

PRO PHARMACEUTICALS INC  
Form 10-K  
March 30, 2009  
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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, 2008

**.. 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**  
(State or other jurisdiction

of incorporation)

**7 Wells Avenue, Newton, Massachusetts**  
(Address of Principal Executive Offices)

**(617) 559-0033**

(Registrant's Telephone Number, Including Area Code)

**04-3562325**  
(I.R.S. Employer

Identification No.)

**02459**  
(Zip 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

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

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  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

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

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, 2008 was \$15.1 million.

The number of shares outstanding of the registrant's common stock as of March 30, 2009 was 50,252,159.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the definitive Proxy Statement for the 2009 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, 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 capital by June 2009, 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 carbohydrate-based therapeutics that we believe enhance existing cancer treatments. We believe our therapeutics could also be used in 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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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, D.V.M., Henry J. Esber, Ph.D. and James T. Gourzis, M.D. resigned from our Board of Directors. Theodore Zucconi, Ph.D., a director of the Company, 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.

Since our inception on July 10, 2000, our primary focus has been the development of a new generation of anticancer treatments using carbohydrate polymers which are aimed at increasing survival and improving the quality of life for cancer patients. Our lead product candidate, DAVANAT<sup>®</sup>, is a patented new chemical entity that we believe, when administered in combination with a chemotherapy, increases the efficacy while reducing adverse side effects of the chemotherapy. We hold the patent on DAVANAT<sup>®</sup>, which was invented by company founders David Platt, Ph.D., our former Chief Executive Officer, and Anatole Klyosov, Ph.D., our Chief Scientist.

In 2002, the Federal Drug Administration or FDA granted us an Investigational New Drug application, or IND, for use of DAVANAT<sup>®</sup> in combination with 5-fluorouracil, or 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<sup>®</sup> New Drug Application, or 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. We believe that using DAVANAT<sup>®</sup> 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<sup>®</sup> 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.

## **Background on Carbohydrates**

In order to function biologically, living organisms require the capability to recognize cellular information and trigger and perform biochemical reactions. Organisms as complex as human beings require systems with extraordinarily large capacity to recognize and translate information on a molecular level because of the tremendous number of different molecular messages that must be quickly and unambiguously deciphered, accepted or rejected. To accomplish this important task, a class of molecules capable of great variation in shape, orientation and composition is required. Carbohydrates serve this function in the body because they have the large range of structural properties, including linkage variations, branching and anomeric isomers, that enable them to provide the required cellular recognition capabilities. These complex molecules are also referred to as polysaccharides or complex sugars.

The particular role of carbohydrates, in this regard, is recognition of molecular information that triggers biological reactions. These activities include signal transmission, cell recognition, interaction and binding by other cells, hormones and viruses. Carbohydrates often accomplish this by working with lectins, which are carbohydrate binding proteins that exist on cells. Biological processes that involve lectin binding include a vast array of cell to cell interactions including infections, toxins and many physiological processes such as control and spread of metastasis, which is the spreading of disease from one part of the body to another and is an important feature of many cancers.

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### **Our Strengths and Strategies**

*Focus on novel therapeutic opportunities provided by carbohydrates.* We believe our company is one of the pioneers focused on development of carbohydrate-based therapeutics. As a result of their structural complexity, carbohydrates have not received as much scientific attention as nucleic acids and proteins, and are not as well understood. 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. Our team has conducted research in therapeutic application of carbohydrate-based therapeutics for approximately 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 this 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.

*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. In addition, our planned 505(b)(2) NDA utilizes a regulatory pathway that is less costly because it allows us to rely on previous FDA findings about safety and efficacy and to refer to data that has been previously published. These NDAs are often used for drugs involving previously-approved products, such as 5-FU. 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 a chemotherapy is a chemical compound, typically used in cancer treatment. Pre-clinical studies indicate that DAVANAT® and other proprietary carbohydrates 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 irinotecan, and biologics, such as Avastin®, so as to improve the clinical benefit to 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

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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<sup>®</sup> than when 5-FU is administered alone in the mice. Our pre-clinical and clinical trial data also show that DAVANAT<sup>®</sup> is tolerable, safe and non-toxic.

Our NDA for DAVANAT<sup>®</sup> will seek FDA approval for co-administration of DAVANAT<sup>®</sup> with 5-FU for intravenous injection for the treatment of colorectal cancer. We plan additional NDAs for DAVANAT<sup>®</sup> 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 carbohydrate-based 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 carbohydrate 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 carbohydrate compounds significantly 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<sup>®</sup>**

DAVANAT<sup>®</sup>, our lead product candidate in development, is a proprietary carbohydrate (polysaccharide) polymer comprised of mannose and galactose carbohydrates 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<sup>®</sup> is based upon interaction with lectins, which are cell surface proteins that bind only to a particular kind of carbohydrate. DAVANAT<sup>®</sup> is formulated to attach to specific lectins (Galectins), which are abundant on the surface of tumor cells, while selectively avoiding healthy tissue. We believe the structure of our carbohydrate is such that it is attracted to lectin receptors that are specific and over-expressed on cancer cells. The receptor effectively interacts with the carbohydrate and 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<sup>®</sup>*

Our pre-clinical studies demonstrate that DAVANAT<sup>®</sup> when used in combination with chemotherapies, such as 5-FU and irinotecan, and biologics, such as Avastin<sup>®</sup>, 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<sup>®</sup> was used in combination with standard therapies. These studies demonstrated that DAVANAT<sup>®</sup> could be used effectively with different chemotherapies and biologics.



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*Clinical Trial Development of DAVANAT®*

Results from our Phase II clinical trial data to date 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<sup>2</sup>) 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.

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

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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.

Please see **Risks Related to our Company** We have one 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, 2008, 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 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.

Please see **Risks Related to our Company** We are a counterclaim defendant in a lawsuit instituted by our former Chief Executive Officer and **Risks Related to the Drug Development Industry** Our competitive position depends on protection of our intellectual property for additional discussion of risks related to protection of our intellectual property based on inventions.

## **Research**

Our initial focus is on the design and analysis of carbohydrate-based compounds 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 approximately \$17.4 million for the cumulative period from inception (July 10, 2000) through December 31, 2008. During the year ended December 31, 2008, and 2007, our expenditures for research and development were approximately \$1.77 million and \$2.05 million, respectively.

On October 31, 2008, our board of directors authorized Medi-Pharmaceuticals, Inc., a Nevada corporation and then our wholly-owned subsidiary, to enter into a joint venture to deploy certain technology we own, as well as original technology to be developed by the joint venture, for use in nutraceutical cardiovascular therapies. This deployment was accomplished by: (i) a merger of FOD Enterprises, Inc., a Nevada corporation, with and into

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Medi-Pharmaceuticals on November 25, 2008, following which Medi-Pharmaceuticals became the surviving corporation and we became the owner of 10% of the outstanding capital stock of Medi-Pharmaceuticals; and (ii) our entering into a license agreement with Medi-Pharmaceuticals dated November 25, 2008, and clarified by an amendment dated December 15, 2008. On February 12, 2009 we terminated the license agreement and entered into a Technology Transfer and Sharing Agreement, or Sharing Agreement, with Medi-Pharmaceuticals. Under the terms of the Sharing Agreement, we and Medi-Pharmaceuticals agreed that we would not work in the area of polysaccharides in heart disease for a period of five years without the consent of Medi-Pharmaceuticals and Medi-Pharmaceuticals will not work in the area of polysaccharides in oncology and liver/kidney fibrosis for a period of five years without our consent. Pursuant to the Sharing Agreement we licensed to Medi-Pharmaceuticals in perpetuity all items of intellectual property owned by us with respect to the use of polysaccharides for heart indications. Further, we granted Medi-Pharmaceuticals access to all of our intellectual property in the area of fibrotic tissue in applications other than liver/kidney fibrosis and Medi-pharmaceuticals granted us access to all intellectual property in the area of kidney/lever fibrosis.

## **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 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 carbohydrate-based platforms. Several companies, such as Momenta Pharmaceuticals Inc., are developing carbohydrate technologies and sequencing of complex sugars 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.

Please see 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.

## **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.

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### *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.

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

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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.

Please see *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.

### *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.

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### *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, 2008, we had eight full-time employees, three of whom were involved primarily in management of our pre-clinical research and development and clinical trials and five of whom were involved primarily in financial management and administration of our company. We also had two part-time contractors, one of whom provides financial management services and the other 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.

*We have incurred net losses to date and must raise additional capital by June 2009 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, 2008 was approximately \$38.6 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.

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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 approximately \$900,000 of unrestricted cash as of March 20, 2009, we believe that we have sufficient cash to meet our financial and operating obligations into June 2009. We will require more cash to fund our operations. 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 must raise additional cash by June 2009, which may include one or more subsequent closings under the Series B Preferred Stock purchase agreement entered into on February 12, 2009, or we may not be able to continue operations and may be forced to seek bankruptcy protection.

***We are 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, our former Chief Executive Officer, filed a lawsuit in Massachusetts against GlycoGenesys, Inc. for claims including breach of contract. GlycoGenesys subsequently named us as a counterclaim defendant alleging, among other things, tortious interference and misappropriation of proprietary rights, and sought monetary damages and injunctive relief related to our intellectual property. We and Dr. Platt are contesting these counterclaims vigorously. In October 2006, Marlborough Research and Development, Inc. (now known as Prospect Therapeutics, Inc.) purchased certain assets including this lawsuit from the GlycoGenesys bankruptcy estate and continue prosecuting the counterclaims against us and Dr. Platt. Concluding that certain disputes of fact could not be resolved as a matter of law, the court on May 27, 2008 denied our motion for summary judgment. Prospect Therapeutics informed the Court that it does not seek monetary damages other than recovery of attorney fees. On December 12, 2008, in response to a motion for withdrawal by counsel in this case, the court amended its order dated October 6, 2008 to state that by January 9, 2009, a default judgment will be entered against us if new defense counsel has not entered an appearance on our behalf or we have not restored our relationship with our current counsel. On January 7, 2009, our successor counsel entered a notice of appearance to represent us at trial which commenced on March 10, 2009. If we do not prevail at trial, we could be prevented from the exclusive use of the intellectual property that is the subject of the litigation and accordingly there could be a material adverse impact on our financial position, results of operations and cash flows.

***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 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. However, if we were to receive an adverse decision, we might be required to pay cash damages to Summer Street which would have a material adverse effect on our financial position.



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### ***Our drug candidates are based on novel unproven technologies.***

Our drug candidates in development are based on novel unproven technologies using proprietary carbohydrate compounds in combination with FDA approved drugs currently used in the treatment of cancer and other diseases. Carbohydrates are difficult to synthesize, and we may not be able to synthesize carbohydrates that would be usable as target delivery vehicles for the anti-cancer drugs we are working with or other therapeutics we intend to develop.

### ***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 our 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.

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.

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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 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.

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*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., 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.

*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,



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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 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

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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 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

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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 and only recently began to be 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. We cannot predict how liquid a market for our stock will be developed on the 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 10,000,000 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 1,742,500 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 issued and outstanding, and Series B-2 preferred stock, comprised of 2,100,000 of which none are outstanding. 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. In addition, the Board has authority to designate the remaining 2,000,000 shares in one or more series with conversion or voting rights, such as multiple votes per share, the result of which could adversely affect the voting rights of holders of 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 200,000,000 shares of common stock, of which 48,052,159 shares were issued and outstanding on December 31, 2008. We have reserved 13,742,500 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, and 66,056,811 shares for issuance upon exercise of our outstanding stock options and warrants. If all of these securities were converted or exercised, a total of approximately 128,000,000 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 approximately 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***

In January 2004, David Platt, Ph.D., our former Chairman and Chief Executive Officer, filed a lawsuit in Massachusetts Superior Court against GlycoGenesys, Inc. for various claims including breach of contract. GlycoGenesys subsequently asserted counterclaims against us and Dr. Platt alleging tortious interference, misappropriation of proprietary rights, defamation and unfair competition, and sought monetary and injunctive relief related to our intellectual property. In October 2006, Prospect Therapeutics, Inc. (formerly known as Marlborough Research and Development, Inc.) purchased selected assets including this lawsuit from the GlycoGenesys bankruptcy estate and continues prosecuting the counterclaims against us and Dr. Platt. Concluding that certain disputes of fact could not be resolved as a matter of law, the court on May 27, 2008 denied our motion for summary judgment. Prospect Therapeutics informed the court that it does not seek monetary damages other than recovery of attorney fees. In response to a motion for withdrawal by counsel in this case, the court on December 12, 2008, amended its order dated October 6, 2008, to state that by January 9, 2009, a default judgment will be entered against us if new defense counsel has not entered an appearance on our behalf or we have not restored our relationship with our current counsel. On January 7, 2009, our successor counsel entered a notice of appearance to represent us at trial which commenced on March 10, 2009. We believe the lawsuit is without merit and intend to contest it vigorously.



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In January 2005, we filed a request with the U.S. Patent and Trademark Office for an inter partes re-examination of U.S. Patent No. 6,680,306 now owned by Prospect Therapeutics, Inc. because we believe that the invention claimed in this patent is anticipated by other inventions (technically, prior art), including our U.S. Patent No. 6,645,946 for DAVANAT. The Patent Office has agreed with our argument throughout the re-examination that all claims stated in the 306 patent are anticipated by prior art. We believe that the actions of the Patent Office support our position that the invention claimed in the DAVANAT® patent is prior art.

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. *Submission of Matters to a Vote of Security Holders***

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

**Table of Contents****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 closing prices for our common stock as reported on the NYSE Alternext US, for the periods indicated below were as follows:

	High	Low
<b>Fiscal Year Ended December 31, 2008</b>		
First Quarter	\$ 0.70	\$ 0.26
Second Quarter	\$ 0.48	\$ 0.25
Third Quarter	\$ 0.39	\$ 0.17
Fourth Quarter	\$ 0.30	\$ 0.05
<b>Fiscal Year Ended December 31, 2007</b>		
First Quarter	\$ 1.39	\$ 0.25
Second Quarter	\$ 0.93	\$ 0.35
Third Quarter	\$ 0.72	\$ 0.31
Fourth Quarter	\$ 0.89	\$ 0.60

**Holder of Common Stock**

As of March 12, 2009, there were approximately 260 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 approximately 4,100 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.

In February 2009, we issued 900,000 shares of Series B-1 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 100% of the value weighted average price of our share price for the 20 consecutive trading days prior to the applicable dividend date; provided, however that there is an effective registration statement covering the shares of Common Stock (for dividend payments due on September 30, 2009 or later) and the issuance of shares does not trigger anti-dilution provisions under other agreements to which we are a party. 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***

**Overview**

We are a development-stage company engaged in the discovery and development of carbohydrate-based therapeutics that we believe enhance existing cancer treatments. We believe our therapeutics could also be used in 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 carbohydrate polymers which are aimed at increasing survival and improving the quality of life for cancer patients. Our lead product candidate, DAVANAT<sup>®</sup>, is a patented new chemical entity that we believe, when administered in combination with a chemotherapy, increases the efficacy while reducing adverse side effects of the chemotherapy. We hold the patent on DAVANAT<sup>®</sup>, which was invented by company founders David Platt, Ph.D., our former Chief Executive Officer, and Anatole Klyosov, Ph.D., our Chief Scientist.

In 2002, the FDA granted us an IND for use of DAVANAT<sup>®</sup> 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<sup>®</sup> in combination with 5-FU enables greater absorption of the chemotherapy in cancer cells while reducing its toxic side effects.

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

To date, DAVANAT<sup>®</sup> has been administered to approximately 100 cancer patients. Data from a Phase II trial for end-stage colorectal cancer patients showed that DAVANAT<sup>®</sup> 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.

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<sup>®</sup> than when 5-FU is administered alone in the mice. Our pre-clinical and clinical trial data also show that DAVANAT<sup>®</sup> is tolerable, safe and non-toxic.

In early 2007, in an effort to lower clinical development costs and accelerate the approval and commercialization of DAVANAT<sup>®</sup>, we chose a regulatory strategy known as a 505(b)(2) NDA. Our 505(b)(2) NDA for DAVANAT<sup>®</sup> will seek FDA approval for co-administration of DAVANAT<sup>®</sup> with 5-FU for intravenous injection for the treatment of colorectal cancer. These 505(b)(2) NDAs are often used for drugs involving previously-approved products and, as a result, are less costly to prepare and file with the FDA. Although we believe, based on the outcome of our clinical trials to date, that DAVANAT<sup>®</sup> when co-administered with 5-FU or biological drugs is superior to the current standard of care, we cannot in a 505(b)(2) NDA claim superiority over the current standard of care. We believe, however, that if and when our 505(b)(2) NDA is approved by the FDA, we are better positioned to attract a strategic partner with the resources to undertake the costly Phase III clinical trials required to produce the data on which to make a superiority claim. We plan to submit the 505(b)(2) NDA for DAVANAT<sup>®</sup>.

We also plan to file additional NDAs for DAVANAT<sup>®</sup> in combination with other chemotherapeutics and biologics. Biologics are therapeutic products based on materials derived from living materials.

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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 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 DMF for DAVANAT<sup>®</sup> to the FDA. This is an important step toward the filing of our DAVANAT<sup>®</sup> 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<sup>®</sup> because it demonstrates our ability to produce commercial quantities of pharmaceutical-grade DAVANAT<sup>®</sup> under 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<sup>®</sup> 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<sup>®</sup> as an adjuvant when administered with 5-FU. Adjuvants are pharmacological or immunological agents that modify the effect of other agents, such as drugs or vaccines. We also plan to file a Special Protocol Assessment (SPA), for the Phase III trial. The benefit of a successful SPA is that the FDA agrees that an uncompleted Phase III trial's design, clinical endpoints and statistical analyses are acceptable for FDA approval. As noted above, using the 505(b)(2) NDA regulatory pathway, which allows us to rely on previous FDA findings, is important to our near-term product development strategy because it enables us to lower the clinical development costs and accelerate the approval and commercialization of DAVANAT<sup>®</sup>.

