

GALECTIN THERAPEUTICS INC

Form 10-K

March 29, 2013

Table of Contents

**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, 2012

.. 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. 001-31791

**GALECTIN THERAPEUTICS INC.**

Nevada  
(State or other jurisdiction

of incorporation)

4960 Peachtree Industrial Blvd., Suite 240, Norcross, GA  
(Address of Principal Executive Offices)

(678) 620-3186

(Registrant's Telephone Number, Including Area Code)

04-3562325  
(I.R.S. Employer

Identification No.)

30071  
(Zip Code)

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

<b>Title of each class</b>	<b>Name of each exchange on which registered</b>
<b>Common Stock, \$0.001 Par Value Per Share</b>	<b>The NASDAQ Capital Market</b>
<b>Units, each consisting of two shares of Common Stock and one Warrant to purchase one share of Common Stock</b>	<b>The NASDAQ Capital Market</b>
<b>Common Stock Purchase Warrants</b>	<b>The NASDAQ Capital Market</b>

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

**None**

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

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

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

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

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, 2012 was \$29.9 million.

The number of shares outstanding of the registrant's common stock as of March 27, 2013 was 16,109,090.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the definitive Proxy Statement for the 2013 Annual Meeting of Stockholders are incorporated by reference into Part III of this Report.

**Table of Contents**

**INDEX TO FORM 10-K**

**FOR THE YEAR ENDED DECEMBER 31, 2012**

	<b>PAGE</b>
<b>PART I</b>	
ITEM 1. <u>Business</u>	2
ITEM 1A. <u>Risk Factors</u>	10
ITEM 1B. <u>Unresolved Staff Comments</u>	22
ITEM 2. <u>Properties</u>	22
ITEM 3. <u>Legal Proceedings</u>	22
ITEM 4. <u>Mine Safety Disclosure</u>	23
<b>PART II</b>	
ITEM 5. <u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	24
ITEM 6. <u>Selected Financial Data</u>	24
ITEM 7. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	24
ITEM 7A. <u>Quantitative and Qualitative Discussions About Market Risk</u>	33
ITEM 8. <u>Financial Statements and Supplementary Data</u>	33
ITEM 9. <u>Changes in and Disagreements With Accountants on Accounting and Financial Disclosure</u>	33
ITEM 9A. <u>Controls and Procedures</u>	33
ITEM 9B. <u>Other Information</u>	34
<b>PART III</b>	
ITEM 10. <u>Directors, Executive Officers and Corporate Governance</u>	35
ITEM 11. <u>Executive Compensation</u>	35
ITEM 12. <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	35
ITEM 13. <u>Certain Relationships, Related Transactions and Director Independence</u>	35
ITEM 14. <u>Principal Accountant Fees and Services</u>	35
<b>PART IV</b>	
ITEM 15. <u>Exhibits and Financial Statement Schedules</u>	36
<u>SIGNATURES</u>	41

**Table of Contents**

**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. These statements include our plans, expectations and goals regarding drugs in development, clinical trials and regulatory approval for any of our drugs or treatments, potential benefits and uses of our drugs, estimates regarding cash and liquidity, expectations regarding our ability to raise additional capital and the sources and timing of such capital, intentions with respect to legal proceedings and costs related to clinical trials. 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.

Although we believe that we have sufficient cash on hand to fund our planned operations into 2014, if we fail to raise additional capital by the end of the first quarter of 2014, 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 (FDA) and by foreign regulatory authorities, which must approve our product candidates in development and could restrict the sales and marketing and pricing of such products.

We may be unable to demonstrate the efficacy and safety of our developmental product candidates in human trials.

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 may be required to 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.



**Table of Contents**

**PART I**

**Item 1. *Business*  
Overview**

We are a development-stage company engaged in drug research and development to create new therapies for fibrotic disease and cancer. Our drug candidates are based on our method of targeting galectin proteins, which are key mediators of biologic and pathologic functions. We use naturally occurring, readily-available plant materials as starting material in manufacturing processes to create proprietary complex carbohydrates with specific molecular weights and other pharmaceutical properties. These complex carbohydrate molecules are appropriately formulated into acceptable pharmaceutical formulations. Using these unique carbohydrate-based candidate compounds that bind and inhibit galectin proteins, we are undertaking the focused pursuit of therapies for indications where galectins have a demonstrated role in the pathogenesis of a given disease. We focus on diseases with serious, life-threatening consequences to patients and those where current treatment options are limited. Our strategy is to establish and implement clinical development programs that add value to our business in the shortest period of time possible and to seek strategic partners when a program becomes advanced and requires additional resources.

We endeavor to leverage our scientific and product development expertise as well as established relationships with outside sources to achieve cost-effective and efficient development. These outside sources, amongst others, provide us with expertise in preclinical models, pharmaceutical development, toxicology, clinical development, pharmaceutical manufacturing, sophisticated physical and chemical characterization, and commercial development. We also have established a collaborative scientific discovery program with leading experts in carbohydrate chemistry and characterization. This discovery program is aimed at the targeted development of new molecules which bind galectin proteins and offer alternative options to larger market segments in our primary disease targets. We are pursuing a development pathway to clinical enhancement and commercialization for our lead compounds in immune enhancement for cancer therapy as well as in both liver fibrosis and fatty liver disease. All of our proposed products are presently in development, including pre-clinical and clinical trials.

We were founded in July 2000 as Pro-Pharmaceuticals, Inc., a Massachusetts corporation. On April 25, 2001, DTR-Med Pharma Corp. ( DTR ), which was incorporated in Nevada on January 26, 2001, entered into a stock exchange agreement with Pro-Pharmaceuticals, Inc., whereby DTR acquired all of the outstanding shares of common stock of Pro-Pharmaceuticals, Inc. On May 10, 2001, DTR changed its name to Pro-Pharmaceuticals, Inc. and on June 7, 2001, the Massachusetts corporation was merged into the Nevada corporation. On May 26, 2011, Pro-Pharmaceuticals, Inc. changed its name to Galectin Therapeutics Inc. In October, 2012, we moved our headquarters to a suburb of Atlanta, GA to be closer to a center of discovery collaboration while maintaining a contract laboratory operation in the Boston area.

**Our Drug Development Programs**

Galectins are a class of proteins that are made by many cells in the body. As a group, these proteins are able to bind to sugar molecules that are part of other proteins in and on the cells of our body. Galectin proteins act as a kind of glue, bringing together molecules that have sugars on them. Galectin proteins are known to be markedly increased in a number of important diseases including scarring of organs (e.g. liver, lung, kidney, and heart) and cancers of many kinds. The increase in galectin protein promotes the disease and is detrimental to the patient.

We have two compounds in development, one intended to be used in the treatment of liver fibrosis and fatty liver disease and the other intended to be used in cancer therapy. These two compounds are produced from completely different, natural, readily available, starting materials, which, following chemical processing, both exhibit the property of binding to and inhibiting galectin proteins.

**Table of Contents**

Our product pipeline is shown below:

Indication	Drug	Status
<b>Fibrosis</b> NASH with Advanced Fibrosis	GR-MD-02	IND submitted January 2013, FDA indicated on March 1, 2013 that we could proceed with a Phase 1 US clinical trial. Phase I clinical trial expected to start Q2-2013

**Cancer Immunotherapy**

Melanoma

GM-CT-01 Phase I/II study in process in Europe

*GR-MD-02.* GR-MD-02 is our lead product candidate for treatment of fibrotic disease. Our preclinical data show that GR-MD-02 has a powerful therapeutic effect on liver fibrosis as shown in several relevant animal models. Therefore, we chose GR-MD-02 as the lead candidate in a development program targeted initially at fibrotic liver disease associated with non-alcoholic steatohepatitis (NASH, or fatty liver disease). In January 2013, an Investigational New Drug ( IND ) was submitted to the FDA with the goal of initiating a Phase I study in patients with NASH and advanced liver fibrosis to evaluate the human safety of GR-MD-02 and pharmacodynamics biomarkers of disease. On March 1, 2013, the FDA indicated we could proceed with a US Phase 1 clinical trial for GR-MD-02 with a development program aimed at obtaining support for a proposed indication of GR-MD-02 for treatment of NASH with advanced fibrosis. Pre-clinical studies also show promise for the combination of GR-MD-02 with other approved immunotherapies and this additional use will be explored for possible advancement into clinical trials.

Our drug candidate provides a promising new approach for the therapy of fibrotic diseases, and liver fibrosis in particular. Fibrosis is the formation of excess connective tissue (collagen and other proteins plus cellular elements such as myofibroblasts) in response to damage, inflammation or repair. When the fibrotic tissue becomes confluent, it obliterates the cellular architecture, leading to scarring and dysfunction of the underlying organ.

*GM-CT-01.* GM-CT-01, our product candidate targeted for selective cancer therapy, is currently in a clinical trial in Europe. In 2012 we initiated a Phase 1/2 clinical trial of GM-CT-01 in combination with a tumor vaccine in patients with advanced melanoma, a deadly skin cancer. The trial is being conducted at three centers in Belgium and one in Luxembourg. The operational conduct of the trial is under the control of the Cancer Centre at the Cliniques Universitaires Saint-Luc and the Ludwig Institute for Cancer Research. Positive results from this study could indicate that inhibiting the Galectin Effect could be an enabling technology for therapy in other tumor types.

We believe there is potential for galectin inhibition to play a key role in the burgeoning area of cancer immunotherapy. For example, there have been two recent approvals of drugs that enhance a patient's immune system to fight cancer: Provenge® (Dendreon; a dendritic cell tumor vaccine) and Yervoy® (BMC; a monoclonal inhibitor of CTLA4 which activates cytotoxic T-cells). With many additional vaccines and immune stimulatory agents in development, industry analysts forecast that this market could grow to over \$7 billion by 2015. It is our goal to use a galectin inhibitor to enhance the immune system function to fight cancer and, most important, that complements other approaches to this type of therapy. Our drug candidates provide a promising new therapeutic approach to enhance the activity of the immune system against cancer cells.

We believe the mechanism of action for GM-CT-01 and GR-MD-02 is based upon interaction with, and inhibition of, galectin proteins, which are expressed at high levels in certain pathological states including inflammation, fibrosis and cancer. While GM-CT-01 and GR-MD-02 are capable of binding to multiple galectin proteins, we believe that they have the greatest affinity for galectin-3, the most prominent galectin implicated in pathological processes. Blocking galectin in cancer and liver fibrosis has specific salutary effects on the disease process, as discussed below.

## **Table of Contents**

### **Liver Fibrosis: New Approach for a Significant Unmet Medical Need**

When an internal organ is exposed to chronic disease one of the responses is that scar tissue is laid down in the organ (this process is called fibrosis). The longer the disease affects the organ, the more fibrous tissue is deposited and this ultimately results in the failure of the organ. This chronic fibrosis of organs may occur in the liver, lung, kidney, and heart, as well as others and, as a result, fibrosis of organs has been estimated to account for as much as 45% of all mortality. Scientific findings during the last few years indicate that the galectin-3 protein is critically important in this fibrotic process in multiple organs.

In the liver, fibrosis is the end result of multiple inflammatory conditions and infections. Progressive liver fibrosis leads to scarring (cirrhosis), which results in reduction of liver function, multiple medical complications and ultimately death. Nearly 500,000 patients have cirrhosis in the United States with close to 50,000 losing their lives yearly. Only a fraction of patients' lives have been saved by liver transplantation at a cost of approximately \$350,000 per transplantation. One condition in particular that frequently leads to cirrhosis is non-alcoholic steatohepatitis, or NASH, a liver disease characterized by the accumulation of fat in the liver with associated inflammation and fibrosis, which can lead to end-stage cirrhosis requiring liver transplantation. The National Institute of Health estimates that 9 to 15 million Americans are affected by NASH and forecasts that the number of Americans affected by this disease is growing due to obesity and diabetes, with the potential to become the leading cause of liver cirrhosis and liver transplantation in the future. Liver transplantation is currently the only therapeutic approach to NASH or other forms of liver fibrosis as, to the best of our knowledge, there are no drug therapies on the market. Organ transplantation is a difficult, risky and costly procedure as organ availability is scarce and there is the risk of developing cirrhosis in the transplanted liver from the same disease that damaged the patient's original liver and therefore, there is a great need for other therapeutic options. All diseases that affect the liver (viral hepatitis, alcoholic liver disease, and fatty liver as examples) lead to the development of scarring of the liver.

The primary focus of the company is to use galectin inhibitors to block galectin-3 and treat organ scarring or fibrosis in the liver. There are no approved therapies for treatment of liver fibrosis. We believe that our drug candidates have the potential to treat NASH and other forms of liver fibrosis. Scientific evidence strongly suggests that galectin-3 is essential for the development of liver fibrosis in animals. Published data show that mice lacking the galectin-3 gene, and thus unable to produce galectin-3, are incapable of developing liver fibrosis in response to toxic insult to the liver (Henderson 2006) and in fatty liver disease (Iacobini 2010). Moreover, mice that do not have the galectin-3 gene are resistant to lung (MacKinnon 2012, Nishi 2007) and kidney fibrosis (Henderson 2008). These published data show that galectin-3 is a critical protein for the development of organ fibrosis. Our drugs, based on experiments in well characterized animal models, are also potentially useful in scarring or fibrosis of other organs such as lung and kidney which expands the possibilities for therapeutic indications.

We have evaluated the ability of GR-MD-02 to block galectin-3 in animal models of liver fibrosis, the conclusions of which yielded positive results. Our pre-clinical data show that GR-MD-02 may have a therapeutic effect on liver fibrosis as shown in several relevant animal models. Therefore, we chose GR-MD-02 as the lead candidate in a development program targeted initially at fibrotic liver disease associated with NASH. We evaluated GR-MD-02 in pre-clinical toxicology and pharmacology studies during 2013 and filed an IND with the FDA in January 2013 for initiating human studies in patients with NASH. In February 2013 we entered into an agreement with CTI Clinical Trial Services to assist with the design, development and conduct of one or more clinical research studies, specifically for services with respect to our Phase I clinical trials to evaluate safety of GR-MD-02 in patients with NASH. The FDA notified us in March 2013 that we may proceed with a Phase I clinical trial for patients with NASH and we expect to begin enrolling patients in the Phase I clinical trial in the second quarter of 2013, with top line results expected by the end of 2013 or early 2014. Depending on the results of the Phase I study, and available funding, we may initiate a Phase II clinical trial in mid-2014 to assess the efficacy of GR-MD-02 in patients with NASH and advanced liver fibrosis with expected top-line clinical results by mid to late 2015. Our Phase II clinical program is likely to include additional clinical trials to fully characterize human response to GR-MD-02 and to better position the Company for a successful Phase III clinical trial program.



