. If we are unsuccessful in raising additional capital before the end of April 2010, we may be required to cease operations or seek bankruptcy protection. In light of our current financial position and the uncertainty of raising sufficient capital to achieve our business plan, there is substantial doubt about our ability to continue as a going concern.

Development of DAVANAT® Technology

In 2002, the FDA granted an Investigational New Drug (IND) application for us to administer DAVANAT® in combination with 5-FU to treat late-stage cancer patients with solid tumors. 5-FU is FDA-approved, and one of the most widely used chemotherapies for treatment of various types of cancer, including colorectal, breast and gastrointestinal. We believe that using DAVANAT® in combination with 5-FU enables greater absorption of the chemotherapy in cancer cells while reducing its toxic side effects.

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The FDA also has granted us an IND for DAVANAT® to be administered with Avastin®, 5-FU and leucovorin in a combination therapy to treat early-stage colorectal cancer patients and an IND for DAVANAT® to be administered with 5-FU to treat early stage bile duct cancer patients. In addition, the FDA also has granted us, on a case-by-case basis, the ability to treat patients with breast cancer in response to physicians requests for so-called compassionate use .

To date, DAVANAT® has been administered to approximately 100 cancer patients. Data from a Phase II trial for end-stage colorectal cancer patients showed that DAVANAT® in combination with 5-FU extended median survival to 6.7 months with significantly reduced side effects, as compared to 4.6 months for best standard of care as determined by the patients physicians. These clinical trials also showed that patients experienced fewer adverse side effects of the chemotherapy and required less hospitalization.

Our pre-clinical and clinical trial data also show that DAVANAT® is well tolerated, safe and non-toxic.

We believe, based on the outcome of our clinical trials to date, that DAVANAT® when co-administered with 5-FU or biological drugs is superior to the current standard of care. We also plan to file NDAs for DAVANAT® in combination with other chemotherapeutics and biologics. Biologics are therapeutic products based on materials derived from living materials.

According to its published guidance, the FDA initially determines whether a NDA filing is complete for purposes of allowing a review, and, if allowed, then determines whether to approve the NDA, a process that takes six or ten months. Upon approval, an applicant may commence commercial marketing and distribution of the approved products. We have retained Camargo Pharmaceutical Services, LLC for regulatory support of our submission with the FDA. Camargo s expertise in regulatory affairs and submissions includes the preparation and submission of NDAs.

In May 2008, we submitted a Drug Master File (DMF) for DAVANAT® to the FDA. This is an important step toward the filing of our DAVANAT® NDA because a DMF contains confidential detailed information in support of the NDA about facilities, processes or articles used in the chemistry, manufacturing, controls, processing, packaging, and storing or stability of drugs. We believe the DMF represents a significant milestone in our eventual commercialization of DAVANAT® because it demonstrates our ability to produce commercial quantities of pharmaceutical-grade DAVANAT® under current Good Manufacturing Process (cGMP) standards. A DMF can be cross-referenced by potential partners to use in combination with other therapies to expedite clinical studies and submission of NDAs.

In September 2008, we submitted a clinical and pre-clinical package to the FDA in support of our DAVANAT® NDA. The FDA reported to us in its minutes for the December 22, 2008 meeting that we will be required to conduct a Phase III trial to demonstrate superiority to the best standard of care for late stage colorectal cancer patients. As part of the Phase III trial, we plan to open the study to conduct a pharmacokinetic (PK) analysis of approximately 60 patients, which may allow us to file an NDA for DAVANAT® as an adjuvant when administered with 5-FU. The Company expects to enroll approximately 300 patients in the Phase III trial. Adjuvants are pharmacological or immunological agents that modify the effect of other agents, such as drugs or vaccines.

Following a hearing with the NYSE Alternext US on December 23, 2008, our appeal of an earlier delisting notice was denied and our common stock ceased to trade on this exchange as of the close of trading on January 9, 2009. On January 21, 2009, our common stock began trading on the OTC Bulletin Board under the symbol PRWP.OB .

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Results of Operations from the Years Ended December 31, 2009 and 2008

Research and Development Expense

	Year ended December 31,		2009 as Compared to 2008	
	2009	2008	$ Change	% Change
	(In thousands, except %)			
Research and development	$ 1,110	$ 1,774	$ (664)	(37)%

We generally categorize research and development expenses as either direct external expense, comprised of amounts paid to third party vendors for services, or all other expenses, comprised of employee payroll and general overhead allocable to research and development. We subdivide external expenses between clinical programs and pre-clinical activities. We consider a clinical program to have begun upon acceptance by the FDA, or similar agency outside of the United States, to commence a clinical trial in humans, at which time we begin tracking expenditures by the product candidate. We have one product candidate DAVANAT® in clinical trials at this time. Clinical program expenses comprise payments to vendors related to preparation for, and conduct of, all phases of the clinical trial, including costs for drug manufacture, patient dosing and monitoring, data collection and management, oversight of the trials and reports of results. Pre-clinical expenses comprise all research and development amounts incurred before human trials begin, including payments to vendors for services related to product experiments and discovery, toxicology, pharmacology, metabolism and efficacy studies, as well as manufacturing process development for a drug candidate.

Our research and development expenses for the years ended December 31, 2009 and 2008 were as follows:

	Year Ended December 31,	
	2009	2008
	(in thousands)	
Direct external expenses:		
Clinical programs	$ 114	$ 244
Pre-clinical activities	310	681
All other research and development expenses	686	849
	$ 1,110	$ 1,774

Clinical program and pre-clinical expenses for the year ended December 31, 2009, decreased compared to the same periods in 2008, due primarily to overall lower activity as a result of cost containment measures. Specifically, the overall decrease for the year ended December 31, 2009 as compared to 2008, is due to decreased stock-based compensation ($173,000), decreased compensation ($47,000) and decreased direct external expenses related to clinical programs and pre-clinical activities ($501,000). Also, during 2008, we incurred costs related to the filing of our DAVANAT® Drug Master File with the FDA as well as expenses related to our Phase II colorectal and biliary cancer trials which were not incurred during 2009. We expect to initiate a Phase III trial as soon as we are able to raise sufficient additional funds which will serve to increase our research and development expense.