On October 31, 2008, our board of directors authorized Medi-Pharmaceuticals, Inc. (Medi-Pharma), a Nevada corporation and then our wholly-owned subsidiary, to enter into a joint venture to deploy certain technology we own, as well as original technology to be developed by the joint venture, for use in nutraceutical cardiovascular therapies. This deployment was accomplished by: (i) a merger of FOD Enterprises, Inc., a Nevada corporation, with and into Medi-Pharma on November 25, 2008, following which Medi-Pharma became the surviving corporation and we became the owner of 10% of the outstanding capital stock of Medi-Pharma; and (ii) our entering into a license agreement with Medi-Pharma November 25, 2008, and clarified by an amendment dated December 15, 2008. Pursuant to the license agreement, we granted Medi-Pharma an exclusive, worldwide perpetual license to commercialize all of our polysaccharide technology exclusively in the field of cardiovascular therapies (both preventative and therapeutic) in exchange for a royalty equal to 10% of Medi-Pharma's net revenues from products sold based on the licensed technology. Medi-Pharm must advance \$1.0 million in cash to us by May 30, 2009 or we will have the ability to terminate the license agreement. On February 12, 2009 we terminated the license agreement and entered into a Technology Transfer and Sharing Agreement, or Sharing Agreement, with Medi-Pharma. Under the terms of the Sharing Agreement, we and Medi-Pharma agreed that we would not work in the area of polysaccharides in heart disease for a period of five years without the consent of Medi-Pharma and Medi-Pharma will not work in the area of polysaccharides in oncology and liver/kidney fibrosis for a period of five years without our consent. Pursuant to the Sharing Agreement we licensed to Medi-Pharma in perpetuity all items of intellectual property owned by us with respect to the use of polysaccharides for heart indications. Further, we granted Medi-Pharma access to all of our intellectual property in the area of fibrotic tissue in applications other than liver/kidney fibrosis and Medi-Pharma granted us access to all intellectual property in the area of kidney/lever fibrosis. At December 31, 2008, Medi-Pharma had no assets.

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

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January 9, 2009. On January 21, 2009 our common stock began trading on the OTC Bulletin Board under the symbol PRWP.OB .

**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, 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, useful lives of intangible assets and accrued liabilities. 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.

*Cash Flow.* Our financial statements have been prepared on a going concern basis with the assumption that we have sufficient cash on hand at March 30, 2009 to fund operations into June 2009 and that by June 2009 we will raise sufficient cash to continue operations.

*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.

*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.

*Convertible Debt Instrument.* Our convertible debt instrument issued in February 2006 (the Debentures ) constitutes a hybrid instrument that has the characteristics of a debt host contract containing several embedded derivative features that would require bifurcation and separate accounting as a derivative instrument pursuant to the provisions of Statement of Financial Accounting Standards ( SFAS ) No. 133, *Accounting for Derivative Instruments and Hedging Activities* ( SFAS 133 ). As permitted by SFAS No. 155, *Accounting for Certain Hybrid Financial Instruments an amendment of FASB Statements No. 133 and 140*, we irrevocably elected to initially and subsequently measure the Debentures in their entirety at fair value with changes in fair value recorded as either a gain or loss in the consolidated statement of operations under the caption Change in fair value of convertible debt instrument. Fair value of the Debentures is determined using a binomial financial valuation model that requires assumptions that are subject to significant management judgment such as volatility of our common share price, interest rates and our intention to redeem the Debentures in cash or common shares. Volatility and interest rate expectations are based on the remaining time to maturity of the Debentures.

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**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 in accordance with SFAS 133. Such warrants do not meet the criteria in paragraph 11(a) of SFAS 133 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 as defined in SFAS 133 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.

**Income Taxes.** We determine if our deferred tax assets and liabilities are realizable on an ongoing basis by assessing our valuation allowance and by adjusting the amount of such allowance, as necessary. At this time our primary deferred tax asset, which is fully reserved, relates to our net operating loss carryforwards. In the determination of the valuation allowance, we have considered future taxable income and the feasibility of tax planning initiatives. Should we determine that it is more likely than not that we will realize certain of our deferred tax assets for which we previously provided a valuation allowance, an adjustment would be required to reduce the existing valuation allowance. In addition, we operate within multiple taxing jurisdictions and are subject to audit in these jurisdictions. These audits may require an extended period of time for resolution. Although we believe that adequate consideration has been made for such issues, there is the possibility that the ultimate resolution of such issues could have an adverse effect on the results of our operations.

**Stock-Based Compensation.** Through December 31, 2005, we accounted for stock-based compensation to employees and non-employee directors under the intrinsic value method in accordance with Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees*, (APB No. 25) and the related interpretations. Under APB No. 25, no compensation expense is recognized for stock options granted to employees at fair market value and with fixed terms. On January 1, 2006, we adopted SFAS 123(R), *Share Based Payment*, (SFAS 123(R)) using the modified prospective method, which results in the provisions of SFAS 123(R) being applied to the consolidated financial statements on a going-forward basis. Prior periods have not been restated. SFAS 123(R) requires companies to recognize stock-based compensation awards granted to its employees as compensation expense on a fair value method. Under the fair value recognition provisions of SFAS 123(R), 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. The grant date fair value of stock options is calculated using the Black-Scholes option-pricing model. 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. We do not anticipate any awards will be forfeited in our calculation of compensation expense due to the limited number of employees that receive stock option grants and our historical employee turnover.

We consider equity compensation to be an important component in attracting and retaining key employees. During the years ended December 31, 2008 and 2007, we awarded approximately 1,130,000 and 1,048,500 stock options, respectively, to employees, consultants and non-employee members of our board of directors for normal services and we recorded approximately \$697,000, and \$616,000 of related stock option expense during the years ended December 31, 2008 and 2007, respectively.

**Results of Operations*****Fiscal Year Ended December 31, 2008 Compared to Fiscal Year Ended December 31, 2007***

**Research and Development Expenses.** Research and development expenses were approximately \$1,774,000 during the year ended December 31, 2008 as compared to approximately \$2,053,000 incurred during the year ended December 31, 2007. 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

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of employee payroll and general overhead allocable to research and development. We subdivide external expenses between clinical programs and preclinical 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<sup>®</sup> 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 year ended December 31, 2008, as compared to the year ended December 31, 2007 were as follows:

	Year Ended December 31, (\$000)	
	2008	2007
Direct external expenses		
Clinical programs	\$ 244	\$ 809
Pre-clinical activities	681	357
All other research and development expenses	849	887
	\$ 1,774	\$ 2,053

Clinical trial costs decreased by approximately \$565,000. The decrease is due principally to lower activity in the Phase II colorectal and biliary cancer trials as we focused on filing our DAVANAT<sup>®</sup> DMF with the FDA, as well as filing an IND and preparations for our NDA filing.

Pre-clinical expenses in 2008 increased by approximately \$324,000 compared to 2007. Of this amount, a \$402,000 increase was due to expense associated with filing our DMF. This increase was offset by approximately \$78,000 in lower activity related to all other research activities. Other research and development costs decreased by approximately \$38,000. Payroll expense decreased by approximately \$152,000 due principally to salary reductions. Stock based compensation increased by approximately \$127,000 and all other spending decreased by approximately \$13,000.

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 hence 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 believe 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 regulation or policy changes during our clinical trials or in the course of review of our clinical data. Please see *Risks Related to Our Company* and *Risks Related to the Drug Development Industry* for additional risks and other factors that make estimates difficult at this time. 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 Expenses.* General and administrative expenses were approximately \$3,552,000 in 2008, a decrease of approximately \$850,000 compared to approximately \$4,402,000 in 2007. 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 costs. Of the

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approximately \$850,000 decrease in expense in 2008, approximately \$666,000 was due to lower legal and accounting expenses, approximately \$135,000 was due to lower payroll expenses as salaries were reduced in an effort to conserve cash. Additionally, non-cash stock based compensation decreased by approximately \$46,000.

*Other Income and Expense.* Other income and expense was income of approximately \$2,175,000 in 2008 as compared to expense of approximately \$2,978,000 in 2007. Of the approximately \$5,153,000 increase, approximately \$4,875,000 was due to change in fair value accounting associated with our warrant liabilities and convertible debenture. Interest expense decreased by approximately \$350,000 as our convertible debenture was paid in full at the end of 2007. Interest income decreased by approximately \$72,000 due principally to lower cash balances.

## **Liquidity and Capital Resources**

As described above and elsewhere in this annual report on Form 10-K, we are a development stage company 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, 2008, we raised a total of \$41.2 million from these offerings and on February 12, 2009 we raised an additional \$1.5 million.

We believe our unrestricted cash on hand of approximately \$318,000 at December 31, 2008, when combined with the \$1.5 million we raised on February 12, 2009, will be sufficient to enable us to meet our financial and operating obligations into June 2009. 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 June 2009, which may include one or more subsequent closings under the Series B Preferred Stock purchase agreement entered into on February 12, 2009, or we may not be able to continue operations and may be forced to seek bankruptcy protection.

Net cash used in operations decreased by approximately \$818,000 to approximately \$4.7 million in 2008, as compared to \$5.5 million in 2007. Cash operating expenses decreased by approximately \$905,000 for the year ended December 31, 2008, and were offset by an increase in working capital needs of approximately \$307,000 and a decrease in interest income of approximately \$72,000. Cash interest expense decreased by approximately \$15,000.

Net cash provided by investing activities was approximately \$9,000 in 2008, as compared to approximately \$4.9 million in 2007. The decrease is due principally to the maturity of a \$5.0 million certificate of deposit in 2007. Approximately \$2,000 was used for purchase of plant and equipment in 2008, and approximately \$5,000 in 2007. No amount was used for patent costs in 2008 as compared to a use of approximately \$37,000 in 2007. Restricted cash decreased by approximately \$11,000 in 2008 and was an increase of approximately \$11,000 during the same period in 2007.

Cash provided by financing activities was approximately \$3.7 million in 2008 principally due to the sale of common stock and warrants in a transaction on February 25, 2008 as more fully described below, as compared to approximately \$1.1 million in 2007. In 2007, we raised approximately \$1.6 million from investors who subscribed to the sale of Series A Convertible Preferred Stock and Warrants on February 4, 2008, as more fully described below. This amount was offset by approximately \$0.5 million of payments related to our convertible debt instrument.

On February 25, 2008, we closed an offering resulting in net proceeds of approximately \$3.4 million from the sale of an aggregate of 7,500,000 shares of common stock at \$0.50 per share, (ii) warrants, with a term of five years, to purchase an aggregate of 7,500,000 shares of common stock at an exercise price of \$0.70 per share, and (iii) warrants, with a term of four months, to purchase an aggregate of 3,000,000 shares of common stock at an



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exercise price of \$0.67 per share. We also issued 206,250 warrants with an exercise price of \$0.70 and a term of 5 years to a placement agent in this transaction.

On February 4, 2008, we closed a private placement begun in October 2007 of Series A 12% convertible preferred stock and related warrants to accredited investors. In this transaction, we sold, at \$1.00 per unit, 1,742,500 units of securities, each unit comprised of (i) one share of Series A 12% convertible preferred stock, (ii) a Series A warrant to purchase one share of common stock for \$1.50, and (iii) a Series B warrant to purchase one share of common stock for \$2.00. Net proceeds from this transaction were approximately \$1.6 million. Approximately \$54,000 of the proceeds was received in 2008.

During 2008, we issued 300,000 warrants exercisable at \$1.00 per share with a term of three years in exchange for \$20,000. Also during 2008, we received \$200,000 for equity consideration to be determined at a later date.

On February 12, 2009, we entered into a securities purchase agreement pursuant to which we agreed to issue and sell to an investor at two or more closings, (i) 3,000,000 shares of our Series B convertible preferred stock with an aggregate stated value of \$6.0 million and convertible into 12,000,000 shares of our common stock and (ii) warrants to purchase 36,000,000 shares of our common stock. On February 12, 2009, the initial closing date under the purchase agreement, we issued and sold (i) 900,000 shares of Series B-1 preferred stock convertible into 3,600,000 shares of our common stock; (ii) Class A-1 warrants exercisable to purchase 1,800,000 shares of our common stock; (iii) Class A-2 warrants exercisable to purchase 1,800,000 shares of our common stock; and (iv) Class B warrants exercisable to purchase 7,200,000 shares of our common stock. Net proceeds from the closing of the initial tranche were approximately \$1.5 million. At one or more subsequent closings under the purchase agreement, we have agreed to issue: (i) up to 2,100,000 shares of Series B-2 preferred stock convertible into 8,400,000 shares of our common stock; (ii) Class A-1 warrants exercisable to purchase up to 4,200,000 shares of our common stock; (iii) Class A-2 warrants exercisable to purchase up to 4,200,000 shares of our common stock; and (iv) Class B warrants exercisable to purchase up to 16,800,000 shares of our common stock for an aggregate purchase price of up to \$4.2 million (less fees and expenses). The securities purchase agreement contains customary representations, warranties, covenants and closing conditions. Upon any subsequent closing under the securities purchase agreement, such representations and warranties must be accurate in all material respects, such covenants must have been performed and such closing conditions must have been satisfied or waived, including without limitation no material adverse effect having occurred with respect to us prior to any subsequent closing. We expect the subsequent closings under the purchase agreement to occur on or before June 15, 2009, which we refer to as the final purchase date. However, if the purchaser has purchased 350,000 or more shares of Series B-2 preferred stock (with a stated amount of \$700,000 or more) by May 13, 2009, then the final purchase date will be automatically extended until August 11, 2009.

The terms and conditions of the Series B-1 preferred stock and Series B-2 preferred stock are identical in all respects except with respect to our redemption rights. Such holders will be entitled to receive cumulative dividends at the rate of 12% per share per annum (compounding monthly) payable quarterly which may, at our option, be paid in cash or common stock valued per share at 100% of the value weighted average price per share for the 20 consecutive trading days prior to the applicable dividend payment date, provided that there is an effective registration statement covering the shares of our common stock (for dividend payments due on September 30, 2009 or later) and the issuance of the shares does not trigger anti-dilution provisions under other agreements to which we are a party. If we do not pay any dividend on the Series B preferred stock, dividends will accrue at the rate of 15% per annum (compounding monthly). Each share of Series B preferred stock is convertible into four shares of our common stock at the conversion price of \$0.50 per share (subject to customary anti-dilution protection adjustments) at the option of (i) the holder, at any time and (ii) us, at any time after February 12, 2010 (and upon 10 days notice) if our common stock is quoted at or above \$1.50 for 15 consecutive trading days and an effective registration statement regarding the underlying shares of common stock is in effect (subject to certain monthly volume limits). Upon notice of not less than 30 trading days, a holder of Series B preferred Stock may require us to redeem, in whole or in part, (i) the Series B-1 preferred stock at any time on or

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after March 12, 2010 and (ii) the Series B-2 preferred stock at any time on or after two years from the date of issuance of such shares of Series B-2 preferred stock. The redemption price will be equal to the sum of the stated value of the Series B preferred stock, plus all accrued but unpaid dividends thereon, as of the redemption date. If we fail for any reason to pay the redemption price in cash on the redemption date, then the holders of the Series B preferred stock requesting redemption may, at their sole option, automatically convert their shares of Series B preferred stock into a promissory note bearing interest at the rate of 15% per year and secured by a lien on all of our assets. So long as any shares of the Series B preferred stock remain outstanding, we are also subject to restrictions limiting, among other things, amendments to our organizational documents; the purchase or redemption of our capital stock; mergers, consolidations, liquidations and dissolutions; sales of assets; dividends and other restricted payments; investments and acquisitions; joint ventures, licensing agreements, exclusive marketing and other distribution agreements; issuances of securities; incurrence of indebtedness; incurrence of liens and other encumbrances and issuances of any common stock equivalents.

Each Class A-1 Warrant, Class A-2 Warrant and Class B Warrant is exercisable at \$0.50 per share of common stock (subject to customary anti-dilution protection adjustments) at any time on or after the date of issuance until the fifth anniversary of the respective issue date. We may, upon 30 days notice and so long as an effective registration statement regarding the underlying shares of common stock is in effect, issue a termination notice with respect to (i) each Class A-1 Warrant on any trading day on which the market value of the common stock for each of the 15 previous trading days exceeded \$1.25 per share (subject to customary anti-dilution protection adjustments) and (ii) each Class A-2 warrant on any trading day on which the market value of the common stock for each of the 15 previous trading days exceeded \$1.75 per share (subject to customary anti-dilution protection adjustments).

On August 11, 2006, we began a five year lease for office space which terminates on September 30, 2011. The lease provides for annual base rental payments of approximately \$235,000 in the first year increasing in each subsequent lease year to approximately \$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 office space lease, a commercial bank has issued a letter of credit collateralized by cash we have on deposit with the bank of approximately \$59,000. Additionally, we have a non-cancellable lease for a car which expires in January 2011.

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.

### ***Impact of New Accounting Standards***

In September 2006, the Financial Accounting Standards Board ( FASB ) issued SFAS No. 157, *Fair Value Measurements* ( SFAS No. 157 ). SFAS No. 157 clarifies the principle that fair value should be based on the assumptions market participants would use when pricing an asset or liability and establishes a fair value hierarchy that prioritizes the information used to develop those assumptions. Under the standard, fair value measurements are separately disclosed by level within the fair value hierarchy. In February 2008, the FASB

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decided that an entity need not apply this standard to non-financial assets and liabilities that are recognized or disclosed at fair value in the financial statements on a non-recurring basis until 2009. We adopted SFAS No. 157 in the first quarter of fiscal year 2008. There was no impact on our financial statements. We currently have warrant liabilities which are measured at fair value at each reporting period using assumptions that are fully disclosed.

In October 2008, the FASB issued FSP No. FAS 157-3, *Determining the Fair Value of a Financial Asset When the Market for that Asset is Not Active* (FSP 157-2), which applies to financial assets that are required or permitted to be measured at fair value in accordance with SFAS No. 157. FSP 157-3 clarifies the application of SFAS No. 157 and provides an example to illustrate key considerations in determining the fair value of a financial asset when the market for that asset is not active. The adoption did not have a significant impact on our financial position or results of operations, nor did it have a significant impact on the valuation techniques used by us in measuring the fair value of its portfolio investments.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities* ( SFAS No. 159 ). SFAS No. 159 provides entities with an option to report selected financial assets and liabilities at fair value, with the objective to reduce both the complexity in accounting for financial instruments and the volatility in earnings caused by measuring related assets and liabilities differently. We adopted SFAS No. 159 in the first quarter of fiscal year 2008. We currently report warrant liabilities at fair value. We have not elected to report any other assets or liabilities at fair value.