## **Table of Contents**

GR-MD-02 is a proprietary galactoarabino-rhamnogalacturonan polysaccharide polymer that is comprised predominantly of galacturonic acid, galactose, arabinose, rhamnose, and smaller amounts of other sugars. Structural studies have shown that GR-MD-02 binds to galectin-1 (Miller 2009 Biochem J.) and to galectin-3 (Galectin Therapeutics Inc. unpublished observations) with binding affinity to galectin-3 being significantly greater than binding to galectin-1. Similar to GM-CT-01, GR-MD-02 targets extracellular galectins.

Some of the intellectual property protection for our GR-MD-02 molecules and key features of this molecule include, amongst others:

Composition of matter patent pending

Method of use patent in liver fibrosis granted (US 8,236,780)

Method of use patents pending in NASH and Cancer Immunotherapy

IND submitted January 2013 for use in patients with NASH with advanced fibrosis; FDA gave approval to proceed with a Phase I clinical trial on March 1, 2013

Low toxicity potential because carbohydrates are metabolized to harmless compounds unlike other drugs that have toxic metabolites.

API (active pharmaceutical ingredient) is relatively inexpensive to manufacture as the starting material is sourced from an abundant natural material In pharmaceutically acceptable form

Compound(s) for subcutaneous administration under development

### **Galectin Inhibition in Cancer Therapy**

We believe the potential exists for galectin inhibition to play an important role in cancer therapy. Galectin proteins, particularly galectin-1 and galectin-3, have been shown to be highly expressed in the majority of cancers and have multiple roles in promoting cancer progression, including tumor cell invasion, metastasis, angiogenesis, and tumor evasion of the immune system. GM-CT-01 has progressed in development for the therapy of colorectal cancer and is currently in a Phase I/II clinical trial in Europe as a combination therapy with a tumor vaccine in patients with advanced melanoma. The current developmental approach for GM-CT-01 is to enhance the activity of the immune system against the cancer.

The role of galectins in cancer immunotherapy can be understood through the *Galectin Effect*, a recent discovery of how tumors avoid the body's own immune system, i.e., the tumors secrete galectin proteins that block the body's efforts to fight tumors. Our current program to block the *Galectin Effect* is based on the research of Dr. Pierre van der Bruggen (of the Ludwig Institute of Cancer Research in Brussels, Belgium), demonstrating that galectin-3, which is produced by the vast majority of human cancers, binds to and blocks the actions of tumor-infiltrating T-lymphocytes, the major immune cell in the body's defense against cancers. Based on these results, we believe that the body's immune cells may be unable to attack and kill tumor cells in the presence of galectins. Using this approach, the mechanism of action for GM-CT-01 seeks to block galectins and, in turn, restore the ability of the T-lymphocytes to kill tumor cells.

In May 2012, we initiated a Phase I/II clinical trial of GM-CT-01 in Belgium in combination with a tumor vaccine in patients with advanced melanoma, a deadly skin cancer. The Belgian Federal Agency of Medicine and Health Products, or FAMHP, granted approval for this clinical trial, which is being conducted at three centers in Belgium and one in Luxembourg. There are two primary cohorts of patients in this study, one where GM-CT-01 is given intravenously (Cohort 1) and a second cohort where GM-CT-01 is given both intravenously and directly injected into a cutaneous metastasis (Cohort 2). Because of patient availability, Cohort 1 is expected to be enrolled faster than Cohort 2. For each cohort, 6 patients will be enrolled in stage one of the study, and if at least one out of six patients has a response (PR or CR by RECIST criteria), the remaining patients will be enrolled up to a total of 23 per cohort. RECIST (Response Evaluation Criteria In Solid Tumors) is a set of published

rules for evaluating the state of progression or remission of tumors in cancer patients. We expect the first stage of

## **Table of Contents**

Cohort 1 of this trial (involving 6 evaluable patients) to be completed in the second or third quarter of 2013 and that it will provide data that could deliver an indication of efficacy. Depending on the results of Stage 1, which is defined as a partial or complete response by RECIST criteria in at least one out of six patients, the study could continue enrollment to complete Stage 2 (46 total patients), initiate a new Phase II trial based on positive results or be halted because of lack of efficacy. Stage 1 of the trial is being funded by the Cancer Centre at the Cliniques Universitaires Saint-Luc and Stage 2 may require funding from the Company, however, we have no commitment to provide funding for such additional trials. Galectin Therapeutics Inc. does not control this Phase I/II clinical trial in Belgium which is being conducted under an EMA-approved IMPD. An IMPD (Investigational Medicinal Product Dossier) is the basis for approval of clinical trials by regulatory authorities in the European Union. Galectin Therapeutics is the sponsor of an open IND application under the FDA for GM-CT-01; no trials are currently being conducted in the U.S.

There are potentially additional pathways for the development of GM-CT-01 for use in treatment of cancer. GM-CT-01 was found to be generally safe when studied in a Phase I clinical trial in end-stage cancer patients with multiple tumor types alone and in combination with 5-Fluorouracil (5-FU), which is an FDA-approved chemotherapy used for treatment of various types of cancer. Three Phase II studies were conducted, but were only partially completed due to financing issues at the time. Based on these completed Phase I and partially completed Phase II clinical trials, we are exploring additional potential indications for the use of GM-CT-01 in combination with cancer chemotherapy.

## **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.

In July 2012, we received a notice of issuance from the U.S. Patent and Trademark Office for the U.S. Patent number 8236780 issued on August 7, 2013 titled Galactose-prolonged polysaccharides in a formulation for antifibrotic therapies. This methods patent covers key methods of derivation and use for our carbohydrate-based galectin inhibitor compound for use in patients with chronic liver disease associated with the development of fibrosis, established liver fibrosis or end-stage scarring, or cirrhosis. The major claim is for a method of obtaining the galectin inhibitor compound, obtaining a composition for parenteral administration in an acceptable pharmaceutical carrier and administering to a subject having at least one of the following: chronic liver disease associated with the development of fibrosis, established liver fibrosis or cirrhosis. The use covers inhibiting or slowing the progression of fibrosis or the reversal of fibrosis. GR-MD-02 is covered by this patent and it provides opportunities for development of additional compounds in the class.

As of December 31, 2012, we held eight U.S. patents, three international patents, and have patent applications pending from the U.S. Patent and Trademark Office. Many of our patents and patent applications cover composition of matter for complex carbohydrate drugs and methods of use for reducing toxicity and enhancing chemotherapeutic drugs by co-administering a polysaccharide with a chemotherapeutic agent or for use in treatment of fibrosis. The scheduled expiration dates of our United States patents span from 2020 to 2032. We have corresponding patent applications pending in Europe, Canada, Israel, Brazil, Japan, China and Australia. Additionally, we have patent applications in other areas to utilize our carbohydrate-based compounds to treat disease other than cancer. See Risk Factors Risks Related to Our Intellectual Property. Our competitive position, in part, is contingent upon protection of our intellectual property.

## **Table of Contents**

### **Research**

Our primary focus is on the design and testing of agents which target galectins in various in vitro and in vivo systems and which moreover demonstrate efficacy in treatment of experimentally induced fibrosis or enhance immune system responsiveness in various tissues and in live animal models. Our prior focus was on the design and analysis of galectin targeting therapeutics to improve the clinical benefit of chemotherapeutic agents and biologics: GM-CT-01 was a result of this effort. We contract with independent laboratories and other facilities to conduct our research, which is designed, evaluated and managed by our scientists. While we conduct in house research related to our compounds at SBH laboratories, we do not anticipate building additional 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 assist in the design of the clinical 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.

In February 2013, the Company established a collaborative drug discovery program with Dr. Geert-Jan Boons ( Dr. Boons ) laboratory located in the Complex Carbohydrate Research Center at the University of Georgia. This program is focused on the discovery of new carbohydrate molecules that can be used in the therapy of diseases where galectin proteins play a major role, including cancer, and inflammatory and fibrotic disorders. The aim of this program is to develop a pipeline of drugs that can target galectins. This is an important goal as follow-on compounds for our drugs currently in development and to extend the potential indications and routes of administration. The Complex Carbohydrate Research Center is a world-class program and Dr. Boons is a world renowned and pre-eminent carbohydrate chemist.

Our research and development expenditures totaled \$27.6 million for the cumulative period from inception (July 10, 2000) through December 31, 2012. During the years ended December 31, 2012 and 2011, our expenditures for research and development were \$4.5 million and \$3.6 million, respectively. We expense all research and development costs as they are incurred.

### **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 pharmaceutical manufacturing capabilities and expertise. 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 well-known and established pharmaceutical suppliers.

Because our products are in the development stage, we have not created a sales and marketing staff to commercialize pharmaceutical products. If we develop products eligible for commercial sale, we will need to develop a sales and marketing capability or rely on third parties such as licensees, collaborators, joint venture partners or independent distributors to market and sell those products. Our dependence on third-party manufacturers and marketers will involve risks relating to our reduced control, and other risks including those discussed in Risk Factors Risks Related to our Company There are risks associated with reliance on third parties for manufacturing, marketing, sales, managed care and distribution infrastructure channels.

### **Competition**

Many biotechnology and pharmaceutical companies are developing new technologies for the treatment of cancer and other diseases. Technologies such as monoclonal antibodies could be competitive with our galectin

## **Table of Contents**

therapeutic platforms. Other companies 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. We expect increased competition in the area of galectins will be fueled by a nearly exponential increase in the publication rate of research papers on galectins.

See Risk Factors Risks Related to Our Company 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 New Drug Applications ( NDAs ), warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, and/or criminal prosecution.

## ***Drug Approval Process***

Drugs may not be marketed in the U.S. until the FDA has approved them. The steps required before a drug may be marketed in the U.S. include:

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 a NDA,
5. Satisfactory completion of an FDA inspection of the manufacturing facility or facilities, at which the drug is produced to assess compliance with current good manufacturing procedures ( 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 numerous in vitro and in vivo 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 and the Company 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 and constant oversight by the FDA or foreign regulatory authorities. 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.

## Edgar Filing: GALECTIN THERAPEUTICS INC - Form 10-K

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.

## **Table of Contents**

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 generally issue an approval letter. If the FDA evaluates the NDA submission or the manufacturing facilities as not acceptable, the FDA will generally outline the deficiencies in the submission and often will request additional testing or information. Even if an applicant submits the requested additional information, the FDA ultimately may decide that the NDA does not satisfy the regulatory criteria for approval. The testing and approval process requires substantial time, effort, and financial resources, and there is no assurance that any approval will be granted on a timely basis, if at all. After approval, certain changes to the approved product, such as adding new indications, manufacturing changes, or additional labeling claims are subject to further FDA review and approval.

See Risk Factors Risks Related to the Regulation of Our Products 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.

### ***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,

## **Table of Contents**

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

### ***Environmental Regulation***

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

### **Employees**

We currently have five full-time employees, two of whom are involved primarily in management of our pre-clinical research and development and clinical trials and three who were involved primarily in management and administration of our Company. We also have two contractors who provide product development, manufacture and clinical trial support and two contractors who provide financial management services.

### **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 have incurred net losses to date and must raise additional capital by the end of the first quarter of 2014 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, 2012 was \$80.0 million and our cumulative net loss applicable to common stockholders as of December 31, 2012 was \$80.3 million. Based on \$9.4 million of unrestricted cash as of December 31, 2012, we believe that we have sufficient cash to meet our financial and operating obligations through the first quarter of 2014. 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 must raise additional cash by the end of the first quarter of 2014, or we may not be able to continue operations and may be forced to seek bankruptcy protection.



## **Table of Contents**

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.

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

We are a development stage company and have not generated any revenues to date. There is no assurance that we will obtain FDA approval of GR-MD-02, GM-CT-01, or any other of our products in development and, even if we do so, that we will generate revenue sufficient to become profitable. Our failure to generate revenue and profit would likely lead to loss of your investment.

***We are largely dependent on the success of our two lead product candidates, GR-MD-02 and GM-CT-01 and we cannot be certain that these product candidates will receive regulatory approval or be successfully commercialized.***

We currently have no products for sale and we cannot guarantee that we will ever have any drug products approved for sale. We and our product candidates are subject to extensive regulation by the FDA and comparable regulatory authorities in other countries governing, among other things, research, testing, clinical trials, manufacturing, labeling, promotion, selling, adverse event reporting and recordkeeping. We are not permitted to market any of our product candidates in or outside the United States until we receive approval of a new drug application for a product candidate from the FDA or the equivalent approval from a foreign regulatory authority. Obtaining FDA approval is a lengthy, expensive and uncertain process.

Before obtaining regulatory approval for the sale of any drug candidate, we must conduct extensive pre-clinical studies and clinical trials to demonstrate the safety and efficacy of our product candidates in humans.

GR-MD-02 our lead product candidate for fibrosis is poised to enter the human clinical trial phase of drug development in the US. GM-CT-01, our second product candidate, is currently in human clinical trials in Belgium for use in combination with peptide vaccine for therapy of metastatic melanoma. We cannot assure you that these trials will yield successful results, that they will lead to the generation of revenue, or that we will obtain regulatory approval in other countries.

There are currently no FDA clinical trials underway for GM-CT-01. The Phase I/II clinical trial in Belgium is being conducted under an IMPD from the EMA, under an FDA-approved IND.

We filed for an IND with the FDA for GR-MD-02 in January 2013 for initiating human clinical trials in patients with NASH, and the FDA notified us in March 2013 that we may proceed with a Phase I clinical trial. Pre-clinical studies and clinical trials are expensive, time-consuming and ultimately may not be successful. The results of pre-clinical and initial clinical testing of these products may not necessarily indicate the results that will be obtained from later or more extensive testing. Also, it is possible to suffer significant setbacks in advanced clinical trials, even after obtaining promising results in earlier trials. For example, even though GM-CT-01 progressed successfully through Phase I and was progressing successfully through Phase II human trials (which were only partially completed due to financing issues in 2010), it may fail in Phase III trials or in later stages of development. We will engage others to conduct our clinical trials, including clinical research organizations and, possibly, government-sponsored agencies. Pre-clinical studies and clinical trials may not start or be completed as we forecast and may not achieve the desired results. The time required to obtain FDA and other approvals is unpredictable but often can take years following the commencement of clinical trials, depending upon the complexity of the drug candidate.

---

**Table of Contents**

*Even if we receive regulatory approval, we may be unable to commercialize our product candidates.*

Even if GR-MD-02, GM-CT-01 and other anticipated product candidates achieve positive results in clinical trials, we may be unable to commercialize them. The availability of government and third party payor reimbursement, and pricing, especially compared to competitor products, could affect our ability to commercialize our product candidates. Our general inability to obtain necessary regulatory approvals and, if obtained, to commercialize our products would substantially impair our viability.