Both the time required and costs we may incur in order to commercialize a drug candidate that would result in material net cash inflow are subject to numerous variables, and therefore we are unable at this stage of our development to forecast useful estimates. Variables that make estimates difficult include the number of clinical trials we may undertake, the number of patients needed to participate in the clinical trial, patient recruitment uncertainties, trial results as to the safety and efficacy of our product, and uncertainties as to the regulatory agency response to our trial data prior to receipt of marketing approval. Moreover, the FDA or other regulatory agencies may suspend clinical trials if we or an agency believes patients in the trial are subject to unacceptable risks, or find deficiencies in the conduct of the clinical trial. Delays or rejections may also occur if governmental

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regulation or policy changes during our clinical trials or in the course of review of our clinical data. Due to these uncertainties, accurate and meaningful estimates of the ultimate cost to bring a product to market, the timing of costs and completion of our program and the period during which material net cash inflows will commence are unavailable at this time.

General and Administrative Expense

	Year ended December 31,		2009 as Compared to 2008	
	2009	2008	$ Change	% Change
	(In thousands, except %)			
General and administrative	$ 4,983	$ 3,552	$ 1,431	40%

General and administrative expenses consist primarily of salaries including stock based compensation, legal and accounting fees, insurance, investor relations, business development and other office related expenses. The primary reason for the increased expense during the year ended December 3, 2009 as compared to 2008 is due to increased business development expenses ($172,000) as we increased our business development efforts, increased stock-based compensation in the form of employee options ($827,000) and increased compensation costs ($765,000) due primarily to the recognition of severance obligations related to the departure of our former chief executive officer. These expense increases were offset by decreased legal and accounting costs ($243,000).

Other Income and Expense

Other income and expense for the years ended December 31, 2009 and 2008 was a loss of $1,369,000 and a gain of $2,175,000, respectively, due primarily to the change in fair value of warrant liabilities.

Liquidity and Capital Resources

As described above in the Overview and elsewhere in this Annual Report on Form 10-K, we are in the development stage and have not generated any revenues. Since our inception on July 10, 2000, we have financed our operations from proceeds of public and private offerings of debt and equity. As of December 31, 2009, we raised a net total of $43.4 million from these offerings. At December 31, 2009, we had $251,000 of unrestricted cash and cash equivalents available to fund future operations.

On January 29, 2010 and March 8, 2010, we completed closings for gross proceeds of $325,000 and $335,000, respectively, (net cash proceeds of $308,00 and $322,000, respectively) of Series B-2 redeemable convertible preferred stock (Series B-2) for a total of 162,500 and 167,500 shares, respectively, of Series B-2 and warrants to purchase shares of common stock. We believe that with the funds from the January 29 and March 8, 2010 closings of the Series B-2 and cash on hand at December 31, 2009, there is sufficient cash to fund operations into April 2010. We will require more cash to fund our operations and believe 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 on terms favorable to us. We are actively seeking to raise additional capital and have significantly reduced our administrative and clinical spending. If we are unsuccessful in raising additional capital before the end of April 2010, we may be required to cease operations or seek bankruptcy protection. In light of our current financial position and the uncertainty of raising sufficient capital to achieve our business plan, there is substantial doubt about our ability to continue as a going concern. Net cash used in operations decreased by $778,000 to $3,887,000 for 2009, as compared to $4,665,000 for 2008. Cash operating expenses decreased principally due to decreased research and development activities and cost containment measures during the period which required overall lower cash expenditures.

No cash was provided by or used in investing activities during 2009, essentially unchanged from the same period in 2008.

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Net cash provided by financing activities was $3,820,000 during 2009 as compared to $3,655,000 during 2008, due primarily to the transactions described below.

On February 12, 2009, the initial closing date under the purchase agreement with 10X Fund LP, the Company issued and sold: (i) 900,000 shares of Series B-1 convertible preferred stock (Series B-1 redeemable convertible preferred stock or Series B-1) convertible into 3,600,000 shares of common stock; (ii) Class A-1 warrants exercisable to purchase 1,800,000 shares of common stock; (iii) Class A-2 warrants exercisable to purchase 1,800,000 shares of common stock; and (iv) Class B warrants exercisable to purchase 7,200,000 shares of common stock. Net cash proceeds from the closing of this offering was $1,548,000. Concurrent with the closing of the Series B-1 transaction, we repaid an investor $200,000 of advances received in 2008.

During 2009, in a series of closings, the Company issued and sold to 10X Fund, LP an aggregate of: (i) 1,330,000 shares of Series B-2 convertible preferred stock (Series B-2 redeemable convertible preferred stock or Series B-2) convertible into 5,320,000 shares of common stock; (ii) Class A-1 warrants exercisable to purchase 2,660,000 shares of common stock; (iii) Class A-2 warrants exercisable to purchase 2,660,000 shares of common stock; and (iv) Class B warrants exercisable to purchase 10,640,000 shares of common stock. Net proceeds from these closings were $2,472,000 in 2009.