In June 2007, the FASB issued EITF 07-3. EITF 07-3 provides that non-refundable advance payments for goods or services that will be used or renders for future research and development activities should be deferred and capitalized. We adopted EITF 07-3 in the first quarter of 2008.

In December 2007, the FASB issued SFAS No. 141(R) *Business Combinations* (SFAS 141(R)). This Statement replaces the original SFAS No. 141. This Statement retains the fundamental requirements in SFAS No. 141 that the acquisition method of accounting (which SFAS No. 141 called the *purchase method*) be used for all business combinations and for an acquirer to be identified for each business combination. The objective of SFAS No. 141(R) is to improve the relevance, and comparability of the information that a reporting entity provides in its financial reports about a business combination and its effects. To accomplish that, SFAS No. 141(R) establishes principles and requirements for how the acquirer:

Recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, and any noncontrolling interest in the acquiree.

Recognizes and measures the goodwill acquired in the business combination or a gain from a bargain purchase.

Determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of the business combination.

This Statement applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008 and may not be applied before that date. We do not expect this standard will have a material effect on us.

In December 2007, the FASB issued SFAS No. 160, *Non-controlling Interests in Consolidated Financial Statements – an amendment of ARB No. 51* (SFAS No. 160). This statement is effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008, with earlier adoption prohibited. This statement requires the recognition of a non-controlling interest (minority interest) as equity in the consolidated financial statements and separate from the parent’s equity. The amount of net income attributable to the non-controlling interest will be included in consolidated net income on the face of the income statement. It also amends certain of ARB No. 51’s consolidation procedures for consistency with the

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requirements of SFAS 141(R) . This statement also includes expanded disclosure requirements regarding the interests of the parent and its non-controlling interest. We are currently evaluating this new statement and anticipate that the statement will not have a significant impact on the reporting of our results of operations.

In April 2008, the FASB issued Staff Position No. FAS 142-3, *Determination of the Useful Life of Intangible Assets* ( FSP FAS 142-3 ). FSP FAS 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS 142, *Goodwill and Other Intangible Assets* ( SFAS 142 ). The intent of FSP FAS 142-3 is to improve the consistency between the useful life of a recognized intangible asset under SFAS 142 and the period of expected cash flows used to measure the fair value of the asset under SFAS 141(Revised) and other applicable accounting literature. FSP FAS 142-3 is effective for fiscal years beginning after December 15, 2008. We are currently evaluating the effect that the adoption of FSP FAS 142-3 will have on our consolidated results of operations and financial condition.

In May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles* (SFAS No. 162). The current hierarchy of generally accepted accounting principles is set forth in the (AICPA) Statement on Auditing Standards (SAS) No. 69, *The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles*. SFAS No. 162 is intended to improve financial reporting by identifying a consistent framework, or hierarchy, for selecting accounting principles to be used in preparing financial statements that are presented in conformity with U.S. generally accepted accounting principles for nongovernmental entities. This Statement is effective November 15, 2008. The adoption of this statement did not have a material effect on our financial condition or results of operations.

In June 2008, the FASB ratified EITF Issue No. 07-5, *Determining Whether an Instrument (or an Embedded Feature) Is Indexed to an Entity's Own Stock* (EITF 07-5). EITF 07-5 provides that an entity should use a two step approach to evaluate whether an equity-linked financial instrument (or embedded feature) is indexed to its own stock, including evaluating the instrument's contingent exercise and settlement provisions. It also clarifies on the impact of foreign currency denominated strike prices and market-based employee stock option valuation instruments on the evaluation. EITF 07-5 is effective for fiscal years beginning after December 15, 2008. We are currently assessing the impact of EITF 07-5 on its consolidated financial position and results of operations.

In November 2008, the FASB ratified Emerging Issues Task Force Issue No. 08-7, *Accounting for Defensive Intangible Assets* ( EITF 08-7 ). EITF 08-7 clarifies the accounting for certain separately identifiable intangible assets which an acquirer does not intend to actively use but intends to hold to prevent its competitors from obtaining access to them. EITF 08-7 requires an acquirer in a business combination to account for a defensive intangible asset as a separate unit of accounting which should be amortized to expense over the period the asset diminishes in value. EITF 08-7 is effective for fiscal years beginning after December 15, 2008, with early adoption prohibited.

### **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.

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**Item 9A(T). 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, 2008. Our management has concluded, based on their evaluation, that as of the end of the period covered by this report, our disclosure controls and procedures were effective as of December 31, 2008 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
- 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 did not fully complete documentation of its testing to verify the effectiveness of the key controls. However, based on the evaluation, and other factors taken into consideration, management concluded that our internal control over financial reporting was effective as of December 31, 2008.

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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 2009 Annual Meeting of Stockholders which is scheduled to be held on May 21, 2009 (the 2009 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](http://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 2009 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 2009 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 2009 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 2009 Proxy Statement.

**Table of Contents****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

<b>Exhibit Number</b>	<b>Description of Document</b>	<b>Note Reference</b>
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	Amended and Restated Bylaws of Pro Pharmaceuticals, Inc.	6
3.7	Amendment to Amended and Restated Bylaws of Pro-Pharmaceuticals, Inc.	7
4.1	Specimen certificate for shares of common stock of registrant.	8
10.1	Pro-Pharmaceuticals, Inc. 2001 Stock Incentive Plan.	9
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		13



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Securities Purchase Agreement dated February 14, 2006, among Pro-Pharmaceuticals, Inc. and the Purchasers named therein.

10.9 Registration Rights Agreement dated February 14, 2006, among Pro-Pharmaceuticals, Inc. and the Purchasers named therein. 13

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<b>Exhibit Number</b>	<b>Description of Document</b>	<b>Note Reference</b>
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
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

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<b>Exhibit Number</b>	<b>Description of Document</b>	<b>Note Reference</b>
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).	
10.40*	Form of Non-Qualified Stock Option Grant Agreement (under the 2009 Incentive Compensation Plan).	
10.41*	Form of Incentive Stock Option Grant Agreement (under the 2009 Incentive Compensation Plan).	
21.1*	Subsidiary of Pro Pharmaceuticals, Inc.	
23.1*	Consent of Deloitte & Touche LLP, an independent registered public accounting firm.	
23.2*	Consent of Vitale, Caturano & 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.

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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.
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.

**Table of Contents****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 30, 2009.

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 Theodore D. Zucconi, Ph.D.	Chief Executive Officer, President and Director	March 30, 2009
/s/ ANTHONY D. SQUEGLIA Anthony D. Squeglia	Chief Financial Officer	March 30, 2009
/s/ GILBERT AMELIO Gilbert Amelio, Ph.D.	Director	March 30, 2009
/s/ JAMES C. CZIRR James C. Czirr	Director	March 30, 2009
/s/ ROD D. MARTIN Rod D. Martin	Director	March 30, 2009
/s/ S. COLIN NEILL S. Colin Neill	Director	March 30, 2009
/s/ STEVEN PRELACK Steven Prelack	Director	March 30, 2009
/s/ JERALD K. ROME Jerald K. Rome	Director	March 30, 2009
/s/ PETER TRABER Peter Traber, M.D.	Director	March 30, 2009



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**Pro-Pharmaceuticals, Inc.**

**(A Development Stage Company)**

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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 sheet of Pro-Pharmaceuticals, Inc. and subsidiary (a development stage company) (the Company ) as of December 31, 2008, and the related consolidated statement of operations, changes in stockholders' deficit, and cash flows for the year ended December 31, 2008, and for the period from inception (July 10, 2000) to December 31, 2008. 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 audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit 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, such consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2008, and the consolidated results of their operations and their cash flows for the year ended December 31, 2008, and for the period from inception (July 10, 2000) to December 31, 2008 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 7, the Company adopted the provisions of Statement of Financial Accounting Standards No. 157, *Fair Value Measurements*, on January 1, 2008.

/s/ Vitale, Caturano & Company, P.C.

Boston, Massachusetts

March 30, 2009

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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 sheet of Pro-Pharmaceuticals, Inc. and subsidiary (a development stage company) (the Company) as of December 31, 2007 and the related consolidated statements of operations, stockholders' deficit, and cash flows for the year then ended and for the period from inception (July 10, 2000) to December 31, 2007 (not presented herein). 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 audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit 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 audit provide a reasonable basis for our opinion.

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of Pro-Pharmaceuticals, Inc. and subsidiary as of December 31, 2007 and the consolidated results of their operations and their cash flows for the year then ended and for the period from inception (July 10, 2000) to December 31, 2007 (not presented herein), in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 2 to the 2007 consolidated financial statements, the Company adopted Financial Accounting Standards Board ( FASB ) Interpretation ( FIN ) No. 48 Accounting For Uncertainty in Income Taxes on January 1, 2007.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the 2007 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 2007 consolidated financial statements. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Deloitte & Touche LLP

Boston, Massachusetts

March 28, 2008

**Table of Contents****PRO-PHARMACEUTICALS, INC.****(A Development-Stage Company)****CONSOLIDATED BALANCE SHEETS**

DECEMBER 31, 2008 AND 2007 (amounts in thousands except share and share data)

	2008	2007
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 318	\$ 1,319
Prepaid expenses and other current assets	62	70
Total current assets	380	1,389
PROPERTY AND EQUIPMENT NET	40	73
RESTRICTED CASH	59	70
INTANGIBLE ASSETS NET	225	250
<b>TOTAL ASSETS</b>	<b>\$ 704</b>	<b>\$ 1,782</b>
<b>LIABILITIES AND STOCKHOLDERS DEFICIT</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$ 447	\$ 601
Accrued expenses	380	362
Accrued dividends payable	52	
Advances received for equity consideration	200	1,637
Total current liabilities	1,079	2,600
WARRANT LIABILITIES	55	2,069
OTHER LONG-TERM LIABILITIES	39	37
Total liabilities	\$ 1,173	\$ 4,706
COMMITMENTS AND CONTINGENCIES (Note 10)		
<b>STOCKHOLDERS DEFICIT:</b>		
Series A 12% Convertible Preferred Stock 5,000,000 authorized, 1,742,500 shares issued and outstanding at December 31, 2008 and 1,667,500 shares subscribed, none issued and outstanding at December 31, 2007	\$ 704	\$
Common stock, \$0.001 par value; 200,000,000 shares authorized; 48,052,159 and 40,364,792 shares of common stock issued and outstanding at December 31, 2008 and 2007, respectively;	48	40
Additional paid-in capital	37,329	32,196
Deficit accumulated during the development stage	(38,550)	(35,160)
Total stockholders deficit	(469)	(2,924)
<b>TOTAL LIABILITIES AND STOCKHOLDERS DEFICIT</b>	<b>\$ 704</b>	<b>\$ 1,782</b>

See notes to consolidated financial statements.



**Table of Contents****PRO-PHARMACEUTICALS, INC.****(A Development-Stage Company)****CONSOLIDATED STATEMENTS OF OPERATIONS****YEARS ENDED DECEMBER 31, 2008, 2007 AND CUMULATIVE PERIOD****FROM INCEPTION (JULY 10, 2000) TO DECEMBER 31, 2008 (amounts in thousands except share and per share data)**

	Years Ended December 31,		Cumulative Period from Inception (July 10, 2000) to December 31, 2008
	2008	2007	
<b>OPERATING EXPENSES:</b>			
Research and development	\$ 1,774	\$ 2,053	\$ 17,355
General and administrative	3,552	4,402	26,007
Total operating loss	(5,326)	(6,455)	(43,362)
<b>OTHER INCOME AND (EXPENSE):</b>			
Interest income	30	102	767
Interest expense		(350)	(4,451)
Change in fair value of convertible debt instrument		(1,032)	(3,426)
Change in fair value of warrant liabilities	2,145	(1,698)	12,161
Total other income (expense)	\$ 2,175	\$ (2,978)	\$ 5,051
<b>NET LOSS</b>	\$ (3,151)	\$ (9,433)	\$ (38,311)
SERIES A 12% CONVERTIBLE PREFERRED STOCK DIVIDEND	(239)		(239)
<b>NET LOSS APPLICABLE TO COMMON STOCK</b>	\$ (3,390)	\$ (9,433)	\$ (38,550)
<b>NET LOSS PER SHARE BASIC AND DILUTED</b>	\$ (0.07)	\$ (0.24)	
<b>WEIGHTED AVERAGE COMMON SHARES OUTSTANDING BASIC AND DILUTED</b>	46,815,250	38,980,548	

See notes to consolidated financial statements.

**Table of Contents****PRO-PHARMACEUTICALS, INC.****(A Development-Stage Company)****CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS (DEFICIT)**

CUMULATIVE PERIOD FROM INCEPTION (JULY 10, 2000)

TO DECEMBER 31, 2008 (amounts in thousands except share data)

	Common Stock		Series A 12% Convertible Preferred Stock		Additional Paid-in Capital	Deferred Compensation	Deficit Accumulated During the Development Stage	Total Stockholders (Deficit) Equity
	Number of Shares	\$0.001 Par Value	Number of Shares	Amount				
Issuance of founders shares in 2000	12,354,670	\$ 12			\$ (3)	\$	\$	\$ 9
Beneficial conversion feature and rights to common stock embedded in convertible note in 2000					222			222
Issuance of common stock and beneficial conversion feature related to convertible note in 2001	660,321	1			1,035			1,036
Issuance of common stock in connection with reverse merger of Pro-Pharmaceuticals-NV in 2001	1,221,890	1			106			107
Conversion of notes payable and accrued interest to common stock in 2001	598,229	1			1,125			1,126
Issuance of warrants to induce conversion of notes payable in 2001					503			503
Issuance of common stock and warrants (net of issuance costs of \$17) in 2001	689,300	1			2,220			2,221
Issuance of common stock (net of issuance costs of \$49) in 2002	185,999				602			602
Issuance of common stock related to 2002 private placement (net of issuance costs of \$212)	3,223,360	3			2,858			2,861
Conversion of notes payable and accrued interest to common stock	105,877				290			290
Issuance of warrants to purchase common stock in consideration for placement of convertible notes payable in 2002					236			236
Issuance of common stock to investors in 2002 private placement (net of issuance costs of \$18)	1,088,000	1			1,069			1,070
Issuance of common stock to consultants for services related to 2002 private placement	12,250				12			12

**Table of Contents****PRO-PHARMACEUTICALS, INC.****(A Development-Stage Company)****CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS (DEFICIT) (Continued)**

CUMULATIVE PERIOD FROM INCEPTION (JULY 10, 2000)

TO DECEMBER 31, 2008 (amounts in thousands except share data)

	Common Stock		Series A 12% Convertible Preferred Stock		Additional Paid-in Capital	Deferred Compensation	Deficit Accumulated During the Development Stage	Total Stockholders (Deficit) Equity
	Number of Shares	\$0.001 Par Value	Number of Shares	Amount				
Receipt of subscription receivable					150			150
Conversion of accrued expenses to common stock and options	201,704				302			302
Issuance of common stock to investors in May, 2003 private placement (net of issuance costs of \$128)	2,399,500	3			4,407			4,410
Fair value of common stock warrants issued to placement agents in May, 2003 private placement					261			261
Issuance of common stock to investors in October, 2003 private placement (net of issuance costs of \$559)	1,314,571	1			1,318			1,319
Cashless exercise of employee stock options	16,629				74			74
Issuance of common stock to investors in April, 2004 private placement (net of issuance costs of \$466)	1,236,111	1			1,897			1,898
Issuance of common stock to investors in August, 2004 private placement (net of issuance costs of \$485)	2,000,000	2			488			490
Common stock issued in 2006 related to convertible debenture conversions	476,202	1			1,744			1,745
Common stock issued in 2006 and 2007 related to convertible debenture redemptions	7,367,831	7			3,941			3,948
Common stock issued in 2007 related to convertible debenture waiver and exchange agreement	5,205,348	5			5,325			5,330
Series A 12% Convertible Preferred Stock issued in a February 4, 2008 private placement (net of cash issuance			1,742,500	704				704

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costs of \$52)

Common stock issued in a

February 25, 2008 offering (net of

cash issuance costs of \$369)	7,500,000	8	1.036	1,044
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**Table of Contents****PRO-PHARMACEUTICALS, INC.****(A Development-Stage Company)****CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS (DEFICIT) (Continued)**

CUMULATIVE PERIOD FROM INCEPTION (JULY 10, 2000)

TO DECEMBER 31, 2008 (amounts in thousands except share data)

	Common Stock		Series A 12% Convertible Preferred Stock	Additional Paid-in Capital	Deferred Compensation	Deficit Accumulated During the Development Stage	Total Stockholders (Deficit) Equity
	Number of Shares	\$0.001 Par Value	Number of Shares	Amount			
Series A 12% Convertible Preferred Dividend						(239)	(239)
Issuance of common stock in payment of Series A 12% Convertible Preferred Dividend	187,367				187		187
Issuance of Common Stock Warrants					20		20
Reclassification of Warrant Liabilities					3,193		3,193
Deferred compensation relating to issuance of stock options					455	(455)	
Amortization of deferred compensation						612	612
Stock compensation expense related to fair market revaluation					157	(157)	
Stock based compensation expense					2,072		2,072
Stock compensation related to the issuance of common shares	7,000				27		27
Net loss since inception						(38,311)	(38,311)
<b>BALANCE, DECEMBER 31, 2008</b>	<b>48,052,159</b>	<b>\$ 48</b>	<b>1,742,500</b>	<b>\$ 704</b>	<b>\$ 37,329</b>	<b>\$ (38,550)</b>	<b>\$ (469)</b>

See notes to consolidated financial statements.