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

As we develop products eligible for clinical trials, we will contract with independent parties to assist us in the design of the trial protocols, arrange for and monitor the clinical trials, collect data and analyze data. For instance, in February 2013, we entered into an agreement with CTI Clinical Trial Services, Inc. and CTI Clinical Consulting Services, Inc. for the purpose of assisting us in the design, development and conduct of one or more clinical research studies from time to time. In accordance with this agreement, CTI will be conducting the Phase I clinical trial for GR-MD-02 to evaluate the drug's safety in subjects with NASH with advanced hepatic fibrosis. In addition, certain clinical trials for our products may be conducted by government-sponsored agencies and will be dependent on governmental participation and funding. Our dependence on independent parties and clinical sites involves risks including reduced control over the timing and other aspects of our clinical trials.

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

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

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

Even if engaged, these distributors may:

fail to satisfy financial or contractual obligations to us;

fail to adequately market our products;

cease operations with little or no notice to us; or

offer, design, manufacture or promote competing formulations or products.

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

## **Table of Contents**

***We are exposed to product liability, pre-clinical and clinical liability risks, which could place a financial burden upon us, should we be sued, because we do not currently have product liability insurance 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; accordingly, 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 such formulations or products by us or our potential collaborators may cause us to assume a portion of or all of the product liability risks. A successful liability claim or series of claims brought against us could have a material adverse effect on our business, financial condition and results of operations.

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

***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 possess greater financial and other resources, larger research and development staffs and more effective marketing and manufacturing organizations than we possess. In addition, academic and government institutions are increasingly likely to enter into exclusive licensing agreements with commercial enterprises, including our competitors, to market commercial products based on technology developed at such institutions. Our competitors may succeed in developing or licensing technologies and products that are more effective, or succeed in obtaining FDA or other regulatory approvals for product candidates before we do. Acquisitions of, or investments in, competing pharmaceutical or biotechnology companies by large corporations could increase such competitors' financial, marketing, manufacturing and other resources.

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

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

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

## **Table of Contents**

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 medications. 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 even if commercialized.

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

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

### ***We depend on key individuals to develop our products and core technologies and pursue collaborative relationships.***

We are highly dependent on Peter G. Traber, M.D. Dr. Traber is our Chief Executive Officer and our Chief Medical Officer who, among other things, designs and leads our pre-clinical and clinical studies, as well as our U.S. and European regulatory processes. The loss of Dr. Traber or failure to attract or retain other key personnel could prevent us from developing our products and core technologies and pursuing collaborative relationships.

### ***We may be unable to comply with our reporting and other requirements under federal securities laws.***

As a publicly traded company, we are subject to the reporting requirements of the Exchange Act. The Exchange Act requires that we file annual, quarterly and current reports. Our failure to prepare and disclose this information in a timely manner could subject us to penalties under federal securities laws, expose us to lawsuits and restrict our ability to access financing. We may be required to 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.

## **Risks Related to the Regulation of our Products**

### ***We will need regulatory approvals to commercialize our products.***

We are required to obtain approval (i) from the FDA in order to sell our products in the U.S. and (ii) from foreign regulatory authorities in order to sell our products in other countries. The FDA's review and approval process is lengthy, expensive and uncertain. Extensive pre-clinical and clinical data and supporting information must be submitted to the FDA for each indication for each product candidate in order to secure FDA approval. Before receiving FDA clearance to market our proposed products, we will have to demonstrate that our products are safe on the patient population and effective for the diseases that are to be treated. Clinical trials, manufacturing and marketing of drugs are subject to the rigorous testing and approval process of the FDA and equivalent foreign regulatory authorities. The Federal Food, Drug and Cosmetic Act and other federal, state and foreign statutes and regulations govern and influence the testing, manufacture, labeling, advertising, distribution and promotion of drugs and medical devices. As a result, regulatory approvals can take several years to acquire and may further require the expenditure of substantial financial, managerial and other resources. The FDA could reject an application or, in the alternative, require us to conduct additional clinical or other studies as part of the regulatory review process. Delays in obtaining or failure to obtain FDA approvals would delay or prevent the commercialization of our product candidates, which would prevent, defer or decrease our receipt of revenues. In addition, should we receive initial regulatory approval, our product candidates will be subject to extensive and rigorous ongoing domestic and foreign government regulation.

## **Table of Contents**

***Even if we obtain regulatory approvals, our marketed drugs will be subject to ongoing regulatory review. If we fail to comply with ongoing regulatory requirements, we could lose our approvals to market drugs, in which case our business would be materially adversely affected.***

Following regulatory approval in the United States of any drugs we may develop, we will remain subject to continuing regulatory review, including the review of adverse drug experiences and clinical results that are reported after our drug products are made available to patients. This would include results from any post marketing tests or vigilance required as a condition of approval. The manufacturer and manufacturing facilities we use to make any of our drug products will also be subject to periodic review and inspection by the FDA. The discovery of any new or previously unknown problems with the product, manufacturer or facility may result in restrictions on the drug or manufacturer or facility, including withdrawal of the drug from the market. We would continue to be subject to the FDA requirements governing the labeling, packaging, storage, advertising, promotion, recordkeeping, and submission of safety and other post-market information for all of our product candidates, even those that the FDA had approved. If we fail to comply with applicable continuing regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approval, product recalls and seizures, operating restrictions and other adverse consequences.

***The drug development process to obtain FDA approval is very costly and time consuming and if we cannot complete our clinical trials in a cost-effective manner, our results of operations may be adversely affected.***

Costs and timing of clinical trials may vary significantly over the life of a project owing to the following non-exclusive reasons:

the duration of the clinical trial;

the number of sites included in the trials;

the countries in which the trial is conducted;

the length of time required and ability to enroll eligible patients;

the number of patients that participate in the trials;

the number of doses that patients receive;

the drop-out or discontinuation rates of patients;

per patient trial costs;

third party contractors failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner;

our drug product candidates having different chemical and pharmacological properties in humans than in lab testing;

the need to suspend or terminate our clinical trials;

## Edgar Filing: GALECTIN THERAPEUTICS INC - Form 10-K

insufficient or inadequate supply or quality of drug product candidates or other necessary materials to conduct our trials;

potential additional safety monitoring, or other conditions required by FDA or comparable foreign regulatory authorities regarding the scope or design of our clinical trials, or other studies requested by regulatory agencies;

problems engaging IRBs to oversee trials or in obtaining and maintaining IRB approval of studies;

the duration of patient follow-up;

the efficacy and safety profile of the product candidate;

the costs and timing of obtaining regulatory approvals; and

the costs involved in enforcing or defending patent claims or other intellectual property rights.

## **Table of Contents**

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

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

***Data obtained from clinical trials may be negative or inconclusive, and are susceptible to varying interpretations, which could delay, limit or prevent regulatory clearances.***

Data already obtained, or in the future obtained, from pre-clinical studies and clinical trials do not necessarily predict the results that will be obtained from later pre-clinical studies and clinical trials. Moreover, pre-clinical and clinical data may be negative or inconclusive. In addition, data is susceptible to varying interpretations. Negative or inconclusive data, or data interpreted in various ways, 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 having obtained promising results in earlier trials. The failure to adequately demonstrate the safety and effectiveness of a proposed formulation or product under development could delay or prevent regulatory clearance of the potential drug. The resulting delays in commercialization could materially harm our business. Our clinical trials may not demonstrate sufficient levels of safety and efficacy necessary to obtain the requisite regulatory approvals for our drugs, and thus, our proposed drugs may not be approved for marketing.

***We will need to obtain FDA approval of any proposed product brand names, and any failure or delay associated with such approval may adversely impact our business.***

A pharmaceutical product cannot be marketed in the U.S. or other countries until it has completed rigorous and extensive regulatory review processes, including approval of a brand name. Any brand names we intend to use for our product candidates will require approval from the FDA regardless of whether we have secured a formal trademark registration from the U.S. Patent and Trademark Office, or the PTO. The FDA typically conducts a review of proposed product brand names, including an evaluation of potential for confusion with other product names. The FDA may also object to a product brand name if it believes the name inappropriately implies medical claims. If the FDA objects to any of our proposed product brand names, we may be required to adopt an alternative brand name for our product candidates. If we adopt an alternative brand name, we would lose the benefit of our existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product brand name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product candidates.

## **Risks Related to Our Intellectual Property**

***Our competitive position is contingent upon the 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 or former employees of the Company. Our success depends, in part, on our ability to obtain patent protection for our products or processes in

## Table of Contents

the U.S. and other countries, protect trade secrets and prevent others from infringing on our proprietary rights. We will only be able to protect our product candidates from unauthorized making, using, selling, offering to sell or importation by third parties to the extent that we have rights under valid and enforceable patents or trade secrets that cover these activities. If we do not adequately protect our intellectual property, competitors may be able to practice our technologies.

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date in the United States. The biotechnology patent situation outside the United States is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed in our pending patent applications or enforced in our issued patents or in third-party patents.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

others may be able to make compounds that are competitive with our product candidates but are not covered by the claims of our patents;

we might not have been the first to make the inventions covered by our pending patent applications;

we might not have been the first to file patent applications for these inventions;

it is possible that our pending patent applications will not result in issued patents;

we may not develop additional proprietary technologies that are patentable; or

the patents of others may have an adverse effect on our business.

We also may rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. 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. Enforcing a claim that a third party illegally obtained, and is using, our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

***We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights and we may be unable to protect our rights to, or use of, our technology.***

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, if any, 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.

If we choose to go to court to stop someone else from using the inventions claimed in our patents, that individual or company would have the right to ask the court to rule that such patents are invalid and/or should not be enforced against that third party. These lawsuits are expensive and we may not have the required resources to pursue such litigation or to protect our patent rights. In addition, there is a risk that the court will decide that these patents are not valid and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity of these patents is upheld, the court will refuse to stop the other party on the ground that such other party's activities do



not infringe our rights in these patents.

## **Table of Contents**

Furthermore, a third party may claim that we are using inventions covered by the third party's patent rights and may go to court to stop us from engaging in our normal operations and activities, including making or selling our product candidates. These lawsuits are costly and could affect our results of operations and divert the attention of managerial and technical personnel. There is a risk that a court would decide that we are infringing the third party's patents and would order us to stop the activities covered by the patents. In addition, there is a risk that a court will order us to pay the other party treble damages for having violated the other party's patents. The biotechnology industry has produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our products or methods of use either do not infringe the claims of the relevant patent and/or that the patent claims are invalid, and we may not be able to do this. Proving invalidity in the U.S., in particular, is difficult since it requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents.

Because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our issued patents or our pending applications or that we were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering technology similar to ours. Any such patent application may have priority over our patent applications and could further require us to obtain rights to issued patents covering such technologies. If another party has filed a United States patent application on inventions similar to ours, we may have to participate in an interference or other proceeding in the PTO or a court to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful, resulting in a loss of our United States patent position with respect to such inventions.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

***Obtaining and maintaining our patent protection depends upon compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.***

The PTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case.

***Our failure to secure trademark registration could adversely affect our ability to market our product candidates and our business.***

Our trademark applications in the United States, when filed, and any other jurisdictions where we may file may not be allowed for registration, and our registered trademarks may not be maintained or enforced. During trademark registration proceedings, we may receive rejections. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the PTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our applications and/or registrations, and our applications and/or registrations may not survive such

## **Table of Contents**

proceedings. Failure to secure such trademark registrations in the United States and in foreign jurisdictions could adversely affect our ability to market our product candidates and our business.

*Confidentiality agreements with employees and others may not adequately prevent disclosure of our trade secrets and other proprietary information and may not adequately protect our intellectual property, which could impede our ability to compete.*

Because we operate in the highly technical field of biotechnology and pharmaceutical development, we rely in part on trade secret protection in order to protect our proprietary trade secrets and unpatented know-how. However, trade secrets are difficult to protect, and we cannot be certain that others will not develop the same or similar technologies on their own. We have taken steps, including entering into confidentiality agreements with all of our employees, consultants and corporate partners to protect our trade secrets and unpatented know-how. These agreements generally require that the other party keep confidential and not disclose to third parties all confidential information developed by the party or made known to the party by us during the course of the party's relationship with us. We also typically obtain agreements from these parties which provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual property rights to us. Enforcing a claim that a party illegally obtained and is using our trade secrets or know-how is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets or know-how. The failure to obtain or maintain trade secret protection could adversely affect our competitive position.

*We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.*

As is common in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

## **Risks Related to Our Common Stock**

*The market price of our common stock may be volatile and adversely affected by several factors.*

The market price of our common stock could fluctuate significantly in response to various factors and events, including but not limited to:

our ability to integrate operations, technology, products and services;

our ability to execute our business plan;

operating results below expectations;

our issuance of additional securities, including debt or equity or a combination thereof, which will be necessary to fund our operating expenses;

announcements of technological innovations or new products by us or our competitors;

loss of any strategic relationship;

Edgar Filing: GALECTIN THERAPEUTICS INC - Form 10-K

industry developments, including, without limitation, changes in healthcare policies or practices or third-party reimbursement policies;

economic and other external factors;

## Table of Contents

period-to-period fluctuations in our financial results; and

whether an active trading market in our common stock develops and is maintained.

In addition, the market price for securities of pharmaceutical and biotechnology companies historically has been highly volatile, and the securities markets have from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. These broad market fluctuations may cause the market price of our common stock to decline substantially.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies have experienced significant stock price volatility in recent years. We may become involved in this type of litigation in the future. Litigation often is expensive and diverts management's attention and resources, which could materially and adversely affect our business.

Additionally, fluctuations in the trading price or liquidity of our common stock may materially and adversely affect, among other things, the interest of investors to purchase our common stock on the open market and, generally, our ability to raise capital.

***Our board of directors has the power to designate, without stockholder approval, additional series of preferred stock, the shares of which could be senior to our common stock and be entitled to conversion or voting rights that adversely affect the holders of our common stock.***

Our articles of incorporation authorize the issuance of capital stock including 20,000,000 authorized undesignated shares (8,001,000 designated as of December 31, 2012), and empowers our board of directors to prescribe, by resolution and without stockholder 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. Accordingly, we may designate and issue additional shares or series of preferred stock that would rank senior to the shares of common stock as to dividend rights or rights upon our liquidation, winding-up, or dissolution.

***Nevada law and our charter documents could make it more difficult for a third party to acquire us and discourage a takeover, which could depress the trading price of our common stock.***

Nevada corporate law and our articles of incorporation and bylaws contain provisions that could discourage, delay, or prevent a change in control of our Company or changes in our management that our stockholders may deem advantageous. For example, holders of our common stock do not have cumulative voting rights in the election of directors, meaning that stockholders owning a majority of our outstanding shares of common stock will be able to elect all of our directors. In addition, because we have more than 200 stockholders of record, we are subject to the business combinations provisions of the Nevada Revised Statutes, or NRS. These provisions could prohibit or delay a merger or other takeover or change in control attempt and, accordingly, may discourage attempts to acquire our company even though such a transaction may be in our stockholders' best interest and offer our stockholders the opportunity to sell their stock at a price above the prevailing market price.