Payments Due Under Contractual Obligations

The following table summarizes the payments due under our contractual obligations at December 31, 2009, and the effect such obligations are expected to have on liquidity and cash flow in future periods:

		Payments due by period (in thousands)			
Contractual Obligations	**Total**	**Less than 1 year**	**1-3 years**	**3-5 years**	**More than 5 years**
Operating leases	$ 434	$ 267	$ 167	$	$
Separation agreement	434	154	280		
Total payments due under contractual obligations	$ 868	$ 421	$ 447	$	$

Operating leases. On May 1, 2006, we entered into an operating lease for office space. The lease commenced on August 11, 2006, and extends for five years and terminates on September 30, 2011. The lease provides for annual base rental payments of $235,000 in the first year, increasing in each subsequent lease year to $244,000, $253,000, $263,000 and $273,000, respectively. In addition to base rental payments included in the contractual obligations table above, we are responsible for our pro-rata share of increases in the operating expenses for the building after calendar year 2006 and taxes for the building after fiscal year 2007. We have the option to extend the term of the lease for an additional five year period at the prevailing market rate at the time of exercise. In connection with this lease, a commercial bank has issued a letter of credit collateralized by cash we have on deposit with the bank of $59,000. Additionally, we have a non-cancellable lease for a car, for our former chief executive officer, which expires in January 2011 and which is included in the severance agreement line of the contractual obligations table.

Separation agreement. In February 2009, we entered into a Separation Agreement in connection with the resignation of David Platt, Ph.D., our former Chief Executive Officer and Chairman of the Board of Directors. The Separation Agreement provides that we shall continue to pay Dr. Platt his current salary at a monthly rate of $21,667 for 24 months and that we may defer payment of a portion of such salary amounts greater than $10,000 per month (so long as Dr. Platt does not receive payments of less than the salary payments being made to the Company s Chief Executive Officer). However, all deferred amounts will continue to accrue and will be payable on the earlier of (i) the Company receiving a minimum of $4.0 million of funding after February 12, 2009, or (ii) February 12, 2011. We also agreed to continue to (i) provide health and dental insurance benefits to Dr. Platt, until the first to occur of February 12, 2011 or the date Dr. Platt and his family become eligible to receive health

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and dental insurance benefits under the plans of a subsequent employer and (ii) make the current monthly lease payments on his automobile until February 12, 2011. We recognized the full amount of the salary, health insurance and automobile during the first quarter of 2009. The remaining liability related to this severance is reflected in accrued expenses ($154,000) and in Other long-term liabilities ($280,000) on our Consolidated Balance Sheet at December 31, 2009.

The Separation Agreement provides for the deferral of a $1.0 million severance payment due to Dr. Platt under his employment agreement until the occurrence of any of the following milestone events: (i) the approval by the Food and Drug Administration for a new drug application (NDA) for any drug candidate or drug delivery candidate based on the DAVANAT® technology (whether or not such technology is patented); (ii) consummation of a transaction with a pharmaceutical company expected to result in at least $10.0 million of equity investment or $50 million of royalty revenue to the Company; or (iii) the renewed listing of our securities on a national securities exchange. Payment upon the events (i) and (iii) may be deferred up to nine months, and if we have insufficient cash at the time of any of such events, we may issue Dr. Platt a secured promissory note for such amount. If we file a voluntary or involuntary petition for bankruptcy, whether or not a milestone event has occurred, such event shall trigger our obligation to pay the $1.0 million with the result that Dr. Platt may assert a claim for such obligation against the bankruptcy estate. Due to the uncertainties regarding the achievement of any of the milestones as described, we have not accrued for the $1.0 million severance as of December 31, 2009. When it is deemed probable that one of the milestone events will be achieved, we will then recognize the $1.0 million severance at that time.

The Separation Agreement also provides that upon (i) the consummation of a transaction with a pharmaceutical company expected to result in at least $10.0 million of equity investment or $50.0 million of royalty revenue, we will grant Dr. Platt fully vested cashless-exercise stock options exercisable to purchase at least 300,000 shares of our common stock for ten (10) years at an exercise price not less than the fair market value of the Common Stock determined as of the date of the grant and (ii) approval by the FDA of the first NDA for any of our drug or drug delivery candidates based on DAVANAT® technology (whether or not such technology is patented), we will grant Dr. Platt fully vested cashless stock option with identical terms to purchase at least 500,000 shares of common stock. Due to the uncertainties regarding the achievement of any of the milestones as described, we have not recognized the value of the unissued stock options as of December 31, 2009. When it is deemed probable that one of the milestone events will be achieved, we will then recognize the expense related to the issuance of the stock options at that time based on the then current fair value.

Other. We have engaged outside vendors for certain services associated with our clinical trials. These services are generally available from several providers and, accordingly, our arrangements are typically cancellable on 30 days notice.

We have engaged outside vendors for certain services associated with our clinical trials. These services are generally available from several providers and, accordingly, our arrangements are typically cancellable on 30 days notice.

Off-Balance Sheet Arrangements

We have not created, and are not a party to, any special-purpose or off-balance sheet entities for the purpose of raising capital, incurring debt or operating parts of our business that are not consolidated into our financial statements. We do not have any arrangements or relationships with entities that are not consolidated into our financial statements that are reasonably likely to materially affect our liquidity or the availability of capital resources.

Critical Accounting Policies and Estimates

Our significant accounting policies are more fully described in Note 2 to our consolidated financial statements included elsewhere in this annual report on Form 10-K. Certain of our accounting policies, however,

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are critical to the portrayal of our financial position and results of operations and require the application of significant judgment by our management, which subjects them to an inherent degree of uncertainty. In applying our accounting policies, our management uses its best judgment to determine the appropriate assumptions to be used in the determination of certain estimates. Our more significant estimates include stock option and warrant liability valuations and performance vesting features of certain of these instruments, useful lives and potential impairment of property and equipment and intangible assets, accrued liabilities, deferred income taxes and cash flow. These estimates are based on our historical experience, terms of existing contracts, our observance of trends in the industry, information available from other outside sources, and on various other factors that we believe to be appropriate under the circumstances. We believe that the critical accounting policies discussed below involve more complex management judgment due to the sensitivity of the methods, assumptions and estimates necessary in determining the related asset, liability, revenue and expense amounts.