**Table of Contents****PRO-PHARMACEUTICALS, INC.****(A Development-Stage Company)****CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS DEFICIT FOR THE YEARS ENDED DECEMBER 31, 2008 AND 2007**

(amounts in thousands except share data)

	Common Stock		Series A 12% Convertible Preferred Stock		Deficit Accumulated	Additional Paid-in Capital	Total Stockholders Deficit
	Number of Shares	Amount	Number of Shares	Amount	During the Development Stage		
BALANCE January 1, 2007	32,518,643	\$ 32			\$ (25,727)	\$ 25,673	\$ (22)
Common stock issued related to convertible debenture redemptions	2,640,801	3				582	585
Common Stock issued related to waiver and exchange agreement	5,205,348	5				5,325	5,330
Stock based compensation expense						616	616
Net loss					(9,433)		(9,433)
BALANCE, DECEMBER 31, 2007	40,364,792	40			(35,160)	32,196	(2,924)
Net loss					(3,151)		(3,151)
Series A 12% Convertible Preferred Stock issued in a February 4, 2008 private placement (net of cash issuance costs of \$52)			1,742,500	704			704
Common stock issued in a February 25, 2008 offering (net of cash issuance costs of \$369)	7,500,000	8				1,036	1,044
Series A 12% Convertible Preferred dividend					(239)		(239)
Issuance of common stock in payment of Series A 12% Convertible Preferred dividend	187,367					187	187
Issuance of common stock Warrants						20	20
Reclassification of warrant liabilities						3,193	3,193
Stock-based compensation expense						697	697
BALANCE, DECEMBER 31, 2008	48,052,159	\$ 48	1,742,500	\$ 704	\$ (38,550)	\$ 37,329	\$ (469)

See notes to consolidated financial statements.

**Table of Contents****PRO-PHARMACEUTICALS, INC.****(A Development-Stage Company)****CONSOLIDATED STATEMENTS OF CASH FLOWS**

YEARS ENDED DECEMBER 31, 2008 and 2007, AND CUMULATIVE PERIOD

FROM INCEPTION (JULY 10, 2000) TO DECEMBER 31, 2008 (amounts in thousands)

	Years Ended December 31,		Cumulative Period from Inception (July 10, 2000) to December 31, 2008
	2008	2007	
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net loss	\$ (3,151)	\$ (9,433)	\$ (38,311)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	49	64	488
Stock-based compensation expense	697	616	2,785
Non-cash interest expense		333	4,279
Change in fair value of convertible debt instrument		1,032	3,426
Change in fair value of warrant liabilities	(2,145)	1,698	(12,161)
Write-off of intangible assets	11	23	181
Changes in other assets and liabilities:			
Prepaid expenses and other current assets	8	61	(59)
Accounts payable and accrued expenses	(136)	111	945
Changes in long term liabilities	2	12	39
Net cash used in operating activities	(4,665)	(5,483)	(38,388)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Maturity of certificate of deposit		5,000	
Purchases of property and equipment	(2)	(5)	(421)
Decrease (increase) in restricted cash	11	(11)	(59)
Increase in patents costs and other assets		(37)	(404)
Net cash provided by (used in) investing activities	9	4,947	(884)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Net proceeds from issuance of common stock and warrants	3,381		28,690
Net proceeds from issuance of Series A Convertible Preferred Stock and Warrants	54	1,637	1,691
Net proceeds from issuance of convertible debt instrument			10,621
Repayment of convertible debt instrument		(555)	(1,641)
Proceeds from issuance of common stock warrants	20		20
Proceeds from shareholder advances	200		209
Net cash provided by financing activities	3,655	1,082	39,590
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(1,001)	546	318
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	1,319	773	
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 318	\$ 1,319	\$ 318

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SUPPLEMENTAL DISCLOSURE Cash paid for interest	\$	\$ 17	\$	114
<b>NON-CASH FINANCING ACTIVITIES</b>				
Issuance of equity warrants in connection with equity offerings				1,172
Conversion of accrued expenses into common stock				303
Cashless exercise of employee stock options				74
Conversion and redemptions of convertible notes and accrued interest into common stock		5,915		12,243
Conversion of extension costs related to convertible notes into common stock				171
Conversion of prepaid interest into common stock			(32)	
Payment of 12% Convertible Preferred dividend in common stock		187		187
Dividends payable on preferred stock		52		52
Issuance of warrants to induce conversion of notes payable				503
Issuance of stock to acquire Pro-Pharmaceuticals-NV				107
See notes to consolidated financial statements.				

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**PRO-PHARMACEUTICALS, INC.**

**(A DEVELOPMENT-STAGE COMPANY)**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1. NATURE OF BUSINESS AND BASIS OF PRESENTATION AND SUBSEQUENT EVENTS**

Pro-Pharmaceuticals, Inc. (the Company) is a development-stage company engaged in the discovery and development of carbohydrate-based therapeutics that are intended to reduce toxicity and improve the efficacy of chemotherapy drugs by combining the drugs with proprietary carbohydrate compounds. The carbohydrate-based compounds also may have application for drugs to treat other diseases and chronic health conditions.

The Company is devoting substantially all of its efforts toward product research and development, and raising capital. In May 2008, the Company submitted a Drug Master File ( DMF ) for the Company's lead product DAVANA<sup>®</sup> to the FDA. The DMF contains confidential detailed information in support of a New Drug Application ( NDA ) about facilities, processes or articles used in the manufacturing, processing, packaging, and storing or stability of drugs.

In September 2008, the Company submitted a clinical and pre-clinical package to the Food and Drug Administration ( FDA ) in support of the Company's DAVANA<sup>®</sup> NDA. The FDA reported to the Company in its minutes for the December 22, 2008 meeting that the Company will be required to conduct a Phase III trial to demonstrate superiority to the best standard of care for late stage colorectal cancer patients.

The Company incurred net losses of approximately \$38.6 million for the cumulative period from inception (July 10, 2000) through December 31, 2008. The Company's net losses have resulted principally from costs associated with (i) research and development expenses, including clinical trial costs, (ii) general and administrative activities and (iii) the Company's financing transactions including interest and the costs related to fair value accounting for the Company's convertible debt instrument and warrant liabilities. As a result of planned expenditures for future research, discovery, development and commercialization activities and potential legal cost to protect its intellectual property, the Company expects to incur additional losses and use additional cash in its operations for the foreseeable future. Through December 31, 2008, the Company had raised approximately \$41.2 million in capital through sale and issuance of common stock, common stock purchase warrants, convertible preferred stock and debt securities in public and private offerings. From inception (July 10, 2000) through December 31, 2008, the Company used cash of approximately \$38.4 million in its operations.

At March 20, 2009, the Company had approximately \$900,000 of non-restricted cash available to fund future operations. The Company believes there is sufficient cash to fund operations into June 2009. If the Company is unsuccessful in raising additional capital before the end of June 2009, the Company may be required to cease operations or seek bankruptcy protection. In light of the Company's current financial position and the uncertainty of raising sufficient capital to achieve its business plan, there is substantial doubt about the Company's ability to continue as a going concern. The accompanying financial statements do not include any adjustments that might result if such circumstances arise.

On January 9, 2009, the Company was delisted from the NYSE Alternext US ( Exchange ), formerly the American Stock Exchange, due to non-compliance with the Exchange minimum shareholders' equity requirements. On January 21, 2009 the Company began trading on the Over-the-Counter Bulletin Board ( OTCBB ) under the symbol PRWP.OB.

The Company is subject to a number of risks similar to those of other development-stage companies, including dependence on key individuals, uncertainty of product development and generation of revenues,

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dependence on outside sources of capital, risks associated with clinical trials of products, dependence on third-party collaborators for research operations, need for regulatory approval of products, risks associated with protection of intellectual property, and competition with larger, better-capitalized companies. Successful completion of the Company's development program and, ultimately, the attainment of profitable operations is dependent upon future events, including obtaining adequate financing to fulfill its development activities and achieving a level of revenues adequate to support the Company's cost structure. There are no assurances that the Company will be able to obtain additional financing on favorable terms, or at all, or successfully market its products.

Cash on hand of approximately \$900,000 at March 20, 2009, is sufficient to fund operations into June 2009. The Company must raise money before June 2009 or the Company may be forced to cease operations or seek bankruptcy protection. There can be no assurance that additional capital will be available to the Company prior to that time. Therefore, there exists substantial doubt about the Company's ability to continue as a going concern. No adjustments have been made to the carrying value of the assets or liabilities despite this uncertainty.

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

The accompanying consolidated financial statements reflect the application of certain accounting policies, as described in this note and elsewhere in the accompanying notes to financial statements.

*Basis of Consolidation* The consolidated financial statements include the accounts of the Company and Pro-Pharmaceuticals Securities Corp., its wholly-owned subsidiary, which was incorporated in Delaware on December 23, 2003. Pro-Pharmaceuticals Securities Corp. holds the cash and cash equivalents that are not required to fund current operating needs. All intercompany transactions have been eliminated.

*Use of Estimates* The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue, expenses and disclosure of contingent assets and liabilities. Management's estimates and judgments include assumptions used in stock option and warrant liability valuations, useful lives of intangible assets, accrued liabilities and various other assumptions that are believed to be reasonable under the circumstances. Actual results could differ from those estimates.

*Cash and Cash Equivalents* The Company considers all highly-liquid investments with original maturities of 90 days or less at the time of acquisition to be cash equivalents.

*Cash Flow* Our financial statements have been prepared on a going concern basis with the assumption that we have sufficient cash to fund operations into June 2009 and that by June 2009 we will raise sufficient cash to continue operations.

*Prepaid and Other Current Assets* Deposits and other assets consist principally of prepaid insurance, and lease deposits on the Company's leased executive office space.

*Property and Equipment* Property and equipment, including leasehold improvements, are stated at cost, net of accumulated depreciation, and are depreciated using the straight-line method over the lesser of the estimated useful lives of the assets or the related lease term.

The estimated useful lives of property and equipment are as follows:

<b>Asset Classification</b>	<b>Estimated Useful Life</b>
Computers and office equipment	Three years
Furniture and fixtures	Five years
Leasehold improvements	Shorter of useful life or life of lease

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*Restricted Cash* Restricted cash consists of security deposits principally for a real estate lease.

*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. Amortization expense in 2008 and 2007 was, approximately \$14,000 and \$20,000 respectively. Gross intangible assets at December 31, 2008 and 2007 totaled approximately \$329,000 and \$340,000 respectively and accumulated amortization at December 31, 2008 and 2007 totaled approximately \$104,000 and \$90,000, respectively.

*Long-Lived Assets* In accordance with Statement of Financial Accounting Standards ( SFAS ) No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets, the Company reviews all long-lived assets for impairment whenever events or circumstances indicate the carrying amount of such assets may not be recoverable. Recoverability of assets to be held or used is measured by comparison of the carrying value of the asset to the future undiscounted net cash flows expected to be generated by the asset. If such asset is considered to be impaired, the impairment recognized is measured by the amount by which the carrying value of the asset exceeds the discounted future cash flows expected to be generated by the asset.

The Company wrote off capitalized patent costs of approximately \$11,000 and \$23,000 in 2008 and 2007, respectively, when it was determined that the underlying intellectual property would have no future benefit to the Company.

*Convertible Debt Instrument* The Company's 7% Convertible Debt instrument issued in 2006 (the Debentures ) constitutes a hybrid instrument that has the characteristics of a debt host contract containing several embedded derivative features that would require bifurcation and separate accounting as a derivative instrument pursuant to the provisions of SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities ( SFAS No. 133 ). As permitted by SFAS No. 155, Accounting for Certain Hybrid Financial Instruments an amendment of FASB Statements No. 133 and 140, the Company irrevocably elected to initially and subsequently measure the Debentures in their entirety at fair value with changes in fair value recorded as either a gain or loss in the consolidated statement of operations under the caption Change in fair value of convertible debt instrument. Fair value of the Debentures is determined using a financial valuation model that requires assumptions that subject to significant management judgment.

*Warrants* The Company has issued common stock warrants in connection with the execution of certain equity and debt financings. Certain warrants are accounted for as derivative liabilities at fair value in accordance with SFAS No. 133. Such warrants do not meet the criteria in paragraph 11(a) of SFAS No. 133 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 as defined in SFAS No. 133 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.

*Research and Development Expenses* Costs associated with research and development are expensed as incurred. The Company defers and capitalizes nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities. Research and development expenses include, among other costs, salaries and other personnel-related costs, and costs incurred by outside laboratories and other accredited facilities in connection with clinical trials and preclinical studies.

*Income Taxes* The Company accounts for income taxes in accordance with SFAS No. 109, Accounting for Income Taxes ( SFAS No. 109 ). This statement requires an asset and liability approach to accounting for income taxes based upon the future expected values of the related assets and liabilities. Deferred income tax assets and liabilities are determined based on the differences between the financial reporting and tax bases of assets and liabilities and for tax loss and credit carry forwards, and are measured using the expected

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tax rates estimated to be in effect when such basis differences reverse. Valuation allowances are established, if necessary, to reduce the deferred tax asset to the amount that will, more likely than not, be realized. In June 2006, the Financial Accounting Standards Board issued FASB Interpretation ( FIN ) No. 48, Accounting for Uncertainty in Income Taxes ( FIN 48 or the Interpretation ). This Interpretation clarifies the accounting for uncertainty in income taxes recognized in accordance with SFAS No. 109. This Interpretation prescribes a more-likely-than not recognition threshold that a tax position will be sustained upon examination and a measurement attribute for the financial statement recognition of a tax position taken or expected to be taken in a tax return. This Interpretation also provides guidance on de-recognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. The Company adopted the provisions of FIN 48 on January 1, 2007. As of the date of adoption, the total amount of unrecognized tax benefits was approximately \$1,031,000 of which approximately \$880,000 if recognized, would impact the effective tax. As a result of the implementation of FIN 48, the Company did not recognize an adjustment to the deficit accumulated during the development stage for the unrecognized tax benefits because the Company has recorded a full valuation allowance against net operating loss carry forwards. There have been no changes in unrecognized tax benefits as a result of the tax positions taken during the current period (See Note 12 for further detail).

*Comprehensive Income (Loss)* Comprehensive income (loss) is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. The Company does not have any items of comprehensive income (loss) other than net losses as reported.

*Fair Value of Financial Instruments* SFAS No. 107, Disclosures About Fair Value of Financial Instruments, requires disclosure of the fair value of certain financial instruments. The Company's financial instruments consist of cash equivalents, accounts payable and accrued expenses. The estimated fair value of these financial instruments approximates their carrying value due to their short-term nature. Additionally, certain common stock warrants are recorded as liabilities at fair value. In September 2006, the Financial Accounting Standards Board issued SFAS No. 157, Fair Value Measurements ( SFAS No. 157 ). SFAS No. 157 clarifies the principle that fair value should be based on the assumptions market participants would use when pricing an asset or liability and establishes a fair value hierarchy that prioritizes the information used to develop those assumptions. Under the standard, fair value measurements are separately disclosed by level within the fair value hierarchy. The Company adopted SFAS No. 157 in the first quarter of fiscal year 2008. See Note 7.

*Concentration of Credit Risk* Financial instruments that subject the Company to credit risk consist of cash and cash equivalents and certificates of deposit. The Company maintains cash and cash equivalents and certificates of deposit with well-capitalized financial institutions. At times, those amounts may exceed federally insured limits. The Company has no significant concentrations of credit risk.

*Stock-Based Compensation* Through December 31, 2005, the Company accounted for stock-based compensation to employees and non-employee directors under the intrinsic value method in accordance with Accounting Principles Board ( APB ) Opinion No. 25, Accounting for Stock Issued to Employees, ( APB No. 25 ) and the related interpretations. Under APB No. 25, no compensation expense was recognized for stock options granted at fair market value and with fixed terms. On January 1, 2006, the Company adopted SFAS No. 123(R), Share-Based Payment, ( SFAS No. 123(R) ) using the modified prospective method, which results in the provisions of SFAS No. 123(R) being applied to the consolidated financial statements on a going-forward basis. Prior periods have not been restated. SFAS No. 123(R) requires companies to recognize stock-based compensation awards as compensation expense on a fair value method. Under the fair value recognition provisions of SFAS No. 123(R), 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. The Company uses the Black-Scholes option-pricing model to calculate the grant date fair value of stock options. The expense recognized over the service period

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is required to include an estimate of the awards that will be forfeited. Previously, the Company recorded the impact of forfeitures as they occurred. FASB Staff Position ( FSP ) No. 123(R)-3, *Transition Election Related to Accounting for the Tax Effects of Share-Based Payment Awards* required an entity to follow either the transition guidance for the additional-paid-in-capital pool as prescribed in SFAS No. 123(R) or the alternative transition method described in FSP No. 123(R)-3. An entity that adopted SFAS No. 123(R) using the modified prospective application method may make a one-time election to adopt the transition method described in the FSP No. 123(R)-3, and may take up to one year from the latter of its initial adoption of SFAS No. 123(R) or the effective date of the FSP No. 123(R)-3 to evaluate the available transition alternatives and make its one-time election. The Company adopted the alternative transition method provided in the FSP No. 123(R)-3 for calculating the tax effects of stock-based compensation under SFAS No. 123(R). Stock-based compensation is more fully described in Note 9.

*Impact of New Accounting Standards* In September 2006, the Financial Accounting Standards Board ( FASB ), issued SFAS No. 157. SFAS No. 157 clarifies the principle that fair value should be based on the assumptions market participants would use when pricing an asset or liability and establishes a fair value hierarchy that prioritizes the information used to develop those assumptions. Under the standard, fair value measurements are separately disclosed by level within the fair value hierarchy. In February 2008, the FASB decided that an entity need not apply this standard to nonfinancial assets and liabilities that are recognized or disclosed at fair value in the financial statements on a nonrecurring basis until 2009. The Company adopted SFAS No. 157 in the first quarter of fiscal year 2008. See Note 7.

In October 2008, the FASB issued FSP No. FAS 157-3, *Determining the Fair Value of a Financial Asset When the Market for that Asset is Not Active* (FSP 157-2), which applies to financial assets that are required or permitted to be measured at fair value in accordance with SFAS No. 157. FSP 157-3 clarifies the application of SFAS No. 157 and provides an example to illustrate key considerations in determining the fair value of a financial asset when the market for that asset is not active. The adoption did not have a significant impact on the Company's financial position or results of operations, nor did it have a significant impact on the valuation techniques used by the Company in measuring the fair value of its portfolio investments.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities* ( SFAS No. 159 ). SFAS No. 159 provides entities with an option to report selected financial assets and liabilities at fair value, with the objective to reduce both the complexity in accounting for financial instruments and the volatility in earnings caused by measuring related assets and liabilities differently. The Company adopted SFAS No. 159 in the first quarter of fiscal year 2008. SFAS No. 159 had no impact on the Company's financial statements as the Company did not elect the option to value selected assets or liabilities at fair value.

In June 2007, the FASB issued Emerging Issues Task Force 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities* ( EITF 07-3 ). EITF 07-3 provides that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities should be deferred and capitalized. The Company adopted EITF 07-3 in the first quarter of fiscal year 2008. This standard had no material effect on the Company.