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

The 10X Fund owns all of our issued and outstanding Series B Preferred Stock, which are convertible into 2,000,000 shares of our common stock. The 10X Fund owns related warrants exercisable to purchase an aggregate of 5,000,000 shares of our common stock. As of December 31, 2012, we have issued 867,527 shares of our common stock as dividends on the Series B Preferred Stock and 1,000,000 shares of our common stock on the exercise of warrants. In addition, (i) James C. Czirr, a managing partner of the 10X Fund and Executive Chairman of our board of directors, owns or controls approximately 862,000,000 shares of our common stock,

## **Table of Contents**

including shares of Series A on an as converted basis, and has the right to acquire approximately 667,000 additional shares of our common stock upon the exercise of outstanding stock options (approximately 317,000 of which are exercisable as of December 31, 2012); and (ii) Rod D. Martin, a managing partner of the 10X Fund and Vice Chairman of our board of directors, owns or controls approximately 91,000 shares of our common stock and has the right to acquire approximately 98,000 additional shares of our common stock upon the exercise of outstanding stock options (approximately 96,000 of which are exercisable as of December 31, 2012). As of December 31, 2012, on a fully diluted basis, assuming conversion of all Series B Preferred Stock and exercise of all outstanding warrants, the 10X Fund would own approximately 38% of our then outstanding shares of common stock, which, together with the shares of our common stock that would be owned by Mr. Czirr and Mr. Martin (assuming exercise of all vested options at that date), would constitute approximately 43% of the then outstanding shares.

As holder of Series B Preferred Stock, the 10X Fund is entitled to elect three directors in a separate class vote, nominate three directors for election by all shares entitled to vote, and provide or withhold consent to a range of fundamental corporate action we may wish to undertake, such as recapitalization, sale of our company, and other matters. Such concentration of stock ownership and related rights could have the effect of delaying, deterring or preventing corporate events that our other security holders may desire or consider beneficial to the company.

*We may issue additional common stock, which might dilute the net tangible book value per share of our common stock.*

Our board of directors has the 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 to, or a premium from, the then-current market 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. We are currently contemplating additional capital raising transactions within the next twelve months, which would likely result in issuances of additional shares which would be dilutive to current shareholders. These issuances would dilute the percentage ownership interest, which would have the effect of reducing your influence on matters on which our stockholders vote, and might dilute the net tangible book value per share 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.

*A sale of a substantial number of shares of the common stock may cause the price of our common stock to decline.*

Our common stock is currently traded on The NASDAQ Capital Market and, despite certain increases of trading volume from time to time, there have been periods when it could be considered thinly-traded, meaning that the number of persons interested in purchasing our common stock at or near bid prices at any given time may be relatively small or non-existent. 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. Some of our shareholders have registration rights to facilitate sales of large blocks of our common stock. We have filed a shelf registration statement to allow registered sales of up to 9.7 million shares by these shareholders. We are currently contemplating additional capital raising transactions within the next twelve months, which would likely result in issuances of additional shares which would be dilutive to current shareholders. In addition, the lack of a robust resale market may require a stockholder who desires to sell a large number of shares of common stock to sell the shares in increments over time to mitigate any adverse impact of the sales on the market price of our stock.

If our stockholders sell, or the market perceives that our stockholders intend to sell for various reasons, including the ending of restriction on resale or the expiration of lock-up agreements such as those entered into in connection with this offering, substantial amounts of our common stock in the public market, including shares

## **Table of Contents**

issued upon the exercise of outstanding options or warrants, the market price of our common stock could fall. Sales of a substantial number of shares of our common stock may make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate. We may become involved in securities class action litigation that could divert management's attention and harm our business.

*We have not paid cash dividends in the past and do not expect to pay cash dividends in the foreseeable future.*

We have never paid cash dividends on our capital stock and do not anticipate paying cash dividends on our capital stock in the foreseeable future. The payment of dividends on our capital stock will depend on our earnings, financial condition and other business and economic factors affecting us at such time as the board of directors may consider relevant. If we do not pay dividends, our common stock may be less valuable because a return on your investment will only occur if the market price of our common stock price appreciates.

*Our shares of common stock and warrants have been and continue to be thinly traded, so you may be unable to sell at or near ask prices or even at all if you need to sell your shares or warrants to raise money or otherwise desire to liquidate your shares or warrants.*

We cannot predict the extent to which an active public market for our common stock and warrants will develop or be sustained. Our common stock is currently traded on The NASDAQ Capital Market and experiences periods when it could be considered thinly-traded. This situation may be attributable to a number of factors, including the fact that we are a small company which is relatively unknown to stock analysts, stock brokers, institutional investors and others in the investment community that generate or influence sales volume, and that even if we came to the attention of such persons, they tend to be risk averse and would be reluctant to follow an unproven company such as ours or purchase or recommend the purchase of our shares until such time as we became more seasoned and viable. As a consequence, there may be periods of several days, weeks or months when trading activity in our shares is minimal or non-existent, as compared to a seasoned issuer which has a large and steady volume of trading activity that will generally support continuous sales without an adverse effect on share price. We cannot give you any assurance that a broader or more active public trading market for our common stock will develop or be sustained, or that current trading levels will be sustained or not diminish.

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

None.

### **Item 2. *Properties***

We lease 3,610 square feet for our executive offices located at 4960 Peachtree Industrial Blvd., Norcross, GA. We also lease approximately 300 square feet in Natick, MA, for use by research and development consultants and which is collocated with one of research and development service vendors. We believe these spaces are suitable for our present operations.

### **Item 3. *Legal Proceedings***

From time to time, the Company is exposed to litigation relating to its operations. The Company is not currently engaged in any legal proceedings that are expected, individually or in the aggregate, to have a material, adverse affect on its financial condition or results of operations, except as noted below:

On October 12, 2012, David Platt, Ph.D., the Company's former Chief Executive Officer and Chairman of the Board of Directors, commenced a lawsuit under the Massachusetts Wage Act against Peter G. Traber, M.D. and Mr. Thomas A. McGauley, who in their capacities as the Company's Chief Executive Officer and Chief

**Table of Contents**

Financial Officer respectively can be held individually liable under the Wage Act for non-payment of wages. The lawsuit is based on the facts and issues raised in the arbitration discussed below regarding the potential payment of the \$1.0 million separation payment under Dr. Platt's Separation Agreement with the Company, and other unspecified wages. The statute provides that a successful claimant may be entitled to multiple damages, interest and attorneys fees. Although the Company is not a party to the lawsuit, it plans to indemnify Dr. Traber and Mr. McGauley consistent with its obligations under the by-laws and applicable law, believes the lawsuit is without merit, and intends a vigorous defense on their behalf.

On May 2, 2012, Dr. Platt instituted arbitration before the American Arbitration Association, seeking a \$1.0 million separation payment based on a claim that a milestone event for payment in accordance with the terms of the Separation Agreement had occurred. Specifically, he argued that he was due payment because the Company's common stock was listed on the NASDAQ Capital Markets and the Company had previously achieved the required market capitalization for the milestone event. The Company's position, however, is that a milestone event has not yet occurred under the Separation Agreement because the Company has not achieved the required market capitalization while listed on the NASDAQ Capital Markets. On November 1, 2012, the arbitrator denied Dr. Platt's demand in all respects. The Company has recorded the payment as an accrued expense payable if and when the milestone event occurs.

On March 29, 2013, the Company instituted arbitration before the American Arbitration Association, seeking to rescind or reform the Separation Agreement discussed above. The Company claims that Dr. Platt fraudulently induced the Company to enter into the Separation Agreement, breached his fiduciary duty to the Company, and was unduly enriched from his conduct. Along with removal of the \$1.0 million milestone payment provided for under the Separation Agreement, the Company is seeking repayment of all separation benefits paid to Dr. Platt to date.

**Item 4. *Mine Safety Disclosures***

Not applicable.



**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**

Our common stock began trading on The NASDAQ Capital Market under the symbol GALT effective March 23, 2012. 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 had been quoted on the OTC Bulletin Board since January 21, 2009 under the symbol PRWP.OB and since June 16, 2011 under the symbol GALT.OB. The high and low sale prices for our common stock as reported on the OTC Bulletin Board and the NASDAQ Capital Market, for the periods indicated as shown below. All share prices reflect the one-for-six reverse split, which was effective March 23, 2012.

	High	Low
<b>Fiscal Year Ended December 31, 2012</b>		
First Quarter	\$ 6.00	\$ 3.75
Second Quarter	\$ 4.40	\$ 1.89
Third Quarter	\$ 3.48	\$ 1.61
Fourth Quarter	\$ 2.24	\$ 1.60
<b>Fiscal Year Ended December 31, 2011</b>		
First Quarter	\$ 8.64	\$ 5.22
Second Quarter	\$ 9.42	\$ 5.88
Third Quarter	\$ 7.80	\$ 4.56
Fourth Quarter	\$ 6.78	\$ 3.84

**Holder of Common Stock**

As of March 19, 2013, there were 290 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 7,250 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.

**Item 6. Selected Financial Data**

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

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

In addition to historical information, the following Management's Discussion and Analysis of Financial Condition and Results of Operations contains forward-looking statements as defined under Section 21E of the Securities Exchange Act of 1934, as amended, and is subject to the safe harbor created therein for forward-looking statements. Such statements include, but are not limited to, statements concerning our anticipated operating results, research and development, clinical trials, regulatory proceedings, and financial resources, and can be identified by use of words such as, for example, anticipate, estimate, expect, project, intend,

## **Table of Contents**

plan, believe and would, should, could or may. All statements, other than statements of historical facts, included herein that address actual events, or developments that the Company expects or anticipates will or may occur in the future, are forward-looking statements, including statements regarding: plans and expectations regarding clinical trials; plans and expectations regarding regulatory approvals; our strategy and expectations for clinical development and commercialization of our products; potential strategic partnerships; expectations regarding the effectiveness of our products; plans for research and development and related costs; statements about accounting assumptions and estimates; expectations regarding liquidity and the sufficiency of cash to fund operations through the first quarter of 2014; our commitments and contingencies; and our market risk exposure. Forward-looking statements are based on current expectations, estimates and projections about the industry and markets in which Galectin Therapeutics operates, and management's beliefs and assumptions. These statements are not guarantees of future performance and involve certain known and unknown risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Such risks and uncertainties are related to, without limitation, our early stage of development; our dependence on outside capital; uncertainties related to our technology and clinical trials, intellectual property protection, uncertainties of regulatory approval requirements for our products; competition and stock price volatility in the biotechnology industry, limited trading volume for our stock, concentration of ownership of our stock, and other risks detailed herein and from time to time in our SEC reports. The following discussion should be read in conjunction with the accompanying consolidated financial statements and notes thereto of Galectin Therapeutics appearing elsewhere herein.

### **Overview**

We are a development-stage company engaged in drug research and development to create new therapies for fibrotic disease and cancer. Our drug candidates are based on our method of targeting galectin proteins, which are key mediators of biologic and pathologic functions. We use naturally occurring, readily-available plant materials as starting material in manufacturing processes to create proprietary complex carbohydrates with specific molecular weights and other pharmaceutical properties. These complex carbohydrate molecules are appropriately formulated into acceptable pharmaceutical formulations. Using these unique carbohydrate-based candidate compounds that bind and inhibit galectin proteins, we are undertaking the focused pursuit of therapies for indications where galectins have a demonstrated role in the pathogenesis of a given disease. We focus on diseases with serious, life-threatening consequences to patients and those where current treatment options are limited. Our strategy is to establish and implement clinical development programs that add value to our business in the shortest period of time possible and to seek strategic partners when a program becomes advanced and requires additional resources.

We endeavor to leverage our scientific and product development expertise as well as established relationships with outside sources to achieve cost-effective and efficient development. These outside sources, amongst others, provide us with expertise in preclinical models, pharmaceutical development, toxicology, clinical development, pharmaceutical manufacturing, sophisticated physical and chemical characterization, and commercial development. We also have established a collaborative scientific discovery program with leading experts in carbohydrate chemistry and characterization. This discovery program is aimed at the targeted development of new molecules which bind galectin proteins and offer alternative options to larger market segments in our primary disease targets. We are pursuing a development pathway to clinical enhancement and commercialization for our lead compounds in liver fibrosis and fatty liver disease as well as in immune enhancement for cancer therapy. All of our proposed products are presently in development, including pre-clinical and clinical trials.

### **2012 Common Stock and Warrant Offering and Reverse Split**

On March 22, 2012, in anticipation of completing a public offering of securities, we effected a one-for-six reverse stock split of our common stock. All common share and per unit amounts in this report, including the financial statements, have been adjusted to reflect the reverse split. Our common stock began trading on The

---

## **Table of Contents**

NASDAQ Capital Market under the symbol GALT on March 23, 2012, and the units and warrants that we sold in the offering began trading on that exchange under the symbols GALTU and GALTW, respectively, on March 28, 2012.

On March 28, 2012, we completed the public offering in which we issued 2,666,722 shares of common stock and related warrants exercisable until March 28, 2017, at \$5.63 per share to purchase 1,333,361 shares of common stock for gross proceeds of \$12.0 million (net cash proceeds of 10.4 million).

### **Our Drug Development Programs**

Galectins are a class of proteins that are made by many cells in the body. As a group, these proteins are able to bind to sugar molecules that are part of other proteins in and on the cells of our body. Galectin proteins act as a kind of glue, bringing together molecules that have sugars on them. Galectin proteins are known to be markedly increased in a number of important diseases including scarring of organs (e.g. liver, lung, kidney, and heart) and cancers of many kinds. The increase in galectin protein promotes the disease and is detrimental to the patient.

We have two compounds in development, one intended to be used in the treatment of liver fibrosis and fatty liver disease and the other intended to be used in cancer therapy. These two compounds are produced from completely different, natural, readily available, starting materials, which, following chemical processing, both exhibit the property of binding to and inhibiting galectin proteins. GR-MD-02, our lead product for treatment of liver fibrosis and fatty liver disease with inflammation and fibrosis, is a proprietary complex polysaccharide polymer possessing both linear and globular structures, which is derived from a plant source. GM-CT-01, our lead product candidate for cancer therapy, is a proprietary linear polysaccharide polymer comprised of mannose and galactose that has a precisely defined chemical structure and which is also derived from a plant source.

We believe the mechanism of action for GR-MD-02 and GM-CT-01 is based upon interaction with, and inhibition of, galectin proteins, which are expressed at high levels in certain pathological states including inflammation, fibrosis and cancer. While GR-MD-02 and GM-CT-01 are capable of binding to multiple galectin proteins, we believe that they have the greatest affinity for galectin-3, the most prominent galectin implicated in pathological processes. Blocking galectin in cancer and liver fibrosis has specific salutary effects on the disease process, as discussed below.