Intangible Assets. Intangible assets include patent costs, consisting primarily of related legal fees, which are capitalized as incurred and amortized over an estimated useful life of five years from issuance. We review the intangible assets for potential impairment on an annual basis or whenever events or changes in circumstances indicate that the asset may be impaired.

Accrued Expenses. As part of the process of preparing our consolidated financial statements, we are required to estimate accrued expenses. This process involves identifying services that third parties have performed on our behalf and estimating the level of service performed and the associated cost incurred on these services as of each balance sheet date in our consolidated financial statements. Examples of estimated accrued expenses include contract service fees in conjunction with pre-clinical and clinical trials, professional service fees, such as those arising from the services of attorneys and accountants and accrued payroll expenses. In connection with these service fees, our estimates are most affected by our understanding of the status and timing of services provided relative to the actual services incurred by the service providers. In the event that we do not identify certain costs that have been incurred or we under- or over-estimate the level of services or costs of such services, our reported expenses for a reporting period could be understated or overstated. The date on which certain services commence, the level of services performed on or before a given date, and the cost of services are often subject to our judgment. We make these judgments based upon the facts and circumstances known to us in accordance with accounting principles generally accepted in the U.S.

Warrants. We have issued common stock warrants in connection with the execution of certain equity and debt financings and consulting agreements. Certain warrants are accounted for as derivative liabilities at fair value. Such warrants do not meet the criteria that a contract should not be considered a derivative instrument if it is (1) indexed to its own stock and (2) classified in stockholders equity. Changes in fair value of derivative liabilities are recorded in the consolidated statement of operations under the caption Change in fair value of warrant liabilities. Warrants that are not considered derivative liabilities are accounted for at fair value at the date of issuance in additional paid-in capital. The fair value of warrants is determined using the Black-Scholes option-pricing model using assumptions regarding volatility of our common share price, remaining life of the warrant, and risk-free interest rates at each period end.

Stock-Based Compensation. Through December 31, 2005, we accounted for stock-based compensation to employees and non-employee directors under the intrinsic value method under which no compensation expense was recognized for stock options granted at fair market value and with fixed terms. On January 1, 2006, we adopted rules requiring companies to recognize stock-based compensation awards as compensation expense on a fair value method. These rules were adopted using the modified prospective method, which applied the rules to the consolidated financial statements on a going-forward basis. Under the fair value recognition provisions, stock-based compensation cost is measured at the grant date based on the fair value of the award and is recognized as expense over the service period, which generally represents the vesting period. For awards that have performance based vesting conditions we recognize the expense over the estimated period that the awards are expected to be earned. We use the Black-Scholes option-pricing model to calculate the grant date fair value of stock options. The expense recognized over the service period is required to include an estimate of the awards that will be forfeited. Previously, we recorded the impact of forfeitures as they occurred.

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Recent Accounting Pronouncements

In June 2009, the Financial Accounting Standards Board (FASB) issued the FASB Accounting Standards Codification (the Codification) as the single source of authoritative U.S. GAAP recognized by the FASB to be applied by nongovernmental entities in preparation of financial statements in conformity with U.S. GAAP. While the adoption of the Codification as of September 30, 2009 changes how the Company references accounting standards, the adoption did not have an impact on its financial position, results of operations, or cash flows.

On January 1, 2009, the principles and requirements for how an acquirer of a business recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, any noncontrolling interest in the acquiree and the goodwill acquired were revised. Disclosure requirements were also established, which will enable financial statement users to evaluate the nature and financial effects of business combinations. Among other things, the amendments to the accounting principles and requirements expand the definitions of a business and business combination, require recognition of contingent consideration at fair value on the acquisition date and require acquisition-related transaction costs to be expensed as incurred. The adoption of these amendments did not have a significant impact on the Company s financial position, results of operations, or cash flows.

On January 1, 2009, the Company adopted the fair value measurements and disclosures provisions for nonfinancial assets and nonfinancial liabilities, which were previously deferred. These provisions establish a framework for measuring fair value and expand financial statement disclosures about fair value measurements. Items to which these provisions apply include nonrecurring fair value measurements of nonfinancial assets and nonfinancial liabilities, or recurring fair value measurements of nonfinancial assets and nonfinancial liabilities, which are not disclosed at fair value in the consolidated financial statements. The Company did not have nonfinancial assets or nonfinancial liabilities covered by these provisions which required remeasurement upon adoption or during the year ended December 31, 2009, and therefore there was no impact of adoption on its financial position, results of operations, or cash flows.

On January 1, 2009, the Company adopted the accounting standard for ownership interests in subsidiaries held by parties other than the parent, which establishes accounting for the amount of consolidated net income attributable to the parent and to the noncontrolling interest, changes in a parent s ownership interest and the valuation of retained noncontrolling equity investments when a subsidiary is deconsolidated. This accounting standard also establishes reporting requirements that provide enhanced disclosures that clearly identify and distinguish between the interests of the parent and the interests of the noncontrolling owners. The impact of adopting this accounting standard on the Company s financial position, results of operations, and cash flows was not significant.

On January 1, 2009, the Company adopted amendments to the accounting standard addressing derivatives and hedging. The amendments change the disclosure requirements for derivative instruments and hedging activities, requiring enhanced disclosures about how and why an entity uses derivative instruments, how instruments are accounted for under U.S. GAAP, and how derivatives and hedging activities affect an entity s financial position, financial performance and cash flows. The adoption of these amendments required additional disclosure only, and therefore did not have an impact on the Company s financial position, results of operations, or cash flows.

On January 1, 2009, the Company adopted amendments to the accounting standard addressing intangibles, goodwill and other assets. The amendments provided new guidance to improve the consistency between the useful life of a recognized intangible asset and the period of expected cash flows used to measure the fair value of the asset under U.S. GAAP. The adoption of these amendments did not have a significant impact on the Company s financial position, results of operations, or cash flows.