In December 2007, the FASB issued SFAS No. 141(R) *Business Combinations* (SFAS 141(R)). This Statement replaces the original SFAS No. 141. This Statement retains the fundamental requirements in SFAS No. 141 that the acquisition method of accounting (which SFAS No. 141 called the *purchase method*) be used for all business combinations and for an acquirer to be identified for each business combination. The objective of SFAS No. 141(R) is to improve the relevance, and comparability of the information that a



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reporting entity provides in its financial reports about a business combination and its effects. To accomplish that, SFAS No. 141(R) establishes principles and requirements for how the acquirer:

Recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, and any noncontrolling interest in the acquiree.

Recognizes and measures the goodwill acquired in the business combination or a gain from a bargain purchase.

Determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of the business combination.

This Statement applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008 and may not be applied before that date. The Company does not expect this standard will have a material effect on the Company.

In December 2007, the FASB issued SFAS No. 160, *Non-controlling Interests in Consolidated Financial Statements - an amendment of ARB No. 51* (SFAS No. 160). This statement is effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008, with earlier adoption prohibited. This statement requires the recognition of a non-controlling interest (minority interest) as equity in the consolidated financial statements and separate from the parent's equity. The amount of net income attributable to the non-controlling interest will be included in consolidated net income on the face of the income statement. It also amends certain of ARB No. 51's consolidation procedures for consistency with the requirements of SFAS 141(R). This statement also includes expanded disclosure requirements regarding the interests of the parent and its non-controlling interest. We are currently evaluating this new statement and anticipate that the statement will not have a significant impact on the reporting of our results of operations.

In April 2008, the FASB issued Staff Position No. FAS 142-3, *Determination of the Useful Life of Intangible Assets* (FSP FAS 142-3). FSP FAS 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142, *Goodwill and Other Intangible Assets* (SFAS No. 142). The intent of FSP FAS 142-3 is to improve the consistency between the useful life of a recognized intangible asset under SFAS No. 142 and the period of expected cash flows used to measure the fair value of the asset under SFAS 141(Revised) and other applicable accounting literature. FSP FAS 142-3 is effective for fiscal years beginning after December 15, 2008. The Company is currently evaluating the effect that the adoption of FSP FAS 142-3 will have on its consolidated results of operations and financial condition.

In May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles* (SFAS No. 162). The current hierarchy of generally accepted accounting principles is set forth in the (AICPA) Statement on Auditing Standards (SAS) No. 69, *The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles*. SFAS No. 162 is intended to improve financial reporting by identifying a consistent framework, or hierarchy, for selecting accounting principles to be used in preparing financial statements that are presented in conformity with U.S. generally accepted accounting principles for nongovernmental entities. This Statement is effective November 15, 2008. The adoption of this statement did not have a material effect on our financial condition or results of operations.

In June 2008, the FASB ratified EITF Issue No. 07-5, "Determining Whether an Instrument (or an Embedded Feature) Is Indexed to an Entity's Own Stock" (EITF 07-5). EITF 07-5 provides that an entity should use a two step approach to evaluate whether an equity-linked financial instrument (or embedded feature) is indexed to its own stock, including evaluating the instrument's contingent exercise and settlement provisions. It also clarifies on the impact of foreign currency denominated strike prices and market-based employee stock option valuation instruments on the evaluation. EITF 07-5 is effective for fiscal years beginning after December 15, 2008. The Company is currently assessing the impact of EITF 07-5 on its consolidated financial position and results of operations.

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In November 2008, the FASB ratified Emerging Issues Task Force Issue No. 08-7, *Accounting for Defensive Intangible Assets*. EITF 08-7 clarifies the accounting for certain separately identifiable intangible assets which an acquirer does not intend to actively use but intends to hold to prevent its competitors from obtaining access to them. EITF 08-7 requires an acquirer in a business combination to account for a defensive intangible asset as a separate unit of accounting which should be amortized to expense over the period the asset diminishes in value. EITF 08-7 is effective for fiscal years beginning after December 15, 2008, with early adoption prohibited. The Company is currently evaluating the effect that the adoption of FSP FAS 142-3 will have on its consolidated results of operations and financial condition.

**3. PROPERTY AND EQUIPMENT**

Property and equipment consists of the following at December 31:

	2008	2007
Leasehold improvements	\$ 15	\$ 15
Computer and office equipment	194	192
Furniture and fixtures	107	107
Total	316	314
Less accumulated depreciation	(276)	(241)
Property and equipment net	\$ 40	\$ 73

Depreciation expense for the years ended December 31, 2008 and 2007 was approximately \$35,000 and \$44,000 respectively.

**4. ACCRUED EXPENSES**

Accrued expenses consist of the following at December 31:

	2008	2007
Legal and accounting fees	\$ 247	\$ 14
Scientific and clinical fees	29	214
Accrued payroll	27	97
Other	77	37
Total	\$ 380	\$ 362

**5. RELATED PARTY TRANSACTIONS**

In 2002, a stockholder and director of the Company agreed to receive compensation for certain 2002 scientific advisory services in the form of 25,354 shares of common stock and 25,354 options at an exercise price of \$2.96 to purchase common stock of the Company. As of December 31, 2002, the Company recorded the deemed fair value of such compensation of approximately \$122,000 as an accrued liability. The common stock was valued at approximately \$76,000, based on the closing price of the publicly traded shares of common stock on the date of grant. The options were valued at approximately \$46,000 using the Black-Scholes option-pricing model, based on a deemed fair value of the Company's common stock of \$3.00 per share. The accrued liability at December 31, 2002 was converted to equity in 2003 when the 25,354 shares of common stock and 25,354 options were issued to this individual.



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On October 31, 2008, the Company's board of directors authorized Medi-Pharmaceuticals, Inc. ( Medi-Pharma ), a wholly-owned subsidiary as of that date, to enter into a joint venture to deploy certain of the Company's technology, as well as original technology to be developed by the joint venture, for use in nutraceutical cardiovascular therapies. This deployment was accomplished by: (i) a merger of FOD Enterprises, Inc., with and into Medi-Pharma on November 25, 2008, following which Medi-Pharma became the surviving corporation and the Company became the owner of 10% of the outstanding capital stock of Medi-Pharma; and (ii) the Company entering into a license agreement with Medi-Pharma dated November 25, 2008, and clarified by an amendment dated December 15, 2008. Pursuant to the license agreement, the Company granted Medi-Pharma an exclusive, worldwide perpetual license to commercialize all of the Company's polysaccharide technology exclusively in the field of cardiovascular therapies (both preventive and therapeutic) in exchange for a royalty equal to 10% of Medi-Pharma's net revenues from products sold based on the licensed technology. Under the terms of the agreement Medi-Pharma must advance \$1.0 million in cash to the Company by May 30, 2009 or the Company will have the ability to terminate the license agreement. On February 12, 2009, the Company terminated the license agreement and entered into a Technology Transfer and Sharing Agreement (the Sharing Agreement ) with Medi-Pharma. Under the terms of the agreement, the Company and Medi-Pharma agreed that the Company would not work in the area of polysaccharides in heart disease for a period of five years without the consent of Medi-Pharma and Medi-Pharma will not work in the area of polysaccharides in oncology and liver/kidney fibrosis for a period of five years without the consent of the Company. Also under the terms of the agreement, the Company licensed to Medi-Pharma, in perpetuity, all items of intellectual property owned by the Company with respect to the use of polysaccharides for heart indications. Further, the Company granted Medi-Pharma access to all of the Company's intellectual property in the area of fibrotic tissue in applications other than liver/kidney fibrosis and Medi-Pharma granted the Company access to all intellectual property in the area of kidney/liver fibrosis.

On February 12, 2009, the Company also entered into a Consulting Agreement (the Consulting Agreement ) with Medi-Pharma pursuant to which the parties agreed that Medi-Pharma will provide (a) certain manufacturing and development services related to DAVANAT<sup>®</sup>, (b) training to the Company's technicians in best practices for laboratory processes and procedures and (c) upon the request of the Company, advice and review relative to current pre-clinical trials and clinical trials, and submissions of information or other documentation, to the FDA related to DAVANAT<sup>®</sup>. The Consulting Agreement provides that to the extent the services are provided by David Platt, Ph.D., Medi-Pharma shall receive no compensation. The term of the Consulting Agreement is until February 12, 2011.

At December 31, 2008, Medi-Pharma had no assets or liabilities and had recorded no income or expense. The Company intends to account for Medi-Pharma under the equity method of accounting.

**6. CONVERTIBLE DEBT, WARRANT LIABILITIES AND WARRANTS**

The Company has raised capital through a number of debt and equity financing transactions. The following provides a chronological description of the Company's debt financings and certain warrants issued in connection with debt and equity financings.

*2000 and 2001 Convertible Notes* During 2001 and 2000, the Company issued approximately \$1,036,000 and \$285,000 of convertible notes, respectively. In August 2001, the Company offered warrants to holders of its outstanding convertible notes as an inducement to convert the notes prior to the maturity. Holders representing approximately \$1,126,000 of the outstanding principal and accrued interest chose to convert at a conversion price of \$2.00 per share and received 598,229 common shares and 562,801 warrants. The unexercised warrants expired in 2005. As described in Note 7, the Company valued the warrants at approximately \$503,000 using the Black-Scholes option-pricing model, and recorded such value as a debt conversion in 2001. In addition, 110,000 warrants were issued to agents as part of this offering. Please see Note 7.

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In May 2002, the Company extended the maturity date on the approximately \$195,000 of convertible notes payable at December 31, 2001. In consideration for the extension, the holders received one-quarter of one share of the Company's common stock for each whole dollar amount of principal outstanding, or 48,750 shares of common stock. The Company deferred approximately \$171,000 in costs associated with the extension, based on the fair value of the Company's common stock of \$3.50 at the time of the extension. These deferred convertible notes payable costs were amortized ratably over the twelve-month extended term of the notes, or until conversion.

In June 2002, approximately \$80,000 in convertible notes payable and approximately \$10,000 in related accrued interest was converted into 45,128 shares of common stock. In October 2002, the Company settled convertible notes payable of approximately \$100,000 through a cash payment of approximately \$86,000 and conversion of approximately \$14,000 of principal into 7,000 shares of common stock pursuant to the original terms of the note. In addition, approximately \$17,000 of related accrued interest was repaid in cash. In 2003 the remaining approximately \$15,000 of convertible note payable was converted into common stock.

During 2002, the remaining approximately \$167,000 of the deferred convertible notes payable extension costs was amortized to interest expense.

*October 2003, April 2004 and August 2004 PIPE Transactions* In connection with the October 2003 PIPE transaction, as described in Note 7, the Company issued 657,293 warrants (the 2003 Investor Warrants) with an initial exercise price of \$5.29 per share to the investors and 65,729 warrants (the 2003 Placement Agent Warrants) with an initial exercise price of \$6.86 per share to its placement agent. The exercise price of the warrants is subject to adjustment pursuant to anti-dilution and other provisions. The fair value of the 2003 Investor Warrants and the 2003 Placement Agent Warrants was determined based on a fair market value of the Company's common stock of \$5.29 per share. The 2003 Investor Warrants and 2003 Placement Agent Warrants were valued at approximately \$2,531,000 and \$191,000, respectively. The Company uses the Black-Scholes pricing model to value these warrants. The 2003 Investor Warrants and the 2003 Placement Agent Warrants were accounted for as freestanding derivative instruments in the consolidated balance sheet under the caption "Warrant Liabilities". Changes in fair value are recognized as either a gain or loss in the consolidated statement of operations under the caption "Change in fair value of warrant liabilities". On October 2, 2008 the 2003 Investor Warrants expired unexercised. The October 2003 Placement Agent Warrants expired unexercised in 2007.

In connection with the April 2004 PIPE transaction, as described in Note 7, the Company issued 618,056 warrants (the April 2004 Investor Warrants) and 61,806 warrants (the April 2004 Placement Agent Warrants) with an initial exercise price of \$5.30 per share to the investors and to the placement agent, respectively. The exercise price of the warrants is subject to adjustment pursuant to anti-dilution and other provisions. The fair value of the April 2004 Investor Warrants and the April 2004 Placement Agent Warrants was determined based on a fair market value of the Company's common stock of \$4.41 per share. The April 2004 Investor Warrants and April 2004 Placement Agent Warrants were valued at approximately \$1,931,000 and \$154,000, respectively. The Company uses the Black-Scholes pricing model to value these warrants. The April 2004 Investor Warrants and April 2004 Placement Agent Warrants were accounted for as freestanding derivative instruments in the consolidated balance sheet under the caption "Warrant Liabilities". Changes in fair value are recognized as either a gain or loss in the consolidated statement of operations under the caption "Change in fair value of warrant liabilities". The April 2004 Placement Agent Warrants expired unexercised in 2007.

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In connection with the August 2004 PIPE transaction, as described in Note 7, the Company issued 2,000,000 warrants (the August 2004 Investor Warrants ) and 100,000 warrants (the August 2004 Placement Agent Warrants ) with an exercise price of \$4.20 per share to the investors and to the placement agent, respectively. The exercise price of the warrants is subject to adjustment solely as a result of stock splits, recapitalizations and similar events. The fair value of the August 2004 Investor Warrants and the August 2004 Placement Agent Warrants was determined based on a fair market value of the Company's common stock of \$3.39 per share. The August 2004 Investor Warrants and August 2004 Placement Agent Warrants were valued at approximately \$4,786,000 and \$239,000, respectively. The Company uses the Black-Scholes pricing model to value these warrants. The August 2004 Investor Warrants and August 2004 Placement Agent Warrants were accounted for as freestanding derivative instruments in the consolidated balance sheet under the caption Warrant Liabilities . Changes in fair value are recognized as either a gain or loss in the consolidated statement of operations under the caption Change in fair value of warrant liabilities .

*February 2006 PIPE Transaction* In February 2006, the Company issued \$10 million in aggregate principal amount of convertible debentures (the Debentures ) together with warrants to purchase approximately 1,490,313 shares of the Company's common stock (the 2006 Investor Warrants ). Additionally, in connection with issuance of the Debentures and Warrants, the placement agent received a fee of approximately \$550,000 and approximately 149,031 fully vested warrants (the 2006 Placement Agent Warrants ) to purchase shares of the Company's common stock. Net proceeds were approximately \$9,300,000 net of approximately \$700,000 in direct transaction costs, including the placement agent fee. Redemptions and conversions of the Debentures are described in the table below.

The Debentures bore interest at 7% and were required to be redeemed in eighteen equal monthly installments beginning in August 2006 and continuing through January 2008. Interest was payable monthly beginning in July 2006. Each redemption installment and accrued interest has been settled in cash or in shares of common stock at the option of the Company. The number of shares deliverable under the share-settlement option was determined based on the lower of (a) \$3.35 per share, as adjusted pursuant to the terms of the Debentures or (b) 90% applied to the average of the lowest five volume-weighted-average trading prices in a twenty day period immediately preceding each share settlement. If the share-settlement option was elected by the Company, the Company was required to make an estimated payment in shares approximately 30 days prior to the scheduled maturity date.

On March 20, 2007, the Company entered into a Waiver and Exchange Agreement (the Agreement ) with six of seven remaining holders of the Debentures, representing approximately \$3,889,000 of the approximately \$4,444,000 outstanding principal. Pursuant to the Agreement, on March 21, 2007, the Company issued approximately 5.2 million shares of its common stock at \$0.75 per share to discharge the principal, accrued and unpaid interest and any other obligations under the Debentures subject to the Agreement. The Agreement also provided that the exercise price of the common stock purchase warrants issued by the Company contemporaneously with the Debentures, would be reduced to \$1.00 (and the number of shares issuable on exercise proportionately increased) to take into account the dilutive effect of this transaction. In connection with the February 2008 finance transactions, discussed in Note 8, as a result of the anti-dilution provisions of the warrant instruments, the exercise price of the investor and placement agent warrants was reduced to \$0.50 and an additional 5,342,770 and 849,477 shares of the Company's common stock are issuable, respectively, upon exercise of the investor and placement agent warrants. The Warrant Agreement contains a provision that limits the number of shares that can be issued to holders of the warrant.

In October 2008, a number of holders representing 7,988,082 of the outstanding Convertible Debenture warrants agreed to waive their right to receive cash, at their option, in the event of a fundamental transaction related to the Company. Because they now receive the same treatment as common shareholders, the warrant liability associated with these warrants was reclassified to stockholders' equity in the fourth quarter of 2008. In addition, the placement agent representing 998,508 of the outstanding Convertible Debenture warrants

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reclassified to stockholders' equity as described above, waived all future rights to the anti-dilution provisions of the warrant agreement. The warrant liabilities were marked to fair market value as of the agreement date resulting in an approximately \$100,000 gain in the fourth quarter of 2008 to change in fair value of warrant liabilities in the consolidated statement of operations and a reclassification of the remaining balance to additional paid in capital of approximately \$530,000. The remaining 2,995,523 of outstanding Convertible Debenture warrants continue to be classified as Warrant liabilities.

On December 14, 2007, the Company made its last scheduled payment of principal and interest of the remaining outstanding Debentures. At December 31, 2007, the Convertible Debenture was repaid in full.

The exercise price of the 2006 Investor and Placement Agent Warrants are subject to certain anti-dilution protections, including for stock splits, stock dividends, change in control events and dilutive issuances of common stock or common stock equivalents, such as stock options, at an effective price per share that is lower than the then conversion price. In the event of a dilutive issuance of common stock or common stock equivalents, the exercise price would be reduced to equal the lower price per share of the subsequent transaction together with a corresponding increase in the number of warrants.

As described in Note 2, the Company irrevocably elected to initially and subsequently measure the Debentures in their entirety at fair value with changes in fair value recognized as either a gain or loss in the consolidated statement of operations. Upon issuance of the Debentures, the Company allocated proceeds received to the Debentures and the 2006 Investor Warrants on a relative fair value basis. As a result of such allocation, the Company determined the initial carrying value of the Debentures to be approximately \$7,747,000. The Debentures were immediately marked to fair value, resulting in a liability in the amount of approximately \$9,126,000 and a charge to Change in fair value of convertible debt instrument of approximately \$1,379,000.