#### ***GR-MD-02 Liver Fibrosis***

The main initiative in our development strategy is the application of galectin inhibition in connection with liver fibrosis, a condition that leads to cirrhosis. We believe that GR-MD-02 has the potential to treat nonalcoholic steatohepatitis (NASH) and other forms of liver fibrosis. The driving factor for our commitment to galectin inhibition for fibrosis is scientific evidence that strongly suggests that galectin-3 is essential for the development of liver fibrosis in animals. Published data show that mice lacking the galectin-3 gene are incapable of developing liver fibrosis in response to toxin insult to the liver and in fatty liver disease. Moreover, mice that do not have the galectin-3 gene are resistant to lung and kidney fibrosis.

We have evaluated the ability of GR-MD-02 to block galectin-3 in animal models of liver fibrosis, the conclusions of which yielded positive results. Our pre-clinical data show that GR-MD-02 may have a therapeutic effect on liver fibrosis as shown in several relevant animal models. Therefore, we chose GR-MD-02 as the lead candidate in a development program targeted initially at fibrotic liver disease associated with NASH. We filed an IND with the FDA in January 2013 for initiating human studies in patients with NASH, and the FDA notified us in March 2013 that we may proceed with a Phase I clinical trial. We plan to start a Phase I clinical trial with GR-MD-02 in patients with NASH during the second quarter of 2013 to assess safety and preliminary evidence of efficacy in humans, with top line results expected by late 2013 or early 2014. In mid-2014, depending on the results of the Phase I study and available funding, we may initiate a Phase II clinical trial to assess the efficacy of GR-MD-02 in patients with NASH and advanced liver fibrosis with expected top-line clinical results by mid to late 2015.

**Table of Contents*****GM-CT-01 Galectin Inhibition in Cancer Therapy***

We believe the potential exists for galectin inhibition to play an important role in cancer therapy. Galectin proteins, particularly galectin-1 and galectin-3, have been shown to be highly expressed in the majority of cancers and have multiple roles in promoting cancer progression, including tumor cell invasion, metastasis, angiogenesis, and tumor evasion of the immune system. GM-CT-01 has progressed in development for the therapy of colorectal cancer and is currently in a Phase I/II clinical trial in Europe as a combination therapy with a tumor vaccine in patients with advanced melanoma. The current developmental approach for GM-CT-01 is to enhance the activity of the immune system against the cancer.

In May 2012, we initiated a Phase I/II clinical trial of GM-CT-01 in Belgium in combination with a tumor vaccine in patients with advanced melanoma, a deadly skin cancer. The Belgian Federal Agency of Medicine and Health Products, or FAMHP, granted approval for this clinical trial, which is being conducted at three centers in Belgium and one in Luxembourg. There are two primary cohorts of patients in this study, one where GM-CT-01 is given intravenously (Cohort 1) and a second cohort where GM-CT-01 is given both intravenously and directly injected into a cutaneous metastasis (Cohort 2). Because of patient availability, Cohort 1 is expected to be enrolled faster than Cohort 2. For each cohort, 6 patients will be enrolled in stage one of the study, and if at least one out of six patients has a response (PR or CR by RECIST criteria), the remaining patients will be enrolled up to a total of 23 per cohort. We expect the first stage of Cohort 1 of this trial (involving 6 evaluable patients) to be completed in the second quarter of 2013 and that it will provide data that could deliver an indication of efficacy. Depending on the results of Stage 1, which is defined as a partial or complete response by RECIST criteria in at least one out of six patients, the study could continue enrollment to complete Stage 2 (46 total patients), initiate a new Phase II trial based on positive results or be halted because of lack of efficacy. Stage 1 of the trial is being funded by the Cancer Centre at the Cliniques Universitaires Saint-Luc and Stage 2 may require funding from the Company, beyond the provision of material, however, we have no commitment to fund Stage 2 of the trial. We do not control this Phase I/II clinical trial in Belgium which is being conducted under an EMA-approved IMPD. We are the sponsor of an open IND application under the FDA for GM-CT-01; no trials are currently being conducted in the U.S.

We previously attempted to gain regulatory approval of GM-CT-01 for use in combination with 5-FU (5-Fluorouracil, an anti-cancer chemotherapy drug) containing chemotherapy regimens for metastatic colorectal cancer in Colombia. This approach had been recommended to the Company by key oncology opinion leaders in Colombia and by PROCAPS S.A. ( PROCAPS ), a Colombia-based pharmaceutical company. There has been no approval of GM-CT-01 in a major region such as the U.S. or Europe and it was determined that approval from the regulatory authority in Columbia (INVIMA) would require additional clinical trial data. Although the Company worked with PROCAPS to design a Phase III clinical trial, a satisfactory plan could not be agreed upon and we terminated the Agreement with PROCAPS (as described below), effective September 29, 2012, and have no current plans to continue attempts to gain approval of GM-CT-01 in Columbia. We had not taken into account projections for any potential revenues from this agreement in our financing plans.

***Agreement with PROCAPS S.A.***

On March 25, 2010, we granted PROCAPS S.A. (in the form of a definitive term sheet) exclusive rights to market and sell GM-CT-01 to treat cancer in Colombia, South America. PROCAPS is an international, privately held pharmaceutical company based in Barranquilla, Colombia. In October 2010, we received a payment of \$200,000 and shipped GM-CT-01 to PROCAPS to be used by PROCAPS to undertake initial steps contemplated by the term sheet. We recorded the \$200,000 payment from PROCAPS as deferred revenue on the condensed consolidated balance sheet as of December 31, 2011, to be recognized when the remaining deliverables of the agreement were completed.

On October 18, 2011, we entered into a Collaboration, Supply, Marketing and Distribution Agreement (the Agreement ) with PROCAPS. The Agreement granted PROCAPS first negotiation rights to enter into similar agreements in other Central and South American countries. We were to be the sole manufacturer and supplier of

**Table of Contents**

GM-CT-01 to PROCAPS. The Agreement obligated PROCAPS to procure regulatory approvals necessary for the marketing and sale of GM-CT-01 naming us as the owner of such approvals to the extent permitted by law, or alternatively hold the approvals for our benefit. PROCAPS was required to pay us a stated fee for each dose it purchases and royalties at an incremental rate determined by annual net sales of GM-CT-01. We retained all intellectual property rights to GM-CT-01 and related products and PROCAPS may not produce, modify, reverse engineer, or otherwise interfere with the GM-CT-01 compound. PROCAPS may not manufacture or sell products that compete with GM-CT-01 during the term of the Agreement and for five years thereafter.

PROCAPS had not obtained approval to sell GM-CT-01 in Columbia as required by the Agreement and, as they were in material breach of the Agreement, we terminated the Agreement, effective September 29, 2012. With no further obligations under the Agreement, we recognized the \$200,000 payment as Other Income in the Statements of Operations during the year ended December 31, 2012.

**Results of Operations from the Years Ended December 31, 2012 and 2011****Research and Development Expense**

	Year ended December 31,		2012 as Compared to 2011	
	2012	2011	\$ Change	% Change
Research and development	\$ 4,527	\$ 3,552	\$ 975	27%

We generally categorize research and development expenses as either direct external expenses, comprised of amounts paid to third party vendors for services, or all other research and development expenses, comprised of employee payroll and general overhead allocable to research and development. 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. 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.

We have two product candidates, GR-MD-02 and GM-CT-01. We filed for an IND for GR-MD-02 in January 2013 and in February 2013 we entered into an agreement with CTI to conduct a Phase I clinical trial of GR-MD-02 which we expect will begin enrolling patients in the second quarter of 2013. In March 2013, the FDA indicated we could proceed with a Phase I human clinical trial of GR-MD-02. GM-CT-01 is in a Phase I/II clinical trial in Europe at this time, which is being conducted in collaboration with the Cancer Centre at the Cliniques Universitaires Saint-Luc and the Ludwig Institute for Cancer Research in Belgium.

Our research and development expenses were as follows:

	Year Ended December 31,	
	2012	2011
Direct external expenses:		
Clinical programs and pre-clinical activities	\$ 2,999	\$ 1,439
All other research and development expenses	1,528	2,113
	\$ 4,527	\$ 3,552

## Table of Contents

Clinical programs and pre-clinical expenses for the year ended December 31, 2012, increased compared to the same period in 2011, due primarily to increased pre-clinical activity on our fibrosis program as we prepared to file an IND in January 2013 and begin a Phase I clinical trial in 2013. Included in clinical programs and pre-clinical costs above, are costs related to clinical trials during 2012 and 2011 of approximately \$205,000 and \$666,000, respectively, which consisted primarily of costs related to drug manufacturing to supply GM-CT-01 for the Phase I/II trial, which, as previously discussed, is not being conducted by us. We expect as we begin our Phase I trial for GR-MD-02, our clinical program costs will increase substantially, as discussed further below. Other research and development expense decreased primarily due to decreased stock-based compensation (\$635,000).

In February 2013, we signed an agreement with CTI Clinical Trial Services, Inc. and CTI clinical Consulting Services, Inc. (collectively CTI ) to conduct our Phase I clinical trial for GR-MD-02. The initial work order related to the contract is for \$2,155,000, which we expect will be expensed over the year ended December 31, 2013 as expenses are incurred. The total costs of conducting the Phase I trial may be greater than the initial work order due to potential additional studies that may be required.

Both the time required and costs we may incur in order to commercialize a drug candidate that would result in material net cash inflow are subject to numerous variables, and therefore we are unable at this stage of our development to forecast useful estimates. Variables that make estimates difficult include the number of clinical trials we may undertake, the number of patients needed to participate in the clinical trial, patient recruitment uncertainties, trial results as to the safety and efficacy of our product, and uncertainties as to the regulatory agency response to our trial data prior to receipt of marketing approval. Moreover, the FDA or other regulatory agencies may suspend clinical trials if we or an agency believes patients in the trial are subject to unacceptable risks, or find deficiencies in the conduct of the clinical trial. Delays or rejections may also occur if governmental regulation or policy changes during our clinical trials or in the course of review of our clinical data. Due to these uncertainties, accurate and meaningful estimates of the ultimate cost to bring a product to market, the timing of costs and completion of our program and the period during which material net cash inflows will commence are unavailable at this time. However, we expect to continue to have substantial research and development expenses for the foreseeable future as we continue to develop our products.

### General and Administrative Expense

	Year ended		2012 as Compared to 2011	
	December 31, 2012	2011	\$ Change	% Change
General and administrative	\$ 5,372	\$ 6,857	\$ (1,485)	(22)%

General and administrative expenses consist primarily of salaries including stock based compensation, legal and accounting fees, insurance, investor relations, business development and other office related expenses. The primary reasons for the decrease for the year ended December 31, 2012 as compared to the same period in 2011 is due to decreased legal expenses (\$119,000) and decreased investor relations and business development costs (\$299,000) as we decreased work related to the PROCAPS agreement which we terminated in 2012, offset by increased insurance and public company related costs (\$113,000). Additionally, in 2011, when it became probable that we would be relisted on a national securities exchange we recognized a \$1.0 million payment due to our former CEO, Dr. Platt. Also, we settled litigation and recognized \$162,000 of related expense in 2011.

### Other Income and Expense

During the year ended December 31, 2012, other income and expense consisted primarily of the \$200,000 payment from PROCAPS which was previously accounted for as deferred income and recognized upon the termination of the PROCAPS Agreement, as previously described.

Other income and expense for the year ended December 31, 2011 included an expense of \$524,000, related to the change in fair value of warrant liabilities. The Company had no warrant liabilities as of December 31, 2012 or during the year then ended or as of December 31, 2011.

**Table of Contents****Liquidity and Capital Resources**

As described above in the Overview and elsewhere in this Annual Report on Form 10-K, we are in the development stage and have not generated any revenues to date. 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, 2012, we raised a net total of \$68.8 million from these offerings. At December 31, 2012, we had \$9,364,000 of unrestricted cash and cash equivalents available to fund future operations. We believe that with the cash on hand at December 31, 2012, there is sufficient cash to fund operations through the first quarter of 2014. We will require more cash to fund our operations and believe we will be able to obtain additional financing. However, there can be no assurance that we will be successful in obtaining such new financing or, if available, that such financing will be on terms favorable to us. We plan to raise additional capital and have significantly reduced our administrative and clinical spending. If we are unsuccessful in raising additional capital before the end of the first quarter of 2014, we may be required to cease operations or seek bankruptcy protection.

We have accrued an expense of \$1,000,000 that is payable to David Platt, Ph.D., the Company's former Chief Executive Officer and Chairman of the Board of Directors, if and when certain company milestone events occur pursuant to his Separation Agreement with the Company; however, on March 29, 2013, we instituted arbitration before the American Arbitration Association, seeking to rescind or reform the Separation Agreement. Depending on the outcome of the arbitration, the accrual could be reversed. The timing and ultimate outcome of this arbitration, though, is uncertain and there is no guarantee that we will be successful in this demand. See Item 3. Legal Proceedings for further description of the arbitration.

Net cash used in operations increased by \$1,824,000 to \$7,500,000 for 2012, as compared to \$5,676,000 for 2011. Cash operating expenses increased principally due to increased research and development activities primarily related to our fibrosis development and preparation for an IND filing and a Phase I clinical trial for GR-MD-02 in 2013, offset by decreased general and administrative expenses as previously discussed.

Cash used in investing activities during 2012 consisted of a decrease in restricted cash by \$64,000 as our \$59,000 secured letter of credit for office space and \$10,000 of secured credit cards were released, offset by equipment purchases of \$5,000 as compared to \$5,000 of equipment purchases in 2011 and \$10,000 to secure credit cards in 2011.

Net cash provided by financing activities was \$10,403,000 during 2012 as compared to \$6,197,000 during 2011, due primarily to the transaction described below.

On March 28, 2012, we issued 2,666,722 shares of common stock and related \$5.63 warrants to purchase 1,333,361 shares of common stock, resulting in gross proceeds of \$12,000,000 (net proceeds of \$10,403,000).

**Payments Due Under Contractual Obligations**

The following table summarizes the payments due under our contractual obligations at December 31, 2012, and the effect such obligations are expected to have on liquidity and cash flow in future periods:

Contractual Obligations	Total	Payments due by period (in thousands)			More than 5 years
		Less than 1 year	1-3 years	3-5 years	
Operating leases	\$ 85	\$ 49	\$ 36	\$	\$
Total payments due under contractual obligations	\$ 85	\$ 49	\$ 36	\$	\$

**Operating leases.**

In September 2012, we entered into an operating lease for office space in Norcross, GA for a term of twenty-six months, beginning on October 1, 2012 and ending November 30, 2014 at a rate of \$3,000 per month.