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On June 30, 2009, the Company adopted amendments to the accounting standard for financial instruments. The amendments require disclosures about the fair value of financial instruments in interim as well as in annual financial statements. The adoption of these amendments has resulted in additional disclosures only in the Company s interim financial statements, and therefore did not impact its financial position, results of operations or cash flows.

On June 30, 2009, the Company adopted amendments to the accounting standard addressing subsequent events. The amendments provide guidance to establish general standards of accounting for and disclosures of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. The amendments require entities to disclose the date through which subsequent events were evaluated as well as the rationale for why that date was selected. This disclosure should alert all users of financial statements that an entity has not evaluated subsequent events after that date in the set of financial statements being presented. The amendments required additional disclosures only, and therefore did not have an impact on our financial position, results of operations, or cash flows. The Company has evaluated events and transactions that occurred between December 31, 2009 and March 12, 2010, which is the date the consolidated financial statements were issued, for possible disclosure and recognition in the financial statements.

Item 8. ***Financial Statements and Supplementary Data***

The financial statements required by this item are attached to this Annual Report on Form 10-K beginning on Page F-1.

Item 9. ***Changes In and Disagreements with Accountants on Accounting and Financial Disclosure***

None.

Item 9A. ***Controls and Procedures***

(a) Evaluation of Disclosure Controls and Procedures

As required by Rule 13a-15 under the Securities Exchange Act of 1934, as of the end of the period covered by this Annual Report, we carried out an evaluation, under the supervision and with the participation of our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of our disclosure controls and procedures as of December 31, 2009. Our management has concluded, based on their evaluation, our disclosure controls and procedures were effective as of December 31, 2009 to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission s rules and forms.

(b) Management s Annual Report on Internal Control Over Financial Reporting

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting. As defined in Rule 13a-15(f) under the Exchange Act, internal control over financial reporting is a process designed by, or under the supervision of, a company s principal executive and principal financial officers and effected by a company s board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. It includes those policies and procedures that:

a) Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of a company;

b) Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of a company are being made only in accordance with authorizations of management and the board of directors of the company; and

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c) Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of a company s assets that could have a material effect on its financial statements.

Because of the inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

The Company s management has used the criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO, to evaluate the effectiveness of the Company s internal control over financial reporting. Management has selected the COSO framework for its evaluation as it is a control framework recognized by the SEC and the Public Company Accounting Oversight Board, that is free from bias, permits reasonably consistent qualitative and quantitative measurement of the Company s internal controls, is sufficiently complete so that relevant controls are not omitted, and is relevant to an evaluation of internal controls over financial reporting.

Management conducted an evaluation of internal controls based on the COSO framework. The evaluation included a full scale, documented risk assessment, based on the principles described in the framework, and included identification of key controls. Management completed documentation of its testing to verify the effectiveness of the key controls. Based on the evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2009.

This annual report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Our management s report was not subject to attestation by our independent registered public accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permit us to provide only our management s report in this annual report.

(c) Changes in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting that occurred during the fourth quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. ***Other Information***

None.

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PART III

Item 10. ***Directors, Executive Officers and Corporate Governance***

The information required by this Item will be contained in our definitive Proxy Statement to be filed with the Securities and Exchange Commission, or SEC, in connection with our 2010 Annual Meeting of Stockholders which is scheduled to be held on May 25, 2010 (the 2010 Proxy Statement) under the captions Election of Directors, Board of Directors Meetings and Committees of the Board, Executive Officers and Section 16(a) Beneficial Ownership Reporting Compliance and is incorporated herein by reference.

We have adopted a Code of Ethics that applies to all our directors, officers and employees. The Code of Ethics is publicly available on our website at www.pro-pharmaceuticals.com. Amendments to the Code of Ethics and any grant of a waiver from a provision of the Code of Ethics requiring disclosure under applicable SEC rules will be disclosed on our website.

Item 11. ***Executive Compensation***

The information required by this Item will be incorporated by reference from the information under the caption Compensation of Named Executive Officers contained in our 2010 Proxy Statement.

Item 12. ***Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters***

The information required by this item will be incorporated by reference from the information under the caption Security Ownership of Certain Beneficial Owners and Management contained in our 2010 Proxy Statement.

Item 13. ***Certain Relationships, Related Transactions and Director Independence***

The information required by this item will be incorporated by reference from the information under the caption Certain Relationships and Related Transactions contained in our 2010 Proxy Statement.

Item 14. ***Principal Accounting Fees and Services***

The information required by this item will be incorporated by reference from the information under the captions Audit Fees , Audit-Related Fees, Tax Fees, All Other Fees and Pre-Approval Policies and Procedures contained in our 2010 Proxy Statement.

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PART IV

Item 15. ***Exhibits and Financial Statement Schedules***

(a) 1. Consolidated Financial Statements

The Consolidated Financial Statements are filed as part of this report.

2. Consolidated Financial Statement Schedules

All schedules are omitted because of the absence of conditions under which they are required or because the required information is included in the Consolidated Financial Statements or notes thereto.