Upon issuance, the Company allocated approximately \$2,253,000 of the initial proceeds to the 2006 Investor Warrants and immediately marked them to fair value resulting in a derivative liability of approximately \$2,654,000 and a charge to change in fair value of warrant liabilities of approximately \$401,000. The Company paid approximately \$700,000 in cash transaction costs and incurred another \$266,000 in costs based upon the fair value of the 2006 Placement Agent Warrants. Such costs were expensed immediately as part of fair value adjustments required in connection with the Debentures and the Company's irrevocable election to initially and subsequently measure the Debentures at fair value with changes in fair value recognized in earnings.

The debt discount in the amount of approximately \$2,253,000 (resulting from the allocation of proceeds) was amortized to interest expense using the effective interest method over the expected term of the Debentures. The Company amortized approximately \$559,000 and \$1,694,000 of this amount in 2007 and 2006 respectively with a corresponding increase in the carrying value of the Debentures. Of this amount approximately \$257,000 and \$1,358,000 was charged to interest expense and approximately \$302,000 and \$336,000 was recorded in additional paid-in capital as a result of redemptions and conversions during 2007 and 2006 respectively. An additional approximately \$93,000 and \$492,000 in interest expense was recorded during 2007 and 2006 respectively based upon the 7% coupon rate.

*February 4, 2008 Transaction* On February 4, 2008, the Company closed a private placement in which it sold units of securities comprised of 1,742,500 shares of Series A 12% Convertible Preferred Stock together with warrants to purchase 1,742,500 shares of common stock exercisable at \$1.50 and warrants to purchase 1,742,500 shares of common stock exercisable at \$2.00. In addition the Company issued to placement agents warrants to purchase 8,400 shares of common stock at \$1.50. The warrants were accounted for as freestanding derivative instruments in the consolidated balance sheet formerly under the caption Warrant Liabilities. These warrants were originally classified as a liability because the February 2006 warrants contain an anti-dilution provision in the event of a subsequent dilutive issuance and the potential number of

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shares issuable exceeded the Company's authorized shares. Changes in fair value were recognized as either a gain or loss in the consolidated statement of operations under the caption "Change in fair value of warrant liabilities". In the second quarter of 2008, the warrants were reclassified to equity as a result of an amendment to the Company's articles of incorporation approved at the May 21, 2008 annual meeting of shareholders increasing the Company's authorized common stock from 100,000,000 to 200,000,000 shares (the "Charter Amendment"). The Charter Amendment authorization of the additional shares coupled with a provision in the February 2006 warrants limiting the number of shares that can be issued to holders of the February 2006 warrants, ensures that sufficient shares are available for issuance upon exercise of these warrants, thereby enabling them to be reclassified from a liability to equity. Through May 21, 2008, these warrants were marked to market resulting in a reduction in warrant liabilities in the balance sheet and an offsetting credit to change in fair value of warrant liabilities in the statement of operations in the amount of approximately \$100,000. The remaining fair value of approximately \$502,000 was credited to additional paid-in capital in the balance sheet. If the Company subdivides or combines its outstanding common stock, or issues additional shares of its capital stock in payment of a stock dividend in respect of its common stock or other securities, the number of shares issuable shall be proportionately increased or decreased, and the exercise price of the warrants shall be proportionately decreased or increased.

*February 25, 2008 Transaction* On February 25, 2008, the Company sold to investors 7,500,000 shares of its common stock, 7,500,000 warrants to purchase shares of common stock exercisable at \$0.70, and 3,000,000 warrants to purchase shares of common stock exercisable at \$0.63. In addition, the Company issued to a placement agent 206,250 warrants to purchase shares of common stock at \$0.70. The warrants were accounted for as freestanding derivative instruments in the consolidated balance sheet under the caption "Warrant Liabilities". These warrants were originally classified as a liability because the February 2006 warrants contain an anti-dilution provision in the event of a subsequent dilutive issuance and the potential number of shares issuable exceeded the Company's authorized shares prior to the Charter Amendment. Changes in fair value were recognized as either a gain or loss in the consolidated statement of operations under the caption "Gain/loss on change in fair value of warrant liabilities". In the second quarter of 2008 the warrants were reclassified to equity as a result of the Charter Amendment. The Charter Amendment authorization of the additional shares coupled with a provision in the February 2006 warrants limiting the number of shares that can be issued to holders of the February 2006 warrants ensures that sufficient shares are available for issuance upon exercise of these warrants, thereby enabling them to be reclassified from a liability to equity. Through May 21, 2008, these warrants were marked to market resulting in a reduction in warrant liabilities in the balance sheet and an offsetting credit to change in fair value of warrant liabilities in the statement of operations in the amount of approximately \$356,000. The remaining fair value of approximately \$2,160,000 was credited to additional paid-in capital in the balance sheet. On December 26, 2008 the 3,000,000 warrants exercisable at \$0.63 expired unexercised. If the Company pays a stock dividend or makes a distribution or combines shares of its common stock, then the number of shares issuable upon exercise of this warrant shall be proportionately adjusted such that the aggregate exercise price of this warrant remains unchanged.

*Investor Relations Group* In May 2008 the Company entered into an agreement with Investor Relations Group ( "IRG" ) for IRG to provide investor relations services to the Company in exchange for cash and warrants on a monthly basis. On September 30, 2008 the Company terminated the agreement under the provisions of the agreement. During the effective contract period IRG earned 39,000 warrants valued at approximately \$3,000. The expense associated with these warrants was calculated using the Black-Scholes option-pricing model and charged to stock compensation expense. Assumptions used to value these warrants are included in the table provided below. The warrants are exercisable at \$0.50 per share for a period of three years.

*Cork Investments* On July 2, 2008 the Company issued 300,000 warrants to an investor in exchange for \$20,000. The warrants are exercisable for common stock at \$1.00 per share for a period of three years. The \$20,000 was credited to additional paid in capital.



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A summary of changes in the Debentures and Warrant Liabilities is as follows:

	Fair Value of Debentures	Fair Value of Warrant Liabilities	Total
Balance January 1, 2007	\$ 5,137	\$ 371	\$ 5,508
Redemptions, at net carrying amount (1)	(556)		(556)
Conversions, related to waiver and exchange agreement dated March 20, 2007 at net carrying amount (2)	(5,315)		(5,315)
Redemptions paid in cash	(555)		(555)
Amortization of debt discount	257		257
Change in fair value of warrant liabilities	1,032	1,698	2,730
<b>Balance December 31, 2007</b>	<b>\$</b>	<b>\$ 2,069</b>	<b>\$ 2,069</b>
Fair value assigned to February 4, 2008 transaction warrants upon issuance		987	987
Fair value assigned to February 25, 2008 transaction warrants upon issuance		2,337	2,337
Reclassification of February 4 and February 25, 2008 warrant liabilities to Stockholders Deficit		(2,663)	(2,663)
Reclassification of February 2006 warrant liabilities to Stockholders Deficit		(530)	(530)
Change in fair value of warrant liabilities		(2,145)	(2,145)
<b>Balance December 31, 2008</b>		<b>55</b>	<b>55</b>

- (1) Represents payments in common stock of principal value of \$481,000 and a fair value adjustment credit of \$75,000. These amounts plus \$29,000 of accrued interest were credited to common stock and additional paid in capital.
- (2) Represents payments in common stock of principal value of \$3,889,000, debt discount charge of \$302,000 and a fair value adjustment credit of \$1,728,000. These amounts plus \$15,000 of accrued interest were credited to common stock and additional paid in capital.

The following table summarizes information with regard to outstanding warrants issued in connection with equity and debt financings and as compensation as of December 31, 2008. The 2001 Placement Agents, 7,988,082 of the February 2006, the February 4, 2008 Transaction and February 25, 2008 Transaction, Cork Investments and Investor Relations Group Warrants are classified as equity. The April 2004, August 2004 and 2,995,523 of the February 2006 Transaction Warrants do not meet the requirements of equity classification and are classified as liabilities:

Issued in Connection With	Number Issued	Exercise Price	Exercisable Date	Expiration Date
<b>April 2004 Transaction (1)</b>				
Investor Warrants	618,056	\$ 3.23	April 7, 2004	April 7, 2009
<b>August 2004 Transaction</b>				
Investor Warrants	2,000,000	\$ 4.20	February 13, 2005	August 12, 2009
Placement Agent Warrants	100,000	\$ 4.20	February 13, 2005	August 12, 2009
<b>February 2006 Transaction</b>				
Investor Warrants Classified as Equity (2)	6,989,574	\$ 0.50	August 15, 2006	August 14, 2011
Investor Warrants Classified as Warrant Liabilities (3)	2,995,523	\$ 0.50	August 15, 2006	August 14, 2011
Placement Agent Warrants Classified as Equity (4)	998,508	\$ 0.50	August 15, 2006	August 14, 2011
<b>2001 Placement Agents</b>				
<b>February 4, 2008 Transaction</b>				
\$1.50 Investor Warrants	1,742,500	\$ 1.50	August 3, 2008	February 4, 2012
\$2.00 Investor Warrants	1,742,500	\$ 2.00	August 3, 2008	February 4, 2012
\$1.50 Placement Agent Warrants	8,400	\$ 1.50	August 3, 2008	February 4, 2012
<b>February 25, 2008 Transaction</b>				
\$0.70 Investor Warrants	7,500,000	\$ 0.70	August 25, 2008	August 25, 2013
\$0.70 Placement Agent Warrants	206,250	\$ 0.70	August 25, 2008	August 25, 2013
Investor Relations Group	39,000	\$ 0.50	September 30, 2008	September 30, 2011
Cork Investments	300,000	\$ 1.00	July 2, 2008	July 2, 2011
<b>Total</b>	<b>25,350,311</b>			

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- (1) The exercise price of the warrants has been adjusted from the initial exercise price of \$5.30 per share to \$3.23 per share due to the subsequent issuance of equity related instruments.
- (2) The exercise price of the warrants has been adjusted from the initial exercise price of \$3.35 per share to \$0.50 per share and an additional 2,548,430 shares of the Company's common stock are issuable upon exercise of the warrants due to subsequent issuance of equity related instruments.

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- (3) The exercise price of the warrants has been adjusted from the initial exercise price of \$3.35 per share to \$0.50 per share and an additional 5,946,354 shares of the Company's common stock are issuable upon exercise of the warrants due to subsequent issuance of equity related instruments.
- (4) The exercise price of the warrants has been adjusted from the initial exercise price of \$3.35 per share to \$0.50 per share and an additional 849,477 shares of the Company's common stock are issuable upon exercise of the warrants due to subsequent issuance of equity related instruments.

**7. FAIR VALUE OF CONVERTIBLE DEBT AND WARRANT LIABILITIES**

Effective January 1, 2008, the Company adopted SFAS No. 157. SFAS No. 157 establishes a new framework for measuring fair value and requires fair value to be determined based on the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset and or liability in an orderly transaction between market participants. SFAS No. 157 establishes market or observable inputs as the preferred source of values, followed by assumptions based on hypothetical transactions in the absence of market inputs. The valuation techniques and disclosures required by SFAS No. 157 are determined by the following hierarchy:

Level 1 Quoted prices for identical instruments in active markets.

Level 2 Quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model derived valuations whose inputs are observable or whose significant value drivers are observable.

Level 3 Significant inputs to the valuation model are unobservable.

The Company uses the Black-Scholes pricing model to calculate fair value of its warrant liabilities.

Key assumptions used to apply these models as of December 31, 2008 and December 31, 2007 are as follows:

	Warrants			
	December 31, 2008		December 31, 2007	
Risk free interest rate	0.11	0.91%	3.16%	3.34%
Expected life	0.27years	2.62 years	0.75 years	3.62 years
Expected volatility of common share price		95%		95%
Common share price	\$	0.09	\$	0.70

As noted above, the Debentures were repaid in full on December 14, 2007. During 2007 the Company used the same binomial financial model as in 2006 to calculate the fair value of the Debentures. The last fair value calculation was performed as of September 30, 2007. The key assumptions used to apply this model on September 30, 2007 were as follows: risk free interest rate 4.12%, expected life 0.25 years, expected volatility of common share price 100% and common price per share \$0.67. When the Company repaid the Debentures, the difference between the fair value of the Debenture, the final cash payment and the remaining debt discount were recorded in the consolidated statement of operations under the caption Change in fair value of the convertible debt instrument.

Below is a summary of our fair value measurements at December 31, 2008:

Description	Value at 12/31/2008	Quoted Prices in	Significant	Significant
		Active Markets for Identical Assets (Level 1)	Other Observable Inputs (Level 2)	Unobservable Inputs (Level 3)
Warrant Liabilities	\$ 55	\$	\$ 55	\$

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**8. STOCKHOLDERS (DEFICIT) EQUITY**

The Company has raised capital through a number of debt and equity financing transactions. The following provides a chronological description of the Company's equity financings and certain warrants issued in connection with such equity financings.

*2001 Private Placement* From May 25, 2001 through December 3, 2001, the Company sold a total of 689,300 shares of common stock for proceeds of approximately \$2,221,000, net of approximately \$17,000 of issuance costs through a private placement of securities (the 2001 Private Placement).

In connection with the 2001 Private Placement, the Company issued 339,200 and 350,100 warrants to purchase common stock at \$6.50 and \$5.00 per share, respectively. The Company valued the warrants at approximately \$886,000, based on a deemed fair market value of the Company's common stock of \$2.28 per share. These warrants expired unexercised in 2005.

As described in Note 6, in August 2001, the Company offered warrants to holders of its outstanding convertible notes as an inducement to convert prior to the maturity of the notes. Holders representing approximately \$1,126,000 of the outstanding principal and accrued interest chose to convert at a conversion price of \$2.00 per share and received 598,229 common shares and 562,801 warrants. These warrants have an exercise price of \$6.50 per share and are immediately exercisable. The Company valued the warrants at approximately \$503,000 based on a deemed fair market value of the Company's common stock of \$2.28 per share. The value of the warrants has been recorded as a debt conversion expense. These warrants expired unexercised in 2005.

In 2002, the Company issued 110,000 warrants to the agents in connection with the 2001 debt offering. The warrants are exercisable immediately at an exercise price of \$3.50 per share and have a 10 year life. The Company valued these warrants at \$236 based on a deemed fair value of the Company's common stock of \$3.50 per share and recorded such value as interest expense in the statement of operations for the year ended December 31, 2002.

*Public Offering* On December 13, 2001, the Company commenced a public offering of 1,428,572 shares of common stock, at a price to the public of \$3.50 per share. The Company concluded the offering on June 30, 2002. The Company sold 185,999 shares of common stock in this offering for proceeds of approximately \$602,000, net of approximately \$49,000 of issuance costs, all in 2002.

*2002 Private Placement* In September 2002, the Company began a private placement (the 2002 Private Placement) of up to 10,000,000 shares of common stock at \$1.00 per share. As of December 31, 2002, the Company had sold 3,223,360 shares for proceeds of approximately \$2,861,000, net of issuance costs of approximately \$212,000 and stock subscription receivable of approximately \$150,000, which related to shares purchased but for which payment had not been received as of December 31, 2002. This offering was closed on January 14, 2003, although subsequent to year end the Company sold an additional 1,088,000 shares for additional proceeds of approximately \$1,070,000, net of approximately \$18,000 of offering costs.

The Company compensated a registered investment adviser with respect to shares purchased by its clients. As of December 31, 2002, the adviser was entitled to receive 173,500 shares of common stock. The Company also agreed to compensate a finder registered under applicable law, and such finder's agents, for identifying qualified investors. As of December 31, 2002, one of the finder's agents was entitled to receive 750 shares of common stock. On January 14, 2003, the Company closed the 2002 Private Placement, at which point the Company agreed to issue the adviser an additional 2,500 shares, and the finder and its other agent an aggregate of 9,750 additional shares and approximately \$3,000 in cash in connection with the shares sold subsequent to December 31, 2002 and through the closing date.

Shares placed by such registered adviser, finder and finder's agent were accounted for as offering costs and valued at \$1.00 per share, consistent with the price paid for the shares placed in the offering. Such offering

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costs were netted against the proceeds of the 2002 Private Placement. Since none of the 174,250 shares had been issued as of December 31, 2002, the Company recorded the obligation to issue such shares as offering costs payable. The additional 12,250 shares issued in January 2003 were also valued at \$1.00 per share and included in the approximately \$18,000 offering costs recorded at the closing. These shares were subsequently issued in 2003.

During 2002, the Company also agreed to issue 2,100 shares of common stock to an employee for finding investors in connection with the 2002 Private Placement. None of the shares had been issued as of December 31, 2002. These shares were subsequently issued in 2003. Accordingly, the Company recorded the obligation to general and administrative expenses in the statement of operations in the amount of approximately \$6,000. On January 14, 2003, the Company closed the 2002 Private Placement, at which point the Company agreed to issue such employee an additional 7,000 shares in connection with shares sold subsequent to December 31, 2002 and through the closing date. The Company recorded an additional obligation of approximately \$27,000 to general and administrative expenses in 2003 representing the fair value of the additional 7,000 shares.

*2002 Related Party Transaction* As discussed in Note 5, the Company agreed to issue 25,354 shares of common stock as payment for 2002 scientific advisory services. These shares were subsequently issued in 2003.

*May 2003 Private Placement* In May 2003, the Company began a private placement of up to 2.5 million shares of common stock at \$2.00 per share. As of the closing on July 15, 2003, the Company had sold 2,399,500 shares of common stock for proceeds of approximately \$4,671,000, net of issuance costs of approximately \$128,000. In connection with this offering the Company issued 109,613 common stock warrants (exercisable at \$5.40 per share) to its placement agents.

The Company valued the warrants at approximately \$261,000 using the Black-Scholes pricing model and recorded the warrant value as offering costs with a corresponding increase to additional paid-in capital. These warrants expired unexercised in 2006.

*October 2003 PIPE Transaction* On October 2, 2003 the Company closed a private offering, structured as a Private Investment, Public Equity ( PIPE ), exempt from registration under Section 4(2) of the Securities Act of 1933, in which it sold to institutional investors 1,314,571 of the 1,428,571 offered shares of common stock at \$3.50 per share for proceeds of approximately \$4,041,000, net of issuance costs of approximately \$559,000. In connection with this offering, the Company issued warrants (defined in Note 6 as the 2003 Investor Warrants and the 2003 Placement Agent Warrants). The Company allocated proceeds from this offering in the amounts of approximately \$2,531,000 and approximately \$191,000 representing the fair value of the 2003 Investor Warrants and the 2003 Placement Agent Warrants, respectively. Please see Note 6 Convertible Debt, Warrant Liabilities and Warrants for additional description of these warrants. These warrants expired unexercised in 2008.