---

**Table of Contents**

The lease provides for free rent for the first two months of the lease and required a security deposit of \$6,000. In addition to base rental payments included in the contractual obligations table above, we are responsible for our pro-rata share of the operating expenses for the building.

In October 2012, we entered into an operating lease for office space collocated with lab space for research and development activities in Massachusetts. The lease is for a period of one year, beginning on October 1, 2012, for a rate of \$15,000 for the term, payable in equal monthly increments.

***Separation agreement.***

In February 2009, we entered into a Separation Agreement in connection with the resignation of David Platt, Ph.D., the Company's former Chief Executive Officer and Chairman of the Board of Directors. The Separation Agreement provides for the deferral of a \$1.0 million separation payment due to Dr. Platt upon the earlier occurrence of any of the following milestone events: (i) the approval by the Food and Drug Administration for a new drug application ( NDA ) for any drug candidate or drug delivery candidate based on the GM-CT-01 technology (whether or not such technology is patented), in which case Dr. Platt is also entitled to a fully vested 10-year cashless-exercise stock option to purchase at least 83,334 shares of common stock at an exercise price not less than the fair market value of the common stock determined as of the date of grant; (ii) consummation of a transaction with a pharmaceutical company expected to result in at least \$10.0 million of equity investment or \$50 million of royalty revenue to the Company, in which case Dr. Platt is also entitled to stock options on the same terms to purchase at least 50,000 shares of common stock; or (iii) the renewed listing of our securities on a national securities exchange and the achievement of a market capitalization of \$100 million. Payment upon the events (i) and (iii) may be deferred up to six months, and if we have insufficient cash at the time of any of such events, we may issue Dr. Platt a secured promissory note for such amount. If we file a voluntary or involuntary petition for bankruptcy, whether or not a milestone event has occurred, such event shall trigger our obligation to pay the \$1.0 million with the result that Dr. Platt may assert a claim for such obligation against the bankruptcy estate. During 2011, when it became probable that our common stock could be relisted on a national securities exchange and eventually reach a market capitalization of \$100 million, we recognized the \$1.0 million severance payment due to Dr. Platt and it is included in accrued expenses at December 31, 2012 and December 31, 2011.

On May 2, 2012, Dr. Platt instituted arbitration before the American Arbitration Association, seeking a \$1.0 million separation payment based on a claim that a milestone event in the Separation Agreement has occurred (see clause (iii) above). On March 22, 2012, the Company's common stock was listed on the NASDAQ Capital Markets, but since that date, the stock has not achieved the required market capitalization. Therefore, it is the Company's position that a milestone event has not yet occurred. The arbitration hearing was held on October 16-17, 2012 and on November 1, 2012, the arbitrator denied Dr. Platt's demand in all respects. Insofar as the Company does not dispute its obligations under the Separation Agreement to pay Dr. Platt upon the occurrence of a milestone event, it has recorded the payment as an accrued expense payable if and when the milestone event occurs.

On October 12, 2012, Dr. Platt commenced a lawsuit under the Massachusetts Wage Act against Dr. Traber and Mr. McGauley who in their capacities as the Company's Chief Executive Officer and Chief Financial Officer respectively can be held individually liable under the Wage Act for non-payment of wages. The lawsuit is based on the facts and issues raised in the arbitration regarding the payment of the \$1.0 million separation payment under the Separation Agreement, and other unspecified wages. The statute provides that a successful claimant may be entitled to multiple damages, interest and attorneys fees. Although the Company is not a party to the lawsuit, it plans to indemnify Dr. Traber and Mr. McGauley consistent with its obligations under the by-laws and applicable law, believes the lawsuit is without merit, and intends a vigorous defense on their behalf.

On March 29, 2013, the Company instituted arbitration before the American Arbitration Association, seeking to rescind or reform the Separation Agreement discussed above. The Company claims that Dr. Platt fraudulently induced the Company to enter into the Separation Agreement, breached his fiduciary duty to the Company, and was unduly enriched from his conduct. Along with removal of the \$1.0 million milestone payment



## **Table of Contents**

provided for under the Separation Agreement, the Company is seeking repayment of all separation benefits paid to Dr. Platt to date. Depending on the outcome of the arbitration, the previously accrued \$1.0 million could be reversed. The timing and ultimate outcome of this arbitration, though, is uncertain and there is no guarantee that we will be successful in this demand.

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

### ***Off-Balance Sheet Arrangements***

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

### **Critical Accounting Policies and Estimates**

Our significant accounting policies are more fully described in Note 2 to our consolidated financial statements included elsewhere in this annual report on Form 10-K. Certain of our accounting policies, however, are critical to the portrayal of our financial position and results of operations and require the application of significant judgment by our management, which subjects them to an inherent degree of uncertainty. In applying our accounting policies, our management uses its best judgment to determine the appropriate assumptions to be used in the determination of certain estimates. Our more significant estimates include stock option and warrant liability valuations and performance vesting features of certain of these instruments, useful lives and potential impairment of property and equipment and intangible assets, accrued liabilities, deferred income taxes and cash flow. These estimates are based on our historical experience, terms of existing contracts, our observance of trends in the industry, information available from other outside sources, and on various other factors that we believe to be appropriate under the circumstances. We believe that the critical accounting policies discussed below involve more complex management judgment due to the sensitivity of the methods, assumptions and estimates necessary in determining the related asset, liability, revenue and expense amounts.

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

*Warrants.* We have issued common stock warrants in connection with the execution of certain equity and debt financings and consulting agreements. Certain warrants, no longer outstanding, had been accounted for as derivative liabilities at fair value. Such warrants did not meet the criteria that a contract should not be considered a derivative instrument if it is (1) indexed to its own stock and (2) classified in stockholders equity. Changes in fair value of derivative liabilities were recorded in the consolidated statement of operations under the caption Change in fair value of warrant liabilities. Warrants that are not considered derivative liabilities are accounted

**Table of Contents**

for at fair value at the date of issuance in additional paid-in capital. The fair value of warrants is determined using the Black-Scholes option-pricing model using assumptions regarding volatility of our common share price, remaining life of the warrant, and risk-free interest rates at each period end.

*Stock-Based Compensation.* Stock-based compensation cost is measured at the grant date based on the fair value of the award and is recognized as expense over the service period, which generally represents the vesting period. For awards that have performance based vesting conditions we recognize the expense over the estimated period that the awards are expected to be earned. We generally use the Black-Scholes option-pricing model to calculate the grant date fair value of stock options. The expense recognized over the service period is required to include an estimate of the awards that will be forfeited.

*Research and Development Expenses.* Costs associated with research and development are expensed as incurred. 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.

*Contingencies.* At the date of issuance, our Series C Super Dividend Convertible Preferred Stock ( Series C ) have an embedded dividend right to continue to receive dividend payments after conversion to common stock (the Series C Post Conversion Dividend Right) which requires bifurcation. The value of this post conversion dividend right on the date of issuance was determined to be de minimis due to the payment of a dividend stream other than the 6% dividend and conversion of Series C prior to the Company achieving sales of GM-CT-01 was deemed improbable at that time. Upon a conversion of the Series C, we will be required to record a liability and the related expense during the period of conversion. In July 2011, 5 shares of Series C were converted into 8,334 shares of common stock and 5 Series C Post Conversion Dividend Rights ( Dividend Rights ) were issued. In January 2013, 5 shares of Series C were converted into 8,334 shares of common stock and 5 Dividend Rights were issued. Per the terms of the Series C, these Dividend Rights shall continue to participate in dividends, however the dividend will only be paid based on sales of GM-CT-01 and will not participate in the 6% dividend. At December 31, 2012, these Dividend Rights were determined to have a de minimis value, as the payment of a dividend (other than the 6% dividend) is considered improbable at this time. The Company will continue to evaluate and assess the Series C Post Conversion Dividend Right for each reporting period.

**Item 7A. *Quantitative and Qualitative Disclosures About Market Risk***

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

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

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

**Item 9. *Changes in and Disagreements With Accountants on Accounting and Financial Disclosure***

None.

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

*(a) Evaluation of Disclosure Controls and Procedures*

As required by Rule 13a-15 under the Securities Exchange Act of 1934, (the Exchange Act ) 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, 2012. Our management has concluded, based on their evaluation, that our disclosure controls and procedures were effective as of December 31, 2012 to ensure that

---

**Table of Contents**

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 completed documentation of its testing to verify the effectiveness of the key controls. Based on the evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2012.

As we are neither a large accelerated filer nor an accelerated filer, as defined in Rule 12b-2 under the Exchange Act, we are exempt from the requirement to include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting.

*(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 of 2012 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**Item 9B. Other Information**

None.

**Table of Contents**

**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 2012 Annual Meeting of Stockholders which is scheduled to be held on May 23, 2013 (the 2013 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.galectintherapeutics.com](http://www.galectintherapeutics.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 2013 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 2013 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 2013 Proxy Statement.

**Item 14. *Principal Accountant 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 2013 Proxy Statement.

**Table of Contents****PART IV****Item 15. Exhibits and Financial Statement Schedules**

## (a) 1. Consolidated Financial Statement Schedules

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

## 2. Consolidated Financial Statement Schedules

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

## 3. Exhibits

Exhibit Number	Description of Document	Note Reference
3.1	Articles of Incorporation of Pro Pharmaceuticals, Inc., dated January 23, 2001, as filed with the Secretary of State of the State of Nevada.	1
3.2	Articles of Merger of Pro-Pharmaceuticals, Inc. (a Massachusetts corporation) into Pro-Pharmaceuticals, Inc. (a Nevada corporation) dated June 6, 2011.	7
3.3	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
3.4	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
3.5	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
3.6	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
3.7	Certificate of Amendment to Articles of Incorporation of Pro Pharmaceuticals, Inc., as filed with the Secretary of State of the State of Nevada on May 27, 2009.	14
3.8	Certificate of Amendment to the Certificate of Designation of Preferences, Rights and Limitations of Series B-1 Convertible Preferred Stock and Series B-2 Convertible Preferred Stock of Pro-Pharmaceuticals, Inc., as filed with the secretary of State of the State of Nevada on August 12, 2009.	15
3.9	Certificate of Amendment No. 2 to the Certificate of Designation of Preferences, Rights and Limitations of Series B-1 Convertible Preferred Stock and Series B-2 Convertible Preferred Stock, as filed with the State of Nevada, on February 17, 2010.	16
3.10	Certificate of Amendment with respect to the Amended and Restated Certificate of Designation of Preferences, Rights and Limitation 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	18

Edgar Filing: GALECTIN THERAPEUTICS INC - Form 10-K

January 26, 2011.

3.11	Certificate of Designation of Preferences, Rights and Limitation of Series C Super Dividend Convertible Preferred Stock of Pro-Pharmaceuticals, Inc., as filed with the Secretary of State of Nevada on December 30, 2010.	19
3.12	Certificate of Amendment to Articles of Incorporation of Pro-Pharmaceuticals, Inc., as filed with the Secretary of the State of Nevada on May 26, 2011	26

**Table of Contents**

<b>Exhibit Number</b>	<b>Description of Document</b>	<b>Note Reference</b>
3.13	Certificate of Change as filed with the Nevada Secretary of State on March 1, 2012.	30
3.14	Amended and Restated Bylaws of Galectin Therapeutics Inc..	6
4.1	Specimen certificate for shares of common stock.	7
4.2	Form of Class A-1 Common Stock Purchase Warrant	5
4.3	Form of Class A-2 Common Stock Purchase Warrant	5
4.4	Form of Class B Common Stock Purchase Warrant	5
4.5	Amended Form of Class A-1 Common Stock Purchase Warrant	20
4.6	Amended Form of Class A-2 Common Stock Purchase Warrant	20
4.7	Amended Form of Class B Common Stock Purchase Warrant	20
4.8	Warrant Agreement dated as of March 28, 2012, between Galectin Theapeutucs Inc. and Continental Stock Transfer and Trust Company, as warrant agent (including form of warrant certificate)	36
10.1	Pro-Pharmaceuticals, Inc. 2001 Stock Incentive Plan.	8
10.2	Pro-Pharmaceuticals, Inc. 2003 Non-employee Director Stock Incentive Plan.	9
10.3	Employment Agreement, effective January 2, 2004, between Pro Pharmaceuticals, Inc. and David Platt.	10
10.4	Form of Incentive Stock Option Agreement (under the 2001 Stock Incentive Plan).	11
10.5	Form of Non-Qualified Stock Option Agreement (under the 2001 Stock Incentive Plan).	11
10.6	Form of Non-Qualified Stock Option Agreement (under the 2003 Non-Employee Director Stock Incentive Plan).	11
10.7	Form of Common Stock Purchase Warrant.	12
10.8	Promissory Note dated February 12, 2009 issued by Pro Pharmaceuticals, Inc. in favor of 10X Fund, L.P.	5
10.9	Security Agreement dated February 12, 2009 between Pro Pharmaceuticals, Inc. and 10X Fund, L.P.	5
10.10	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
10.11	Registration Rights Agreement dated February 12, 2009 between Pro Pharmaceuticals, Inc. and 10X Fund, L.P.	5
10.12	Separation Agreement dated February 12, 2009 between Pro Pharmaceuticals, Inc. and David Platt, Ph.D.	5
10.13	Pro-Pharmaceuticals, Inc. 2009 Incentive Compensation Plan.	5
10.14	Form of Restricted Stock Grant Agreement (under the 2009 Incentive Compensation Plan).	13
10.15	Form of Non-Qualified Stock Option Grant Agreement (under the 2009 Incentive Compensation Plan).	13
10.16	Form of Incentive Stock Option Grant Agreement (under the 2009 Incentive Compensation Plan).	13

**Table of Contents**

<b>Exhibit Number</b>	<b>Description of Document</b>	<b>Note Reference</b>
10.17	Agreement with the 10X Fund L.P., dated February 11, 2010.	16
10.18	Common Stock Purchase Warrant dated August 3, 2010 issued to Peter Traber.	17
10.19	Letter Agreement Between 10X Fund, L.P. and Pro-Pharmaceuticals, Inc.	17
10.20	Form of Securities Purchase Agreement for Series C Super Dividend Convertible Preferred Stock	21
10.21	Agreement dated January 21, 2011, between Pro-Pharmaceuticals, Inc. and 10X Fund L.P.	20
10.22	Non-Qualified Stock Option Agreement dated March 7, 2011	22
10.23	Amended Employment Agreement dated March 8, 2011 between Anthony D. Squeglia, and Pro-Pharmaceuticals, Inc.	23
10.24	Amended Employment Agreement dated March 8, 2011 between Maureen Foley, and Pro-Pharmaceuticals, Inc.	23
10.25	Amended Employment Agreement dated March 31, 2011 between Anatole Klyosov, and Pro-Pharmaceuticals, Inc.	24
10.26	Employment Agreement dated March 31, 2011 between Eli Zomer and Pro-Pharmaceuticals, Inc.	24
10.27	Separation Agreement dated March 31, 2011 between Pro-Pharmaceuticals, Inc. and Theodore D. Zucconi	24
10.28	Agreement dated April 22, 2011, between Pro-Pharmaceuticals, Inc. and Sigma-Aldrich, Inc.	25
10.29	Employment Agreement dated March 31, 2011 between Peter Traber, and Galectin Therapeutics Inc.	26
10.30	Employment Agreement dated June 28, 2011 between James C. Czirr, and Galectin Therapeutics Inc.	27
10.31	Collaboration, Supply, Marketing and Distribution Agreement dated October 18, 2011 between PROCAPS S.A. and Galectin Therapeutics Inc.	29
10.32	Non-Qualified Stock Option Agreement for Peter G. Traber, M.D.	28
10.33	Non-Qualified Stock Option Agreement for James C. Czirr	28
10.34	Consulting Agreement, dated March 2, 2012 between Galectin Therapeutics Inc. and Thomas A. McGauley	31
10.35	Independent Consulting Agreement dated April 30, 2012, between Scott L. Friedman, M.D. and Galectin Therapeutics Inc.	32
10.36	Amended Employment Agreement dated July 19, 2012 between Maureen Foley and Galectin Therapeutics Inc.	32
10.37	Employment Agreement dated August 27, 2012, 2012 between Harold H. Shlevin and Galectin Therapeutics Inc.	32
10.38	Independent Consulting Agreement dated September 19, 2012 between Thomas A. McGauley and Galectin Therapeutics Inc.	32
21.1*	Subsidiaries of Galectin Therapeutics Inc.	
23.1*	Consent of McGladrey LLP, an independent registered public accounting firm.	