3. Exhibits

Exhibit Number	Description of Document	Note Reference
3.1	Articles of Incorporation of Pro Pharmaceuticals, Inc., dated January 23, 2001, as filed with the Secretary of State of the State of Nevada.	1
3.2	Certificate of Amendment to Articles of Incorporation of Pro Pharmaceuticals, Inc., as filed with the Secretary of State of the State of Nevada on May 28, 2004.	2
3.3	Certificate of Designation of Preferences, Rights and Limitations of Series A 12% Convertible Preferred Stock of Pro Pharmaceuticals, Inc., as filed with the Secretary of State of the State of Nevada on October 5, 2007.	3
3.4	Certificate of Amendment to Articles of Incorporation of Pro Pharmaceuticals, Inc., as filed with the Secretary of State of the State of Nevada on May 29, 2008.	4
3.5	Certificate of Designation of Preferences, Rights and Limitations of Series B-1 Convertible Preferred Stock and Series B-2 Convertible Preferred Stock of Pro Pharmaceuticals, Inc., as filed with the Secretary of State of the State of Nevada on February 11, 2009.	5
3.6	Certificate of Amendment to Articles of Incorporation of Pro Pharmaceuticals, Inc., as filed with the Secretary of State of the State of Nevada on May 27, 2009.	24
3.7	Certificate of Amendment to the Certificate of Designation of Preferences, Rights and Limitations of Series B-1 Convertible Preferred Stock and Series B-2 Convertible Preferred Stock of Pro-Pharmaceuticals, Inc., as filed with the secretary of State of the State of Nevada on August 12, 2009.	25
3.8	Certificate of Amendment No. 2 to the Certificate of Designation of Preferences, Rights and Limitations of Series B-1 Convertible Preferred Stock and Series B-2 Convertible Preferred Stock, as filed with the State of Nevada, on February 17, 2010.	26
3.9	Amended and Restated Bylaws of Pro Pharmaceuticals, Inc.	6
3.10	Amendment to Amended and Restated Bylaws of Pro-Pharmaceuticals, Inc.	7
4.1	Specimen certificate for shares of common stock of registrant.	8
4.2	Form of Class A-1 Common Stock Purchase Warrant	5

4.3	Form of Class A-2 Common Stock Purchase Warrant	5
4.4	Form of Class B Common Stock Purchase Warrant	5
10.1	Pro-Pharmaceuticals, Inc. 2001 Stock Incentive Plan.	9

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Exhibit Number	Description of Document	Note Reference
10.2	Pro-Pharmaceuticals, Inc. 2003 Non-employee Director Stock Incentive Plan.	10
10.3	Employment Agreement, effective January 2, 2004, between Pro Pharmaceuticals, Inc. and David Platt.	11
10.4	Form of Incentive Stock Option Agreement (under the 2001 Stock Incentive Plan).	12
10.5	Form of Non-Qualified Stock Option Agreement (under the 2001 Stock Incentive Plan).	12
10.6	Form of Non-Qualified Stock Option Agreement (under the 2003 Non-Employee Director Stock Incentive Plan).	12
10.7	Form of 7% Convertible Debenture issued on February 14, 2006.	13
10.8	Securities Purchase Agreement dated February 14, 2006, among Pro-Pharmaceuticals, Inc. and the Purchasers named therein.	13
10.9	Registration Rights Agreement dated February 14, 2006, among Pro-Pharmaceuticals, Inc. and the Purchasers named therein.	13
10.10	Form of Common Stock Purchase Warrant issued on February 14, 2006.	13
10.11	Office Lease Agreement dated May 2, 2006 between NS 5/27 Acquisition LLC, landlord, and Pro Pharmaceuticals, Inc., tenant.	14
10.12	Waiver and Exchange Agreement dated March 21, 2007.	15
10.13	Employment Agreement effective October 1, 2007 between Theodore D. Zucconi, President, and Pro Pharmaceuticals, Inc.	16
10.14	Employment Agreement dated May 1, 2003 between Anthony D. Squeglia, and Pro-Pharmaceuticals, Inc. filed upon succession as Chief Financial Officer effective October 1, 2007.	17
10.15	Form of Securities Purchase Agreement for units of Series A 12% Convertible Preferred Stock and Common Stock Purchase Warrants.	3
10.16	Form of Registration Rights Agreement entered into pursuant to Securities Purchase Agreement identified as Exhibit 10.15	3
10.17	Form of Common Stock Purchase Warrant issued pursuant to Securities Purchase Agreement identified as Exhibit 10.15.	3
10.18	Form of Common Stock Purchase Warrant issued pursuant to Securities Purchase Agreement identified as Exhibit 10.15.	3
10.19	Amended and Restated Employment Agreement dated December 20, 2007 between Anthony D. Squeglia and Pro Pharmaceuticals, Inc.	18
10.20	Amended and Restated Employment Agreement dated December 19, 2007 between Theodore D. Zucconi and Pro Pharmaceuticals, Inc.	19
10.21	Securities Purchase Agreement dated February 14, 2008 between Pro Pharmaceuticals, Inc. and Alpha Capital, Rockmore Investment Master Fund, Ltd., Iroquois Master Fund, Ltd., Cranshire Capital, L.P., Hudson Bay Fund, L.P., Hudson Bay Overseas Fund, Ltd., Truk International Fund, L.P., Truk Opportunity Fund, LLC, ICM Business Trust, Ionic Capital Master Fund, Ltd., Highbridge Capital Management, LLC, Portside Growth & Opportunity Fund, Millenium Partners, L.P., Peter Hauser, Peter L. Hauser IRA, Enable Growth Partners L.P., George Macricostas, CAMOFI Master LDC, Cougar Trading, LLC, Brio Capital L.P., Fairfield Investments.	20