*April 2004 PIPE Transaction* On April 7, 2004, the Company closed a private equity offering, structured as a PIPE in which it sold to certain institutional investors 1,236,111 shares of common stock at \$3.60 per share for proceeds of approximately \$3,983,000, net of cash issuance costs of approximately \$466,000. In connection with this offering, the Company issued warrants (defined in Note 6 as the April 2004 Investor Warrants and the April 2004 Placement Agent Warrants). The Company allocated proceeds from this offering in the amounts approximately \$1,931,000, and approximately \$154,000 representing the relative fair value of the April 2004 Investor Warrants and the April 2004 Placement Agent Warrants, respectively. Please see Note 6. Convertible Debt, Warrant Liabilities and Warrants for additional description of these warrants which are recorded as derivative liabilities. The placement agent warrants expired unexercised in 2007.

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*August 2004 PIPE Transaction* On August 12, 2004, the Company closed a private offering, structured as a PIPE in which it sold to certain institutional investors 2,000,000 shares of common stock at \$3.00 per share for proceeds of approximately \$5,515,000, net of cash issuance costs of approximately \$485,000. In connection with this offering the Company issued warrants (defined in Note 6 as the August 2004 Investor Warrants and the August 2004 Placement Agent Warrants). The Company allocated proceeds from this offering in the amounts of approximately \$4,786,000 and approximately \$239,000 representing the fair value of the August 2004 Investor Warrants and the August 2004 Placement Agent Warrants, respectively. Please see Note 6. *Convertible Debt, Warrant Liabilities and Warrants* for additional description of these warrants, which are recorded as derivative liabilities.

In 2004, the stockholders approved an increase in the number of undesignated shares that the Company is authorized to issue by 5,000,000 such that the total number of authorized undesignated shares following the effectiveness of such increase is 10,000,000 at December 31, 2006. Currently 2,000,000 shares remain undesignated. 5,000,000 have been designated for Series A 12% Convertible Preferred Stock, of which, 1,742,500 have been authorized and are outstanding, 900,000 have been designated for Series B-1 Preferred Stock and 2,100,000 have been designated for Series B-2 Preferred Stock.

*February 4, 2008 Private Placement.* On February 4, 2008, the Company closed a private placement begun in October 2007 of its Series A 12% Convertible Preferred Stock ( Series A Preferred ) and related warrants. In this transaction, the Company sold units of securities at \$1.00 per unit, each unit comprised of (i) one share of Series A Preferred, (ii) a warrant to purchase one share of common stock for \$1.50, and (iii) a warrant to purchase one share of common stock for \$2.00. Each share of the Series A Preferred is entitled to dividends at the rate of 12% per annum payable at the Company's option in cash or shares of common stock valued at the higher of \$1.00 per share or 100% of the value weighted average price of the Company's share price for the 20 consecutive trading days prior to the applicable dividend payment date. Dividends are payable semi-annually on March 30 and September 30. The dividend paid on the initial dividend payment date is calculated from the date the Company deposited each subscription advance. The Company recorded dividends of approximately \$239,000 in 2008 and issued 187,367 shares of common stock for dividend payments in 2008.

The shares of Series A Preferred are entitled to vote as a class with the Company's common stock and each share of Series A Preferred is convertible at any time to one share of common stock, subject to adjustment in the event of a stock dividend, stock split or combination, reclassification or similar event. The Company has the right to require conversion if the closing price of the common stock exceeds \$3.00 for 15 consecutive trading days and a registration statement covering the resale of the shares of common stock issuable upon conversion of the Series A Preferred is then in effect. The Series A Preferred has no liquidation preferences with respect to common stock. Each warrant is exercisable solely for cash beginning August 3, 2008 and expires on February 4, 2012. The exercise price of each warrant is adjustable in the event of a stock split or stock combination, capital reorganization, merger or similar event.

As of December 31, 2007, the Company had received subscription advances of approximately \$1,667,500 for the units of securities described above. In 2008, the Company received additional subscription advances of approximately \$75,000 resulting in total gross proceeds of approximately \$1,742,500. On February 4, 2008 the Company closed the private placement. The Company incurred approximately \$52,000 of cash transaction costs resulting in net cash proceeds of approximately \$1,690,500. In addition, the Company incurred approximately \$3,000 of costs for warrants issued to placement agents. Proceeds of approximately \$984,000 were allocated to investor warrants using the Black-Scholes method with the following assumptions as of February 4, 2008: risk free interest rate 2.51%, volatility 95%, fair market value of the company's common stock on February 4, 2008, and the share price on the closing date of the transaction of \$0.59.

The warrants were determined to have the characteristics of derivative liabilities in accordance with SFAS No. 133, *Accounting for Derivative Financial Instruments Indexed to and Potentially Settled in a Company's Own Stock* and were originally accounted for as liabilities.

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In the second quarter of 2008, these warrants liabilities were marked to market resulting in a change in fair value of warrant liabilities gain in the Statement of Operations of approximately \$100,000 and as a consequence of the Charter Amendment increasing the Company's authorized shares of common stock were reclassified to Stockholders' Equity. Please see Note 6. Convertible Debt, Warrant Liabilities and Warrants for further explanation.

*February 25, 2008 Offering* On February 25, 2008, the Company closed an offering in which it sold to investors (i) an aggregate of 7,500,000 shares of the Company's common stock at \$0.50 per share, (ii) warrants, which expire on August 25, 2013, to purchase an aggregate of 7,500,000 share of the Company's common stock at an exercise price of \$0.70 per share, and (iii) warrants, which expire on December 26, 2008, to purchase an aggregate of 3,000,000 shares of the Company's common stock at an exercise price of \$0.63 per share. In addition, the Company issued to a placement agent warrants, which expire on August 25, 2013, to purchase 206,250 shares of the Company's common stock at an exercise price of \$0.70. The warrants are exercisable beginning on August 25, 2008. The warrants provide for cashless exercise if at any time during the term of the warrants if there is no effective registration statement for the issuance or resale of the underlying warrant shares. The exercise price of each warrant is adjustable in the event of a stock split or stock combination, capital reorganization, merger or similar event. On December 26, 2008, the 3,000,000 warrants exercisable at \$0.63 expired unexercised.

The Company received net proceeds of approximately \$3,381,000 net of cash transaction costs of approximately \$369,000. In addition the Company incurred approximately \$56,000 of costs for warrants issued to a placement agent. Proceeds of approximately \$2,281,000 were allocated to investor warrants using the Black-Scholes method with the following assumptions as of February 25, 2008.

	<b>5 Year Warrants Exercisable at \$0.70</b>	<b>4 Month Warrants Exercisable at \$0.63</b>
Risk Free Interest Rate	2.94%	2.13%
Volatility	95%	95%
Fair market value of the Company's common stock	\$0.40	\$ 0.40

The warrants were determined to have the characteristics of derivative liabilities in accordance with SFAS No. 133, Accounting for Derivative Financial Instruments Indexed to and Potentially Settled in a Company's Own Stock and were originally accounted for as liabilities.

In the second quarter of 2008, these warrants liabilities were marked to market resulting in a change in fair value of warrant liabilities gain in the Statement of Operations of approximately \$356,000 and as a consequence of the Charter Amendment increasing the Company's authorized shares of common stock were reclassified to Stockholders' Equity. Please see Note

On July 2, 2008, the Company issued 300,000 warrants to Cork Investments in exchange for \$20,000. The warrants are exercisable for common stock at \$1.00 per share for a period of three years. The \$20,000 was credited to additional paid in capital.

On November 19, 2008, the Company filed a registration statement on Form S-1 with the SEC for a rights offering to distribute, at no charge, subscription rights to purchase shares of its common stock to its existing holders. The registration statement has not yet become effective. On February 17, 2009 the Company announced that it has postponed its previously announced rights offering. Subject to market conditions, the Company will determine whether it will proceed with the rights offering after it files its Annual Report on Form 10-K with the Securities and Exchange Commission.

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*Summary of Stock-Based Compensation Plans* In October 2001, the Company's Board of Directors adopted the Pro-Pharmaceuticals, Inc. 2001 Stock Incentive Plan (the Incentive Plan), which permits awards of incentive and nonqualified stock options and other forms of incentive compensation to employees and non-employees such as directors and consultants. The Board has 5,000,000 shares of common stock for issuance upon exercise of grants made under the Incentive Plan. Options granted under the Incentive Plan vest either immediately or over a period of up to three years, and expire 3 years to 10 years from the grant date. At December 31, 2008, 845,000 shares were available for future grant under the Incentive Plan.

In 2003, the stockholders approved the Pro-Pharmaceuticals, Inc. 2003 Non-Employee Director Stock Option Plan (the Director Plan), which permits awards of stock options to non-employee directors. The stockholders reserved 1,000,000 shares of common stock for issuance upon exercise of grants made under the Director Plan. At December 31, 2008, 762,750 shares were available for future grant under the Director Plan.

In addition, the Company has awarded 464,604 non-plan stock option grants to non-employees. The non-plan grants have vesting periods and expiration dates similar to those options granted under the Incentive Plan. 364,250 non-plan grants are outstanding at December 31, 2008.

Stock-based compensation expense for both employees and non-employees totaled approximately \$697,000 and \$616,000 in 2008 and 2007, respectively. Members of the Board of Directors receive stock options for each Board and Committee meeting attended. The options are typically granted in the year following service. The Company expenses the value of stock options as earned. In 2008 and 2007, Board members earned approximately 57,000 and 67,000 stock options respectively.

The fair value of the equity instruments granted to employees and non-employees, including options and warrants, is determined using the Black-Scholes option-pricing model. Key assumptions used to apply this option-pricing model are as follows:

	2008		2007		Cumulative Period from Inception (July 10, 2000) to December 31, 2008
Risk-free interest rate	1.55%	2.66%	3.41%	4.45%	3.05%
Expected life of the options	5 years		5 years		3.99 years
Expected volatility of the underlying stock	95%		95%		92%
Expected dividend rate	None		None		None

As noted above, the fair value of stock options is determined by using the Black-Scholes option pricing model. In general employee options vest over a period of three years. Board of Director and other options vest upon grant. For all options granted since January 1, 2006 the Company has used five years as the option term which represents the estimated life of options granted. Prior to January 1, 2006 the Company used three years as the option term.

The volatility of the common stock is estimated using a combination of historical and implied volatility, as discussed in SEC Staff Accounting Bulletin No. 107. By using this combination, the Company is taking into consideration the historical realized volatility, as well as factoring in estimates of future volatility that the Company believes will differ from historical volatility as a result of the market performance of the common stock, the volume of activity of the underlying shares, the availability of actively traded common stock options, and overall market conditions.



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The risk-free interest rate used in the Black-Scholes option pricing model is determined by reference to historical U.S. Treasury zero-coupon bond issues with terms equal to the expected terms of the equity awards. In addition, an expected dividend yield of zero is used in the option valuation model, because the Company does not expect to pay any cash dividends in the foreseeable future. Lastly, in accordance with SFAS No. 123(R), the Company is required to estimate forfeitures at the time of grant and revise those estimates in subsequent periods if actual forfeitures differ from those estimates. In order to determine an estimated pre-vesting option forfeiture rate, the Company used historical forfeiture data. This estimated forfeiture rate has been applied to all unvested options outstanding as of January 1, 2006 and to all options granted since January 1, 2006. Therefore, stock-based compensation expense is recorded only for those options that are expected to vest. At December 31, 2008, the Company does not anticipate any awards will be forfeited in the calculation of compensation expense due to the limited number of employees that receive stock option grants and the Company's historical employee turnover.

The following table summarizes the stock option activity in the stock based compensation plans from January 1, 2007 through December 31, 2008:

	Shares	Exercise Price Per Share		Weighted Average Exercise Price
Outstanding, January 1, 2007	3,059,354	\$ 1.90	5.80	\$ 3.60
Granted	1,048,500	0.63	1.01	0.94
Forfeited	(430,000)	1.01	5.80	2.82
Outstanding, December 31, 2007	3,677,854	\$ 0.63	4.05	\$ 2.93
Granted	1,130,000	0.38	0.44	0.44
Forfeited	(101,354)	2.96	4.05	3.64
Outstanding, December 31, 2008	4,706,500	\$ 0.38	4.05	\$ 2.32

The following tables summarize information about stock options outstanding at December 31, 2008:

Options Outstanding			Options Exercisable			
Exercise Price		Number of Shares	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Number of Shares	Weighted Average Exercise Price
\$0.38	\$0.70	1,355,000	4.07	\$ 0.48	1,309,667	\$ 0.48
\$1.01	\$2.70	955,500	3.69	\$ 1.32	575,503	\$ 1.52
\$2.92	\$4.05	2,396,000	3.80	\$ 3.75	2,301,003	\$ 3.75
		4,706,500	3.86	\$ 2.32	4,186,173	\$ 2.42

The weighted-average grant-date fair values of options granted during 2008 and 2007 were \$0.32, and \$0.70, respectively. As of December 31, 2008 there were 520,327 of unvested options which will vest as follows: 307,663 in 2009 and 212,664 in 2010. Total expected unrecognized compensation cost related to such unvested options is approximately \$208,000, which is expected to be recognized over a weighted average period of 0.7 years. As of December 31, 2008, there was no aggregate intrinsic value of outstanding options based on the Company's closing common stock price of \$0.09. As of December 31, 2008 there was no aggregate intrinsic value of outstanding fully vested options and exercisable options, based on the Company's closing common stock price of \$0.09.

No options were exercised during the years ended December 31, 2008 and 2007. No cash has been received from the exercise of employee stock options during the cumulative period from inception to December 31, 2008. The intrinsic value of options exercised for the cumulative period from inception was \$74 resulting from the cashless exercise of options in October 2003.



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During the years ended December 31, 2008 and 2007, and the cumulative period from inception to December 31, 2008, 1,293,317, 485,169 and 4,186,173 stock options, net of forfeitures, vested respectively. The total fair value of options vested during the years ended December 31, 2008 and 2007 and the cumulative period from inception to December 31, 2008 was approximately \$714,000, \$491,000 and \$6,282,000, respectively.

*Other Stock Based Compensation Transactions* During 2001, the Company entered into a consulting agreement with a non-employee, who was also a Board member and former member of the Audit Committee, pursuant to which the Company granted 200,000 options to purchase common stock at an exercise price of \$3.50 in consideration for services to be performed. At the time of issuance, these options were valued at approximately \$239,000 based on a deemed fair market value of the Company's common stock of \$2.28 per share. A portion of these options vested during fiscal years 2001 and 2002, and the remainder vested in 2003. The Company recorded fair value adjustments of approximately \$28,000 and \$16,000 related to the unvested consultant options during 2003 and 2002, respectively. Total expense for the years ended December 31, 2003, 2002 and 2001 related to these options was approximately \$71,000, \$64,000 and \$147,000, respectively.

In March 2002, the Company entered into a second agreement with the same non-employee, by which the Company granted 2,000 options a month to purchase common stock at an exercise price of \$3.50 in consideration for monthly consulting services. On November 11, 2002 such agreement was superseded by an amendment, which was effective retroactively to the date of the original agreement, March 1, 2002. Under the amended agreement, the Company granted 24,000 options on March 1, 2002, which vest at a rate of 2,000 options per month, as services are performed. These options were valued at approximately \$11,000 using the Black-Scholes option-pricing model, based on a grant date fair value of the Company's common stock of \$2.16 per share. During 2002, the Company recorded an approximately \$41,000 charge to stock compensation expense related to the 20,000 options that vested during the year. As of December 31, 2002, the Company had deferred compensation of approximately \$11,000 that related to the remaining unvested options, which was recognized in 2003.

In June 2003, the Company entered into a third agreement with the same non-employee, by which the Company granted 24,000 options effective retroactively to March 1, 2003, which vest at a rate of 2,000 options per month as services are performed. These options were valued at approximately \$33,000 using the Black-Scholes option-pricing model, based on a fair market value of the Company's common stock of \$3.50 per share. The consulting arrangement was concluded on March 1, 2004. The Company recorded fair value adjustments of approximately (\$2,000) and \$21,000 related to the unvested consultant options during 2004 and 2003, respectively. Total expense for the years ended December 31, 2004 and 2003 related to these options was approximately \$17,000 and \$40,000, respectively.

In January 2003, the Company granted 100,000 options at an exercise price of \$3.50 to a Board member for consulting services unrelated to services performed as a director. One-third of the options vested immediately and the balance vests in equal amounts on the first and second anniversaries of the award. The options were valued at approximately \$156,000 using the Black-Scholes option-pricing model, based on a fair market value of the Company's common stock of \$2.80 per share. The consulting services were completed and the consulting arrangement was concluded as of March 31, 2004. The Company recorded fair value adjustments of approximately \$4,000 and \$82,000 related to the unvested consultant options during 2004 and 2003, respectively. Total expense for the years ended December 31, 2004 and 2003 related to these options was approximately \$51,000 and \$193,000, respectively.

In May 2003, the Company granted 10,000 options at an exercise price of \$3.50 to a new member of the Scientific Advisory Board. One-half of the options vested immediately and the balance vests on the second anniversary. These options were valued at approximately \$16,000 using the Black-Scholes option-pricing model based on a fair market value of the Company's common stock of \$2.80 per share. The Company

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recorded fair value adjustments of approximately \$2,000 and \$6,000 related to the unvested consultant options during 2004 and 2003, respectively. Total expense for the years ended December 31, 2004 and 2003 related to these options was approximately \$5,000 and \$13,000, respectively.

In September 2003, the Company granted 25,000 options each to a Board member and to a member of the Scientific Advisory Board for consulting services. The options were exercisable immediately at \$4.05 per share. These options were valued using the Black-Scholes option-pricing model based on a grant date fair value of the Company's common stock of \$2.44 per share. The Company recorded an approximately \$122,000 charge to stock compensation expense in 2003 related to these awards.

In October 2003, in connection with the resignation of its former Chief Financial Officer, the Company accelerated the vesting on 100,000 options granted to such officer in September 2003 at an exercise price of \$4.05, which was equal to the fair market value of the common stock on the date of grant. As the fair market value of the common stock was \$4.45 per share at the time the vesting was accelerated, the Company recorded an approximately \$40,000 charge to stock compensation expense as required under APB No. 25 and related interpretations. Also, in October 2003, such officer exercised on a cashless basis 50,000 options at an exercise price of \$2.97 per share resulting in the issuance of 16,629 shares. As the fair market value of the Company's common stock on the date of exercise was \$4.45 per share, the Company recorded a charge of approximately \$74,000 to stock compensation expense in 2003 related to the exercise of these options.