**Table of Contents**

Exhibit Number	Description of Document	Note Reference
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.	
101.INS***	XBRL Instance document.	
101.SCH***	XBRL Taxonomy Extension Schema Document.	
101.CAL***	XBRL Taxonomy Calculation Linkbase Document.	
101.DEF***	XBRL Taxonomy Definition Linkbase Document.	
101.LAB***	XBRL Taxonomy Label Linkbase Document.	
101.PRE***	XBRL Taxonomy Presentation Linkbase Document.	

\* Filed herewith.

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

\*\*\* Submitted electronically herewith.

1. Incorporated by reference to the Company's Registration Statement on Form 10-SB, as filed with the Commission on June 13, 2001.
2. Incorporated by reference to the Company's Quarterly Report on Form 10-Q filed with the Commission on August 16, 2004.
3. Incorporated by reference to the Company's Current Report on Form 8-K filed with the Commission on October 9, 2007.
4. Incorporated by reference to the Company's Current Report on Form 8-K filed with the Commission on June 2, 2008.
5. Incorporated by reference to the Company's Current Report on Form 8-K filed with the Commission on February 18, 2009.
6. Incorporated by reference to the Company's Current Report on Form 8-K filed with the Commission on December 17, 2007.
7. Incorporated by reference to the Company's Annual Report on Form 10-K as filed with the Commission on March 30, 2012.
8. 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.
9. Incorporated by reference to the Company's Registration Statement on Form S-8, as filed with the Commission on October 22, 2003.
10. 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.
11. 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.
12. Incorporated by reference to the Company's Current Report on Form 8-K as filed with the Commission on February 15, 2008.
13. Incorporated by reference to the Company's Annual Report on Form 10-K as filed with the Commission on March 30, 2009.
14. Incorporated by reference to the Company's Current Report on Form 8-K filed with the Commission on May 28, 2009.

**Table of Contents**

15. Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the period ended June 30, 2009 as filed with the Commission on August 14, 2009.
16. Incorporated by reference to the Company's Current Report on Form 8-K as filed with the Commission on February 17, 2010.
17. Incorporated by reference to the Company's Quarterly Report on Form 10-Q as filed with the Commission on August 13, 2010.
18. Incorporated by reference to the Company's Current Report on Form 8-K as filed with the Commission on January 27, 2011.
19. Incorporated by reference to the Company's Current Report on Form 8-K as filed with the Commission on January 6, 2011.
20. Incorporated by reference to the Company's Current Report on Form 8-K as filed with the Commission on January 27, 2011.
21. Incorporated by reference to the Company's Current Report on Form 8-K as filed with the Commission on January 6, 2011.
22. Incorporated by reference to the Company's Current Report on Form 8-K as filed with the Commission on March 9, 2011.
23. Incorporated by reference to the Company's Current Report on Form 8-K as filed with the Commission on March 14, 2011.
24. Incorporated by reference to the Company's Current Report on Form 8-K as filed with the Commission on April 6, 2011.
25. Incorporated by reference to the Company's Current Report on Form 8-K as filed with the Commission on April 28, 2011.
26. Incorporated by reference to the Company's Current Report on Form 8-K as filed with the Commission on June 2, 2011.
27. Incorporated by reference to the Company's Current Report on Form 8-K as filed with the Commission on July 5, 2011.
28. Incorporated by reference to the Company's Current Report on Form 8-K as filed with the Commission on August 15, 2011.
29. Incorporated by reference to the Company's Quarterly Report on Form 10-Q as filed with the Commission on November 10, 2011.
30. Incorporated by reference to the Company's Current Report on Form 8-K as filed with the Commission on March 23, 2012.
31. Incorporated by reference to the Company's Quarterly Report on Form 10-Q as filed with the Commission on May 11, 2012.
32. Incorporated by reference to the Company's Quarterly Report on Form 10-Q as filed with the Commission on November 9, 2012.

**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 29, 2013.

GALECTIN THERAPEUTICS INC.

By: /s/ PETER G. TRABER  
 Name: Peter G. Traber, M.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/ PETER G. TRABER Peter G. Traber, M.D.	Chief Executive Officer, President and Director (principal executive officer)	March 29, 2013
/s/ THOMAS A. MCGAULEY Thomas A. McGauley	Chief Financial Officer (principal financial and accounting officer)	March 29, 2013
/s/ JAMES C. CZIRR James C. Czirr	Executive Chairman and Director	March 29, 2013
/s/ ROD D. MARTIN Rod D. Martin	Vice-Chairman and Director	March 29, 2013
/s/ GILBERT F. AMELIO Gilbert F. Amelio	Director	March 29, 2013
/s/ ARTHUR R. GREENBERG Arthur R. Greenberg	Director	March 29, 2013
/s/ KEVIN D. FREEMAN Kevin D. Freeman	Director	March 29, 2013
/s/ JOHN MAULDIN John Mauldin.	Director	March 29, 2013
/s/ STEVEN PRELACK Steven Prelack	Director	March 29, 2013

Edgar Filing: GALECTIN THERAPEUTICS INC - Form 10-K

/s/ H. PAUL PRESSLER	Director	March 29, 2013
H. Paul Pressler		
/s/ JERALD K. ROME	Director	March 29, 2013
Jerald K. Rome		
/s/ MARC RUBIN	Director	March 29, 2013
Marc Rubin, M.D.		

**Table of Contents**

**Galectin Therapeutics Inc.**

**(A Development Stage Company)**

**Table of Contents**

<u>1. Report of Independent Registered Public Accounting Firm</u>	F-1
<u>2. Consolidated Balance Sheets as of December 31, 2012 and 2011</u>	F-2
<u>3. Consolidated Statements of Operations for the years ended December 31, 2012 and 2011 and for the cumulative period from inception (July 10, 2000) to December 31, 2012</u>	F-3
<u>4. Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit) for the years ended December 31, 2012 and 2011 and for the cumulative period from inception (July 10, 2000) to December 31, 2012</u>	F-4
<u>5. Consolidated Statements of Cash Flows for the years ended December 31, 2012 and 2011 and for the cumulative period from inception (July 10, 2000) to December 31, 2012</u>	F-16
<u>6. Notes to Consolidated Financial Statements</u>	F-17

**Table of Contents**

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Stockholders of Galectin Therapeutics Inc.

Norcross, Georgia

We have audited the accompanying consolidated balance sheets of Galectin Therapeutics Inc. and subsidiaries (a development stage company) (the Company) as of December 31, 2012 and 2011, and the related consolidated statements of operations, changes in redeemable convertible preferred stock and stockholders' equity (deficit), and cash flows for the years then ended, and for the period from inception (July 10, 2000) to December 31, 2012. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. The financial statements for the period from inception (July 10, 2000) to December 31, 2009 were audited by other auditors and our opinion, insofar as it relates to cumulative amounts included for such prior periods, is based solely on the report of other such auditors.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits 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, based on our audits and the report of other auditors, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2012 and 2011, and the results of their operations and their cash flows for the years then ended, and for the period from inception (July 10, 2000) to December 31, 2012 in conformity with U.S. generally accepted accounting principles.

/s/ McGladrey LLP

Boston, Massachusetts

March 29, 2013

F-1

**Table of Contents****GALECTIN THERAPEUTICS INC.****(A Development-Stage Company)****CONSOLIDATED BALANCE SHEETS**

	<b>December 31,</b>	
	<b>2012</b>	<b>2011</b>
	<b>(in thousands)</b>	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 9,364	\$ 6,397
Prepaid expenses and other current assets	153	104
<b>Total current assets</b>	<b>9,517</b>	<b>6,501</b>
Property and equipment, net	8	6
Restricted cash and security deposit	6	69
Intangible assets, net	30	36
<b>Total assets</b>	<b>\$ 9,561</b>	<b>\$ 6,612</b>
<b>LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS EQUITY (DEFICIT)</b>		
Current liabilities:		
Accounts payable	\$ 397	\$ 384
Accrued expenses	1,161	1,551
Accrued dividends payable	80	80
Deferred income		200
<b>Total current liabilities</b>	<b>1,638</b>	<b>2,215</b>
<b>Other long-term liabilities</b>	<b>6</b>	
<b>Total liabilities</b>	<b>1,644</b>	<b>2,215</b>
<b>Commitments and contingencies (Note 11)</b>		
Series B-1 12% redeemable convertible preferred stock; 900,000 shares authorized, issued and outstanding at December 31, 2012 and 2011, redemption value and liquidation value: \$1,800,000, at December 31, 2012	1,698	1,681
Series B-2 12% redeemable convertible preferred stock; 2,100,000 shares authorized, issued and outstanding at December 31, 2012 and 2011, redemption value and liquidation value: \$4,200,000, at December 31, 2012	2,900	2,687
Series C super dividend convertible preferred stock; 1,000 shares authorized, 220 issued and outstanding at December 31, 2012 and 2011, redemption value: \$5,204,000, liquidation value: \$2,233,000 at December 31, 2012	2,154	2,154
<b>Stockholders' equity (deficit):</b>		
Undesignated stock, \$0.01 par value; 20,000,000 shares authorized at December 31, 2012 and 2011, 8,001,000 shares designated at December 31, 2012 and 2011		
Series A 12% convertible preferred stock; 5,000,000 shares authorized, 1,562,500 issued and outstanding at December 31, 2012 and 2011	632	632
	16	13

## Edgar Filing: GALECTIN THERAPEUTICS INC - Form 10-K

Common stock, \$0.001 par value; 50,000,000 shares authorized at December 31, 2012 and 2011, 16,060,853 and 12,919,538 issued and outstanding at December 31, 2012 and 2011, respectively

Additional paid-in capital	80,535	66,367
Deficit accumulated during the development stage	(80,018)	(69,137)
<b>Total stockholders' equity (deficit)</b>	<b>1,165</b>	<b>(2,125)</b>
<b>Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)</b>	<b>\$ 9,561</b>	<b>\$ 6,612</b>

See notes to consolidated financial statements.

F-2



**Table of Contents****GALECTIN THERAPEUTICS INC.****(A Development-Stage Company)****CONSOLIDATED STATEMENTS OF OPERATIONS**

	<b>Year Ended December 31,</b>		<b>Cumulative from inception (July 10, 2000) to December 31, 2012</b>
	<b>2012</b>	<b>2011</b>	
	<b>(in thousands, except per share amounts)</b>		
Operating expenses:			
Research and development	\$ 4,527	\$ 3,552	\$ 27,610
General and administrative	5,372	6,857	47,036
Total operating expenses	9,899	10,409	74,646
Total operating loss	(9,899)	(10,409)	(74,646)
Other income (expense):			
Interest income	24	18	818
Interest expense			(4,451)
Change in fair value of convertible debt instrument			(3,426)
Change in fair value of warrant liabilities		(524)	9,022
Other income	200		691
Total other income (expense)	224	(506)	2,654
Net loss	\$ (9,675)	\$ (10,915)	\$ (71,992)
Preferred stock dividends	(976)	(1,568)	(4,235)
Preferred stock accretion	(230)	(230)	(4,045)
Net loss applicable to common stockholders	\$ (10,881)	\$ (12,713)	\$ (80,272)
Basic and diluted net loss per share	\$ (0.72)	\$ (1.06)	
Shares used in computing basic and diluted net loss per share	15,131	11,986	

See notes to consolidated financial statements.