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Exhibit Number	Description of Document	Note Reference
10.22	Form of Common Stock Purchase Warrant issued on February 25, 2008.	20
10.23	Placement Agent Agreement dated February 12, 2008 between Maxim Group LLC and Pro Pharmaceuticals, Inc.	20
10.24	Amended and Restated Employment Agreement dated January 23, 2009 between Anthony D. Squeglia and Pro Pharmaceuticals, Inc.	21
10.25	Amended and Restated Employment Agreement dated January 23, 2009 between Maureen Foley and Pro Pharmaceuticals, Inc.	21
10.26	License Agreement dated November 25, 2008, as amended by letter dated December 15, 2008, between Pro Pharmaceuticals, Inc. and Medi-Pharmaceuticals, Inc.	22
10.27	Securities Purchase Agreement dated February 12, 2009 between Pro Pharmaceuticals, Inc. and 10X Fund, L.P.	5
10.28	Form of Class A-1 Common Stock Purchase Warrant issued in connection with Securities Purchase Agreement identified as Exhibit 10.27.	5
10.29	Form of Class A-2 Common Stock Purchase Warrant issued in connection with Securities Purchase Agreement identified as Exhibit 10.27.	5
10.30	Form of Class B Common Stock Purchase Warrant issued in connection with Securities Purchase Agreement identified as Exhibit 10.27.	5
10.31	Promissory Note dated February 12, 2009 issued by Pro Pharmaceuticals, Inc. in favor of 10X Fund, L.P.	5
10.32	Security Agreement dated February 12, 2009 between Pro Pharmaceuticals, Inc. and 10X Fund, L.P.	5
10.33	Escrow Agreement dated February 12, 2009 among Pro Pharmaceuticals, Inc., 10X Fund, L.P. and Investment Law Group of Gillett, Mottern & Walker, LLP, as Escrow Agent.	5
10.34	Registration Rights Agreement dated February 12, 2009 between Pro Pharmaceuticals, Inc. and 10X Fund, L.P.	5
10.35	Technology Transfer and Sharing Agreement dated February 12, 2009 between Pro Pharmaceuticals, Inc. and Medi-Pharmaceuticals, Inc.	5
10.36	Consulting Agreement dated February 12, 2009 between Pro Pharmaceuticals, Inc. and Medi-Pharmaceuticals, Inc.	5
10.37	Separation Agreement dated February 12, 2009 between Pro Pharmaceuticals, Inc. and David Platt, Ph.D.	5
10.38	Pro-Pharmaceuticals, Inc. 2009 Incentive Compensation Plan.	5
10.39	Form of Restricted Stock Grant Agreement (under the 2009 Incentive Compensation Plan).	23
10.40	Form of Non-Qualified Stock Option Grant Agreement (under the 2009 Incentive Compensation Plan).	23
10.41	Form of Incentive Stock Option Grant Agreement (under the 2009 Incentive Compensation Plan).	23
10.42	Employment Agreement dated May 21, 2009 between Theodore D. Zucconi, Ph.D. and Pro-Pharmaceuticals, Inc.	24

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Exhibit Number	Description of Document	Note Reference
10.43	Letter Agreement with 10X Fund, LP dated August 11, 2009.	25
10.44	Agreement with the 10X Fund L.P., dated February 11, 2010.	26
21.1*	Subsidiaries of Pro Pharmaceuticals, Inc.	
23.1*	Consent of Caturano and Company, PC, an independent registered public accounting firm.	
31.1*	Certification Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934.	
31.2*	Certification Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934.	
32.1**	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	
32.2**	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	

* Filed herewith.

** Furnished herewith and not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

1. Incorporated by reference to the Company s Registration Statement on Form 10-SB, as filed with the Commission on June 13, 2001.
2. Incorporated by reference to the Company s Quarterly Report on Form 10-Q filed with the Commission on August 16, 2004.
3. Incorporated by reference to the Company s Current Report on Form 8-K filed with the Commission on October 9, 2007.
4. Incorporated by reference to the Company s Current Report on Form 8-K filed with the Commission on June 2, 2008.
5. Incorporated by reference to the Company s Current Report on Form 8-K filed with the Commission on February 18, 2009.
6. Incorporated by reference to the Company s Current Report on Form 8-K filed with the Commission on December 17, 2007.
7. Incorporated by reference to the Company s Current Report on Form 8-K filed with the Commission on April 14, 2008.
8. Incorporated by reference to the Company s Registration Statement on Form S-1 (File No. 333-155491), as filed with the Commission on November 19, 2008.
9. Incorporated by reference to the Company s Quarterly Report on Form 10-QSB for the quarter ended September 30, 2001 filed with the Commission on November 14, 2001.
10. Incorporated by reference to the Company s Registration Statement on Form S-8, as filed with the Commission on October 22, 2003.
11. Incorporated by reference to the Company s Annual Report on Form 10-K for the fiscal year ended December 31, 2003, as filed with the Commission on March 30, 2004.
12. Incorporated by reference to the Company s Quarterly Report on Form 10-Q for the period ended September 30, 2004 as filed with the Commission on November 19, 2004.
13. Incorporated by reference to the Company s Current Report on Form 8-K as filed with the Commission on February 15, 2006.
14. Incorporated by reference to the Company s Current Report on Form 8-K as filed with the Commission on May 5, 2006.
15. Incorporated by reference to the Company s Current Report on Form 8-K as filed with the Commission on March 21, 2007.

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16. Incorporated by reference to the Company s Current Report on Form 8-K as filed with the Commission on September 27, 2007.
17. Incorporated by reference to the Company s Current Report on Form 8-K as filed with the Commission on October 4, 2007.
18. Incorporated by reference to the Company s Current Report on Form 8-K as filed with the Commission on December 21, 2007.
19. Incorporated by reference to the Company s Current Report on Form 8-K as filed with the Commission on December 26, 2007.
20. Incorporated by reference to the Company s Current Report on Form 8-K as filed with the Commission on February 19, 2008.
21. Incorporated by reference to the Company s Current Report on Form 8-K as filed with the Commission on January 23, 2009.
22. Incorporated by reference to Amendment No. 1 to the Company s Registration Statement on Form S-1 (File No. 333-155491), as filed with the Commission on February 2, 2009.
23. Incorporated by reference to the Company s Annual Report on Form 10-K as filed with the Commission on March 30, 2009.
24. Incorporated by reference to the Company s Current Report on Form 8-K filed with the Commission on May 28, 2009.
25. Incorporated by reference to the Company s Quarterly Report on Form 10-Q for the period ended June 30, 2009 as filed with the Commission on August 14, 2009.
26. Incorporated by reference to the Company s Current Report on Form 8-K as filed with the Commission on February 17, 2010.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on March 12, 2010.