In March 2004, the Company issued 25,000 options in fulfillment of a September 2003 agreement with an investor relations firm. The agreement obligated the Company to pay a monthly retainer and issue options at a rate of 5,000 options per month, up to a maximum of 100,000 options, exercisable at \$5.80 per share as services are performed. The Company concluded the engagement in February 2004. The options were exercisable immediately and expired on March 26, 2007. Accordingly, the Company recorded approximately \$29,000 as stock compensation expense in 2003 on the 15,000 options that vested as of December 31, 2003 and an additional stock compensation expense of approximately \$23,000 in 2004 on the 10,000 options that vested in January and February 2004. The stock compensation expense was determined based on a fair market value of the options when the options were earned. These options expired unexercised in 2007.

In April 2004, the Company entered into an agreement with an investor relations firm. The agreement obligated the Company to pay a monthly retainer and issue options at a rate of 5,000 per month up to a maximum of 60,000 options exercisable at \$5.16 per share as services are performed. During 2004, 45,000 options were earned but not issued. During 2005 15,000 options were earned and the full 60,000 options were issued. The Company recorded approximately \$67,000 in 2004 and \$14,000 in 2005 as stock compensation expense related to this agreement. The stock compensation expense was determined based on the fair market value of the options when the options were earned. The options were exercisable immediately and expired three years from the agreement date. These options expired unexercised in 2007.

In November 2005, the Company issued 5,000 options to a member of the Scientific Advisory Board for consulting services. The options were exercisable immediately at \$2.61 per share. These options were valued using the Black-Scholes option-pricing model based on a grant date fair value of the Company's common stock of \$1.35 per share which was the fair market value at the date of the grant. The Company recorded an approximately \$7,000 charge to stock compensation expense in 2005 related to this award.

In March 2006 the Company issued 15,000 options to a consultant for consulting services. 5,000 of the options were exercisable immediately, 5,000 options vest in March 2008 and 5,000 options vest in March 2009. The options are exercisable at \$3.75 per share. These options were valued using the Black-Scholes option-pricing model based on a grant date fair value of the Company's common stock of \$2.20 per share which was the fair market value at the date of the grant. The Company is recording an approximately \$33,000 charge to stock compensation expense over the vesting period of the options.

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In December 2007, the Company issued 5,000 options to a consultant for consulting services. The options were exercisable immediately at \$0.63 per share. These options were valued using the Black-Scholes option-pricing model based on a grant date fair value of the Company's common stock of \$0.46 per share which was the fair market value at the date of the grant. The Company recorded an approximately \$2,000 charge to stock compensation expense in 2007 related to this award.

In April 2008, the Company issued 48,000 options to a consultant for consulting services. The options were exercisable immediately at \$0.44 per share. These options were valued using the Black-Scholes option-pricing model based on a grant date fair value of the Company's common stock of \$0.39 per share which was the fair market value at the date of the grant. The Company recorded an approximately \$15,000 charge to stock compensation expense in 2008 related to this award.

**10. EARNINGS PER SHARE**

Basic loss per share is based on the weighted-average number of common shares outstanding during each period. Diluted loss per share is based on basic shares as determined above plus the incremental shares that would be issued upon the assumed exercise of in-the-money stock options and warrants using the treasury stock method and convertible debenture using the if-converted method. The computation of diluted net loss per share does not assume the issuance of common shares that have an anti-dilutive effect on net loss per share. For the years ended December 31, 2008 and 2007, all stock options and warrants were excluded from the computation of diluted net income (loss) per share. During the year ended December 31, 2007 all potential shares related to the conversion of the convertible debenture were excluded from the computation of diluted net income (loss) per share since to include them would be anti-dilutive and as of December 31, 2007 the convertible debenture has been repaid in full. Dilutive shares which could exist pursuant to the exercise of outstanding stock options and warrants at December 31, 2008 and 2007 totaled approximately 30,056,811 and 11,954,561, respectively. These amounts were not included in the calculation because their affect would have been anti-dilutive.

	2008	2007
Net Loss Applicable to Common Stock-basic and diluted	\$ (3,390)	\$ (9,433)
Weighted average common shares outstanding-basic and diluted	46,815,250	38,980,548
Net Loss Per Share-basic and diluted	\$ (0.07)	\$ (0.24)

**11. COMMITMENTS AND CONTINGENCIES**

*Lease Commitments* The Company leases its facility under a non-cancelable operating lease that expires in August 2011. In connection with the operating lease, the Company has issued a letter of credit which is secured by restricted cash on deposit with the bank as a security deposit of approximately \$59. Rent expense under these operating leases was approximately \$250,000 and \$259,000, for the years ended December 2008 and 2007, respectively.

Future minimum payments under this lease as of December 31, 2008 are approximately as follows:

Year ended December 31,	
2009	\$ 267
2010	276
2011	168
Total lease payments	\$ 711

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*Contingency* In January 2004, David Platt, Ph.D., the Company's former Chairman and Chief Executive Officer, filed a lawsuit in Massachusetts Superior Court against GlycoGenesys, Inc. for various claims including breach of contract. GlycoGenesys asserted counterclaims against the Company and Dr. Platt alleging tortious interference, misappropriation of proprietary rights, defamation and unfair competition, and sought monetary damages and injunctive relief related to the Company's intellectual property. Prospect Therapeutics, Inc. (formerly known as Marlborough Research and Development, Inc.) purchased certain assets including this lawsuit from the GlycoGenesys bankruptcy estate and continues prosecuting the counterclaims against the Company and Dr. Platt. Concluding that certain disputes of fact could not be resolved as a matter of law, the Court on May 27, 2008 denied the Company's motion for summary judgment. Prospect Therapeutics informed the Court that it does not seek monetary damages other than recovery of attorney fees. The trial began on March 10, 2009. The Company and Dr. Platt believe the counterclaims are without merit and intend to contest them vigorously. Additionally, the Company believes that any impact on the financial statements is neither probable nor reasonably estimable and therefore no amounts have been recorded as of December 31, 2008.

The Company's Board of directors authorized the indemnification of Dr. Platt for the expenses of his defense of the counterclaims. In the year ended December 31, 2008, Company incurred no expenses in connection with this defense. Through December 31, 2008, the Company has incurred cumulative expenses of approximately \$438,000 in connection with this defense.

In January 2005, the Company filed a request with the U.S. Patent and Trademark Office for an inter partes re-examination of U.S. Patent No. 6,680,306 ( '306 ) now owned by Prospect Therapeutics, Inc. because the Company believes that the invention claimed in this patent is anticipated by other inventions (technically, prior art ), including the Company's U.S. Patent No. 6,645,946 for DAVANA<sup>®</sup>. The Patent Office has agreed with the Company's argument throughout the re-examination that all claims stated in the '306 patent are anticipated by prior art. The Company believes that the actions of the Patent Office support the Company's position that the invention claimed in the DAVANA<sup>®</sup> patent is prior art relative to the '306 patent.

On January 30, 2008, Custom Equity Research, Incorporated (d/b/a Summer Street Research Partners) ( Summer Street ) filed a lawsuit against the Company 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 the Company. 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 the Company from October 17, 2007 through November 16, 2008. The Company 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, the Company filed its answer, denying Summer Street's material allegations. No trial date has been set for this matter. The Company believes the lawsuit is without merit and intends to contest it vigorously. Additionally, the Company believes that any impact on the financial statements is neither probable nor reasonably estimable and therefore no amounts have been recorded as of December 31, 2008.

In the ordinary course of business, the Company may from time to time be involved in other legal matters that in the Company's estimation will not have a material adverse impact on it. The Company records accruals for such contingencies to the extent that the Company concludes that their occurrence is probable and the related damages are estimable.

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The Company adopted the provisions of FIN 48 on January 1, 2007. As a result of the implementation of FIN 48, the Company recognized approximately a \$1,031 increase in the liability for unrecognized tax benefits, which was accounted for as a reduction to the January 1, 2007, related deferred tax asset and the corresponding valuation allowance.

The components of the net deferred tax assets are as follows at December 31:

	2008	2007
Operating loss carryforwards	\$ 15,436	\$ 14,187
Tax credit carryforwards	165	82
Other temporary differences	(20)	19
	15,581	14,288
Less valuation allowance	(15,581)	(14,288)
Net deferred tax asset	\$	\$

The primary factors affecting the Company's income tax rates were as follows:

	2008	2007
Tax benefit at U.S. statutory rates	(34.0%)	(34.0%)
State tax benefit	(6.2%)	(6.2%)
Permanent differences	(13.6%)	(12.1%)
Research and development credits	(2.5%)	(0.8%)
Valuation allowance	56.3%	28.9%
	0%	0%

As of December 31, 2008, the Company has federal and state net operating loss carryforwards totaling \$40,556,000 and \$31,203,000, respectively, which expire through 2028. In addition, the Company has federal and state research and development credits of \$110,000 and \$52,000 and investment tax credits of approximately \$4,000, which expire through 2028. Changes in the Company's ownership, as defined by Section 382 of the Internal Revenue Code, could limit the amount of carryforwards which may be realized in future periods. Because of the Company's limited operating history and its recorded losses, management has provided, in each of the last two years, a 100% allowance against the Company's net deferred tax assets.

The following is a tabular reconciliation of the total amounts of unrecognized tax benefits for the year:

Beginning Uncertain Tax Benefits	\$ 1,082
Current Year Increase	
Current Year Decrease	
Current Year Interest/Penalties	
Settlements	
Expire Statutes	
Ending Uncertain Tax Benefits	\$ 1,082

Included in the balance of unrecognized tax benefits at December 31, 2008, are \$1,082 of tax benefits \$890 of which, would affect the effective tax rate. We have not recognized an adjustment to the deficit accumulated during the development stage for unrecognized tax benefits because we have recorded a full valuation allowance against net operating loss carry forwards.





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Since the Company's net deferred tax assets and the unrecognized tax benefits determined under FIN 48 would not result in a cash payment, the Company has not accrued for any interest and penalties relating to these unrecognized tax benefits. Should the Company incur interest and penalties related to income taxes, those amounts would be included in income tax expense.

Total amounts of unrecognized tax benefits are not expected to significantly increase or decrease within 12 months of the reporting date.

The Company is subject to taxation in the U.S. and various states. Based on the history of net operating losses all jurisdictions and tax years are open for examination until the operating losses are utilized or the statute of limitations expires.

**13. SUBSEQUENT EVENTS**

On February 12, 2009, the Company entered into a securities purchase agreement pursuant to which it agreed to issue and sell to an investor at two or more closings, (i) 3,000,000 shares its Series B convertible preferred stock with an aggregate stated value of \$6.0 million and convertible into 12,000,000 shares of common stock and (ii) warrants to purchase 36,000,000 shares of common stock. On February 12, 2009, the initial closing date under the purchase agreement, the Company issued and sold (i) 900,000 shares of Series B-1 preferred stock 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 proceeds from the closing of the initial tranche were approximately \$1.5 million. At one or more subsequent closings under the purchase agreement, the Company has agreed to issue: (i) up to 2,100,000 shares of Series B-2 preferred stock convertible into 8,400,000 shares of common stock; (ii) Class A-1 warrants exercisable to purchase up to 4,200,000 shares of common stock; (iii) Class A-2 warrants exercisable to purchase up to 4,200,000 shares of common stock; and (iv) Class B warrants exercisable to purchase up to 16,800,000 shares of common stock for an aggregate purchase price of up to \$4.2 million (less fees and expenses). The Purchase Agreement contains customary representations, warranties, covenants and closing conditions. Upon any subsequent closing under the Purchase Agreement, such representations and warranties must be accurate in all material respects, such covenants must have been performed and such closing conditions must have been satisfied or waived, including without limitation no material adverse effect having occurred with respect to the Company prior to any subsequent closing. The Company expects the subsequent closings under the purchase agreement to occur on or before June 15, 2009 (the Final Purchase Date). However, if Purchaser has purchased 350,000 or more shares of Series B-2 preferred stock (with a stated amount of \$700,000 or more) by May 13, 2009, then the Final Purchase Date will be automatically extended until August 11, 2009.

The terms and conditions of the Series B-1 preferred stock and Series B-2 preferred stock are identical in all respects except with respect to the Company's redemption rights. Such holders will be entitled to receive cumulative dividends at the rate of 12% per share per annum (compounding monthly) payable quarterly which may, at the Company's option, be paid in cash or common stock valued per share at 100% of the value weighted average price per share for the 20 consecutive trading days prior to the applicable dividend payment date; provided, however, that there is an effective registration statement covering the shares of the Company's common stock (for dividend payments due on September 30, 2009 or later) and the issuance of the shares does not trigger anti-dilution provisions under other agreements to which the Company is a party. If the Company does not pay any dividend on the Series B preferred stock, dividends will accrue at the rate of 15% per annum (compounding monthly). Each share of Series B preferred stock is convertible into four shares of common stock at the conversion price of \$0.50 per share (subject to customary anti-dilution protection adjustments) at the option of (i) the holder, at any time and (ii) the Company, at any time after February 12, 2010 (and upon 10 days notice) if the common stock is quoted at or above \$1.50 for 15 consecutive trading days and an effective registration statement regarding the underlying shares of common

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stock is in effect (subject to certain monthly volume limits). Upon notice of not less than 30 trading days, a holder of Series B preferred Stock may require the Company to redeem, in whole or in part, (i) the Series B-1 preferred stock at any time on or after March 12, 2010 and (ii) the Series B-2 preferred stock at any time on or after two years from the date of issuance of such shares of Series B-2 preferred stock. The redemption price will be equal to the sum of the stated value of the Series B preferred stock, plus all accrued but unpaid dividends thereon, as of the redemption date. If the Company fails for any reason to pay the redemption price in cash on the redemption date, then the holders of the Series B preferred stock requesting redemption may, at their sole option, automatically convert their shares of Series B preferred stock into a promissory note bearing interest at the rate of 15% per year and secured by a lien on all of the Company's assets. So long as any shares of the Series B preferred stock remain outstanding, the Company is also subject to restrictions limiting, among other things, amendments to the Company's organizational documents; the purchase or redemption of the Company's capital stock; mergers, consolidations, liquidations and dissolutions; sales of assets; dividends and other restricted payments; investments and acquisitions; joint ventures, licensing agreements, exclusive marketing and other distribution agreements; issuances of securities; incurrence of indebtedness; incurrence of liens and other encumbrances and issuances of any common stock equivalents.

Each Class A-1 warrant, Class A-2 warrant and Class B warrant is exercisable at \$0.50 per share of common stock (subject to customary anti-dilution protection adjustments) at any time on or after the date of issuance until the fifth anniversary of the respective issue date. The Company may, upon 30 days notice and so long as an effective registration statement regarding the underlying shares of common stock is in effect, issue a termination notice with respect to (i) each Class A-1 warrant on any trading day on which the market value of the common stock for each of the 15 previous trading days exceeded \$1.25 per share (subject to customary anti-dilution protection adjustments) and (ii) each Class A-2 warrant on any trading day on which the market value of the common stock for each of the 15 previous trading days exceeded \$1.75 per share (subject to customary anti-dilution protection adjustments).

The Company is required to use its commercially reasonable efforts to (i) as soon as reasonably possible, register for resale under the Securities Act of 1933 all shares of common stock underlying (x) the Series B preferred stock (including shares of common stock issued as a dividend thereon) and (y) the warrants issued under the Purchase Agreement and (ii) keep the registration statement effective for a period of ninety (90) days or until such registrable securities have been sold. The Company has agreed to pay all registration expenses incurred by it in connection with the registration.

On February 12, 2009, David Platt, Ph.D., resigned as Chairman of the Company's Board of Directors and as Chief Executive Officer of the Company and each of Dale H. Conaway, D.V.M, Henry J. Esber, Ph.D., and James T. Gourzis, M.D., resigned from the Company's Board of Directors. Theodore Zucconi, Ph.D., who is a director of the Company, was named Chief Executive Officer and President of the Company. Also, on February 12, 2009, James C. Czirr, Rod Martin, Gilbert Amelio, Ph.D., and Peter Traber, M.D., were elected to the Company's Board of Directors.

Also on February 12, 2009, in connection with the transactions described above, the Company entered into a Separation Agreement (the "Separation Agreement") with its former Chief Executive Officer, David Platt, Ph.D. In connection with the termination of Dr. Platt's employment and as contemplated by his Employment Agreement dated as of January 2, 2004 (the "Employment Agreement"), the Separation Agreement will govern the terms of Dr. Platt's termination of employment.

The Separation Agreement provides that the Company shall continue to pay Dr. Platt his current salary at the monthly rate of \$21,667 for 24 months and that the Company may defer payment of a portion of such salary amounts above \$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 upon the earlier to occur of (i) the Company receiving a

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minimum of \$4.0 million of funding after February 12, 2009, or (ii) February 12, 2011. The Company 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 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.

The Company may defer a severance payment of \$1.0 million due to Dr. Platt under his Employment Agreement until the occurrence of any of the following events (each, a Milestone Event ): (i) approval by the Food and Drug Administration of 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 \$50.0 million of royalty revenue to the Company; or (iii) the renewed listing of our securities on a national securities exchange and the achievement of a market capitalization of \$100.0 million. Payment upon the events referred to in clause (i) and (iii) may be deferred up to six months, and if the Company has insufficient cash at the time of any of such events, it may issue Dr. Platt a secured promissory note for such amount. If the Company files a voluntary or involuntary petition for bankruptcy, whether or not a Milestone Event has occurred, such event shall trigger the Company's obligation to pay the \$1.0 million with the result that Dr. Platt may assert a claim for such obligation against the bankruptcy estate.

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, the Company will grant Dr. Platt fully vested cashless-exercise stock options exercisable to purchase at least 300,000 shares of the Company's 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 ( Cashless Stock Options ) and (ii) approval by the FDA of the first NDA for any of the Company's drug or drug delivery candidates based on DAVANAT® technology (whether or not such technology is patented), the Company will grant Dr. Platt fully vested Cashless Stock Options to purchase at least 500,000 shares of common stock.