PRO-PHARMACEUTICALS, INC.

By: /s/ Theodore D. Zucconi
Name: Theodore D. Zucconi, Ph.D.
Title: Chief Executive Officer and President

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Theodore D. Zucconi	Chief Executive Officer, President and Director	March 12, 2010
Theodore D. Zucconi, Ph.D.		
/s/ Anthony D. Squeglia	Chief Financial Officer	March 12, 2010
Anthony D. Squeglia		
/s/ James C. Czirr	Executive Chairman and Director	March 12, 2010
James C. Czirr		
/s/ Rod D. Martin	Vice-Chairman and Director	March 12, 2010
Rod D. Martin		
/s/ Arthur A. Greenberg	Director	March 12, 2010
Arthur A. Greenberg		
/s/ S. Colin Neill	Director	March 12, 2010
S. Colin Neill		
/s/ Steven Prelack	Director	March 12, 2010
Steven Prelack		
/s/ Gilbert F. Amelio	Director	March 12, 2010
Gilbert F. Amelio		
/s/ Peter Traber	Director	March 12, 2010
Peter Traber, M.D.		

/s/ JERALD K. ROME	Director	March 12, 2010

Jerald K. Rome

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Pro-Pharmaceuticals, Inc.

(A Development Stage Company)

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4.	Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders Deficit for the years ended December 31, 2009 and 2008 and for the cumulative period from inception (July 10, 2000) to December 31, 2009	F-4
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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of Pro-Pharmaceuticals, Inc.

Newton, Massachusetts

We have audited the accompanying consolidated balance sheets of Pro-Pharmaceuticals, Inc. and subsidiary (a development stage company) (the Company) as of December 31, 2009 and 2008, and the related consolidated statement of operations, changes in redeemable convertible preferred stock and stockholders deficit, and cash flows for the years then ended, and for the period from inception (July 10, 2000) to December 31, 2009. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2009 and 2008, and the consolidated results of their operations and their cash flows for the years then ended, and for the period from inception (July 10, 2000) to December 31, 2009 in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company s recurring losses from operations and stockholders deficit raise substantial doubt about its ability to continue as a going concern. Management s plans concerning these matters are also discussed in Note 1 to the consolidated financial statements. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

As discussed in Note 8 to the financial statements, the Company changed the manner in which it accounts for certain warrants effective January 1, 2009.

/s/ Caturano and Company, P.C.

Boston, Massachusetts

March 12, 2010

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PRO-PHARMACEUTICALS, INC.

(A Development-Stage Company)

CONSOLIDATED BALANCE SHEETS

	December 31, 2009	2008
	(in thousands)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 251	$ 318
Prepaid expenses and other current assets	53	62
Total current assets	304	380
Property and equipment, net	17	40
Restricted cash	59	59
Intangible assets, net	56	225
Total assets	$ 436	$ 704
LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS DEFICIT		
Current liabilities:		
Accounts payable	$ 221	$ 447
Accrued expenses	779	380
Accrued dividends payable	52	52
Advances received for equity consideration		200
Total current liabilities	1,052	1,079
Warrant liabilities	1,633	55
Other long-term liabilities	304	39
Total liabilities	2,989	1,173
Commitments and contingencies (Note 12)		
Series B-1 12% redeemable convertible preferred stock; 900,000 shares authorized, issued and outstanding at December 31, 2009 and none at December 31, 2008, redemption value: $1,800,000, liquidation value: $1,800,000 at December 31, 2009	1,270	
Series B-2 12% redeemable convertible preferred stock; 2,100,000 shares authorized, 1,330,000 issued and outstanding at December 31, 2009 and none at December 31, 2008, redemption value: $2,660,000, liquidation value of $2,660,000 at December 31, 2009	644	
Stockholders deficit:		
Series A 12% convertible preferred stock; 5,000,000 shares authorized, 1,642,500 and 1,742,500 issued and outstanding at December 31, 2009 and 2008, respectively	664	704
Common stock, $0.001 par value; 300,000,000 and 200,000,000 shares authorized at December 31, 2009 and 2008, respectively, 51,742,090 and 48,052,159 issued and outstanding at December 31, 2009 and 2008, respectively	52	48

Additional paid-in capital	42,532	37,329
Deficit accumulated during the development stage	(47,715)	(38,550)
Total stockholders deficit	(4,467)	(469)
Total liabilities, redeemable convertible preferred stock and stockholders deficit	$ 436	$ 704

See notes to consolidated financial statements.

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PRO-PHARMACEUTICALS, INC.

(A Development-Stage Company)

CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,		Cumulative from inception (July 10, 2000) to December 31, 2009
	2009	2008	
	(in thousands, except per share amounts)		
Operating expenses:			
Research and development	$ 1,110	$ 1,774	$ 18,465
General and administrative	4,983	3,552	30,990
Total operating expenses	6,093	5,326	49,455
Total operating loss	(6,093)	(5,326)	(49,455)
Other income and (expense):			
Interest income	3	30	770
Interest expense			(4,451)
Change in fair value of convertible debt instrument			(3,426)
Change in fair value of warrant liabilities	(1,374)	2,145	10,787
Other income	2		2
Total other income (expense)	(1,369)	2,175	3,682
Net loss	$ (7,462)	$ (3,151)	$ (45,773)
Series A 12% preferred stock dividend	(209)	(239)	(448)
Series B-1 12% preferred stock dividend	(204)		(204)
Series B-2 12% preferred stock dividend	(137)		(137)
Series B preferred stock accretion	(1,280)		(1,280)
Accretion of Series B-2 beneficial conversion feature	(127)		(127)
Net loss applicable to common stockholders	$ (9,419)	$ (3,390)	$ (47,969)
Basic and diluted net loss per share			