Table of Contents

## GALECTIN THERAPEUTICS INC.

## (A Development-Stage Company)

## CONSOLIDATED STATEMENT OF CHANGES IN REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)

Cumulative Period From Inception (July 10, 2000) to December 31, 2012

(in thousands except share data)

	Series B-1 12% Redeemable Convertible Preferred Stock		Series B-2 12% Redeemable Convertible Preferred Stock		Series C Super Dividend Convertible Preferred Stock		Series A 12% Convertible Preferred Stock		Stockholders' Deficit			
	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Common Stock	Deficit Accumulated During the Period	Total Stockholders' Deficit	
<b>Issuance of founders shares July 10, 2000</b>		\$		\$		\$		\$	2,059,112	\$ 2	\$ 7	\$ 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									110,054		1,036	1,036
Issuance of common stock in connection with reverse merger of Pro-Pharmaceuticals-NV in 2001									203,649		107	107
Conversion of notes payable and accrued interest to common stock in 2001									99,705		1,126	1,126

F-4

Table of Contents

## GALECTIN THERAPEUTICS INC.

(A Development-Stage Company)

## CONSOLIDATED STATEMENT OF CHANGES IN REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS EQUITY (DEFICIT) (Continued)

Cumulative Period From Inception (July 10, 2000) to December 31, 2012

(in thousands except share data)

	Series B-1 12% Redeemable Convertible Preferred Stock		Series B-2 12% Redeemable Convertible Preferred Stock		Series C Super Dividend Convertible Preferred Stock		Series A 12% Convertible Preferred Stock		Stockholders Common Stock		Deficit		
	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Additional Paid-In Capital	Deficit Accumulated During the Development Stage	Total Stockholders Deficit
Issuance of warrants to induce conversion of notes payable in 2001											503		503
Issuance of common stock and warrants (net of issuance costs of \$17,000) in 2001									114,884		2,221		2,221
Issuance of common stock (net of issuance costs of \$49,000) in 2002									31,000		602		602
Issuance of common stock related to 2002 private placement (net of issuance costs of \$212,000)									537,227	1	2,860		2,861
Conversion of notes payable and accrued									17,647		290		290

interest to  
common  
stock  
Issuance of  
warrants to  
purchase  
common  
stock in  
consideration  
for placement  
of convertible  
notes payable  
in 2002

236

236

F-5

Table of Contents

## GALECTIN THERAPEUTICS INC.

## (A Development-Stage Company)

## CONSOLIDATED STATEMENT OF CHANGES IN REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS EQUITY (DEFICIT) (Continued)

Cumulative Period From Inception (July 10, 2000) to December 31, 2012

(in thousands except share data)

	Series B-1 12% Redeemable Convertible Preferred Stock		Series B-2 12% Redeemable Convertible Preferred Stock		Series C Super Dividend Convertible Preferred Stock		Series A 12% Convertible Preferred Stock		Stockholders Common Stock		Deficit		
	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Additional Paid-In Capital	Deficit Accumulated During the Development Stage	Total Stockholders Deficit
Issuance of common stock to investors in 2002 private placement (net of issuance costs of \$18,000)									181,334		1,070		1,070
Issuance of common stock to consultants for services related to 2002 private placement									2,042		12		12
Receipt of subscription receivable											150		150
Conversion of accrued expenses to common stock and options									33,618		302		302
Issuance of common stock to investors in May, 2003									399,917	1	4,409		4,410

private  
placement  
(net of  
issuance  
costs of  
\$128,000)

F-6

**Table of Contents****GALECTIN THERAPEUTICS INC.****(A Development-Stage Company)****CONSOLIDATED STATEMENT OF CHANGES IN REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS EQUITY (DEFICIT) (Continued)**

Cumulative Period From Inception (July 10, 2000) to December 31, 2012

(in thousands except share data)

	Series B-1 12% Redeemable Convertible Preferred Stock		Series B-2 12% Redeemable Convertible Preferred Stock		Series C Super Dividend Convertible Preferred Stock		Series A 12% Convertible Preferred Stock		Stockholders Common Stock		Deficit		
	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Additional Paid-In Capital	Deficit Accumulated During the Development Stage	Total Stockholders Deficit
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 \$559,000)									219,096		1,319		1,319
Cashless exercise of employee stock options									2,772		74		74
Issuance of									206,019		1,898		1,898

common  
stock to  
investors  
in April,  
2004  
private  
placement  
(net of  
issuance  
costs of  
\$466,000)

F-7



**Table of Contents****GALECTIN THERAPEUTICS INC.****(A Development-Stage Company)****CONSOLIDATED STATEMENT OF CHANGES IN REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS EQUITY (DEFICIT) (Continued)**

Cumulative Period From Inception (July 10, 2000) to December 31, 2012

(in thousands except share data)

	Series B-1 12% Redeemable Convertible Preferred Stock		Series B-2 12% Redeemable Convertible Preferred Stock		Series C Super Dividend Convertible Preferred Stock		Series A 12% Convertible Preferred Stock		Stockholders Common Stock		Deficit		Total Stockholders Deficit
	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Additional Paid-In Capital	Deficit Accumulated During the Development Stage	
Issuance of common stock to investors in August, 2004 private placement (net of issuance costs of \$485,000)									333,334	1	489		490
Common stock issued in 2006 related to convertible debenture conversions									79,367		1,745		1,745
Common stock issued in 2006 and 2007 related to convertible debenture redemptions									1,227,972	1	3,947		3,948
Common stock issued in 2007 related to convertible debenture									867,558	1	5,329		5,330

waiver and  
exchange  
agreement

F-8

Table of Contents

## GALECTIN THERAPEUTICS INC.

## (A Development-Stage Company)

## CONSOLIDATED STATEMENT OF CHANGES IN REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS EQUITY (DEFICIT) (Continued)

Cumulative Period From Inception (July 10, 2000) to December 31, 2012

(in thousands except share data)

	Series B-1 12% Redeemable Convertible Preferred Stock		Series B-2 12% Redeemable Convertible Preferred Stock		Series C Super Dividend Convertible Preferred Stock		Series A 12% Convertible Preferred Stock		Stockholders Common Stock		Deficit		
	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Additional Paid-In Capital	Deficit Accumulated During the Development Stage	Total Stockholders Deficit
Series A 12% Convertible Preferred Stock issued in a February 4, 2008 private placement (net of cash issuance costs of \$52,000)							1,742,500	704					704
Common stock issued in a February 25, 2008 offering (net of cash issuance costs of \$369,000)									1,250,000	1	1,043		1,044
Issuance of common stock in payment of Series A 12% Convertible Preferred Dividend									160,330		875	(922)	(47)
Issuance of Common Stock Warrants											20		20
Reclassification of Warrant Liabilities											3,193		3,193
											455		455

Deferred  
compensation  
relating to  
issuance of  
stock options

F-9

**Table of Contents****GALECTIN THERAPEUTICS INC.****(A Development-Stage Company)****CONSOLIDATED STATEMENT OF CHANGES IN REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS EQUITY (DEFICIT) (Continued)**

Cumulative Period From Inception (July 10, 2000) to December 31, 2012

(in thousands except share data)

	Series B-1 12% Redeemable Convertible Preferred Stock		Series B-2 12% Redeemable Convertible Preferred Stock		Series C Super Dividend Convertible Preferred Stock		Series A 12% Convertible Preferred Stock		Stockholders Common Stock		Deficit			
	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Additional Paid-In Capital	Development Stage	Total Stockholders Deficit	
Stock compensation expense related to fair market revaluation												157	157	
Stock based compensation expense												11,635	11,635	
Stock compensation related to the issuance of common shares									12,515			53	53	
Cumulative effect of adoption of new accounting principle												(458)	254	(204)
Issuance of Series B-1 redeemable convertible preferred stock and warrants, net of issuance costs of \$300,000	900,000	395											1,105	1,105

Accretion of  
Series B-1  
redeemable  
convertible  
preferred  
stock to  
redemption  
value

1,303

(1,303) (1,303)

F-10

Table of Contents

## GALECTIN THERAPEUTICS INC.

## (A Development-Stage Company)

## CONSOLIDATED STATEMENT OF CHANGES IN REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS EQUITY (DEFICIT) (Continued)

Cumulative Period From Inception (July 10, 2000) to December 31, 2012

(in thousands except share data)

	Series B-1 12% Redeemable Convertible Preferred Stock		Series B-2 12% Redeemable Convertible Preferred Stock		Series C Super Dividend Convertible Preferred Stock		Series A 12% Convertible Preferred Stock		Stockholders' Equity		Deficit		
	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Additional Paid-In Capital	Deficit Accumulated During the Development Stage	Total Stockholders' Equity
Issuance of Series B-2 redeemable convertible preferred stock and warrants, net of issuance costs of \$188,000			2,100,000	1,174							2,761		2,761
Beneficial conversion feature recognized on issuance of series B-2 redeemable convertible preferred stock				(1,016)							1,016		1,016
Issuance of Series C super dividend convertible preferred stock, net of issuance costs of					225	2,203							

\$47,000

Conversion  
of Series C  
super  
dividend  
convertible  
preferred  
stock to  
common  
stock

(5)

(49)

8,334

49

49

F-11



**Table of Contents****GALECTIN THERAPEUTICS INC.****(A Development-Stage Company)****CONSOLIDATED STATEMENT OF CHANGES IN REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS EQUITY (DEFICIT) (Continued)**

Cumulative Period From Inception (July 10, 2000) to December 31, 2012

(in thousands except share data)

	Series B-1 12% Redeemable Convertible Preferred Stock		Series B-2 12% Redeemable Convertible Preferred Stock		Series C Super Dividend Convertible Preferred Stock		Series A 12% Convertible Preferred Stock		Stockholders Common Stock		Deficit		
	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Additional Paid-In Capital	Deficit Accumulated During the Stage	Total Stockholders Deficit
Accretion of Series B-2 redeemable convertible preferred stock to redemption value				2,057								(2,057)	(2,057)
Series B-1 12% redeemable convertible preferred stock dividend									298,807		1,034	(1,034)	
Series B-2 12% redeemable convertible preferred stock dividend									568,721		2,022	(2,022)	
Series C super dividend convertible preferred stock dividend									63,119		224	(257)	(33)
				685								(685)	(685)

Accretion of beneficial conversion feature for Series B-2				
Issuance of restricted common stock	454,167	1	(1)	
Issuance of common stock upon exercise of warrants	3,419,570	3	14,304	14,307

F-12

**Table of Contents****GALECTIN THERAPEUTICS INC.****(A Development-Stage Company)****CONSOLIDATED STATEMENT OF CHANGES IN REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS EQUITY (DEFICIT) (Continued)****Cumulative Period From Inception (July 10, 2000) to December 31, 2012****(in thousands except share data)**

	Series B-1 12% Redeemable Convertible Preferred Stock		Series B-2 12% Redeemable Convertible Preferred Stock		Series C Super Dividend Convertible Preferred Stock		Series A 12% Convertible Preferred Stock		Common Stock		Additional Paid-In Capital		Deficit Accumulated During the Development Stage	Total Stockholders Deficit
	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount				
Issuance of common stock upon exercise of options									398,937	1	361			362
Conversion of Series A to common stock							(180,000)	(72)	30,000		72			
2012 Issuance of common stock and warrants, net of issuance costs of \$1,597,000									2,666,722	3	10,400			10,403
Issuance of shares related to reverse split of common stock									3,324					
Net loss since inception													(71,992)	(71,992)
<b>Balance at December 31, 2012</b>	<b>900,000</b>	<b>\$ 1,698</b>	<b>2,100,000</b>	<b>\$ 2,900</b>	<b>220</b>	<b>\$ 2,154</b>	<b>1,562,500</b>	<b>\$ 632</b>	<b>16,060,853</b>	<b>\$ 16</b>	<b>\$ 80,535</b>	<b>\$ (80,018)</b>	<b>\$</b>	<b>1,165</b>

See notes to consolidated financial statements.



Table of Contents

## GALECTIN THERAPEUTICS INC.

(A Development-Stage Company)

## CONSOLIDATED STATEMENT OF CHANGES IN REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)

For the Years Ended December 31, 2012 and 2011

(amounts in thousands except share data)

	Series B-1 12% Redeemable Convertible Preferred Stock		Series B-2 12% Redeemable Convertible Preferred Stock		Series C Super Dividend Convertible Preferred Stock		Series A 12% Convertible Preferred Stock		Common Stock		Stockholders' Equity		Deficit Accumulated During the Stage	Total Stockholders' Deficit
	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Additional Paid-In Capital	Development		
<b>Balance at December 31, 2010</b>	<b>900,000</b>	<b>\$ 1,664</b>	<b>2,100,000</b>	<b>\$ 2,474</b>	<b>212</b>	<b>\$ 2,073</b>	<b>1,592,500</b>	<b>\$ 644</b>	<b>10,651,535</b>	<b>\$ 11</b>	<b>\$ 54,075</b>	<b>\$ (56,424)</b>	<b>\$ (1,694)</b>	
Accretion of Series B redeemable convertible preferred stock		17		159								(176)	(176)	
Accretion of beneficial conversion feature for Series B-2				54								(54)	(54)	
Issuance of Series C super dividend convertible preferred stock					13	130								
Series A 12% convertible preferred stock dividend									30,321		180	(179)	1	
Series B-1 12% redeemable convertible preferred stock dividend									59,588		378	(378)		
Series B-2 12% redeemable convertible preferred stock dividend									139,037		881	(881)		
Series C super dividend convertible preferred stock dividend									17,066		97	(130)	(33)	
Issuance of restricted common stock									20,834					
Issuance of common stock upon exercise of warrants									1,771,383	2	7,216		7,218	
Issuance of common stock upon exercise of options									216,440		234		234	
Conversion of Series A to common stock							(30,000)	(12)	5,000		12			
Conversion of Series C to common stock					(5)	(49)			8,334		49		49	
Stock-based compensation expense											3,245		3,245	

Edgar Filing: GALECTIN THERAPEUTICS INC - Form 10-K

Net loss													(10,915)	(10,915)
Balance at December 31, 2011	900,000	\$ 1,681	2,100,000	\$ 2,687	220	\$ 2,154	1,562,500	\$ 632	12,919,538	\$ 13	\$ 66,367	\$ (69,137)	\$ (2,125)	

F-14

Table of Contents

## GALECTIN THERAPEUTICS INC.

## (A Development-Stage Company)

## CONSOLIDATED STATEMENT OF CHANGES IN REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS EQUITY (DEFICIT) (Continued)

For the Years Ended December 31, 2012 and 2011

(amounts in thousands except share data)

	Series B-1 12% Redeemable Convertible Preferred Stock		Series B-2 12% Redeemable Convertible Preferred Stock		Series C Super Dividend Convertible Preferred Stock		Series A 12% Convertible Preferred Stock		Common Stock		Stockholders Deficit		Total Stockholders Deficit
	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Additional Paid-In Capital	Deficit Accumulated During the Development Stage	
Accretion of Series B redeemable convertible preferred stock		17		157								(174)	(174)
Accretion of beneficial conversion feature for Series B-2				56								(56)	(56)
Issuance of common stock and warrants, net of issuance costs of \$1,597,000									2,666,722	3	10,400		10,403
Issuance of shares related to reverse split of common stock									3,324				
Series A 12% convertible preferred stock dividend									31,250		103	(103)	
Series B-1 12% redeemable convertible preferred stock dividend									95,584		224	(224)	
Series B-2 12% redeemable convertible preferred stock dividend									223,027		522	(522)	
Series C super dividend convertible preferred stock dividend									46,053		127	(127)	
Issuance of common stock to consultants									11,348		26		26
Issuance of common stock upon exercise of warrants									12,177				
Issuance of common stock upon exercise of options									51,830				
Stock-based compensation expense											2,766		2,766
Net loss												(9,675)	(9,675)
<b>Balance at December 31, 2012</b>	<b>900,000</b>	<b>\$ 1,698</b>	<b>2,100,000</b>	<b>\$ 2,900</b>	<b>220</b>	<b>\$ 2,154</b>	<b>1,562,500</b>	<b>\$ 632</b>	<b>16,060,853</b>	<b>\$ 16</b>	<b>\$ 80,535</b>	<b>\$ (80,018)</b>	<b>\$ 1,165</b>

See notes to consolidated financial statements.

F-15



**Table of Contents****GALECTIN THERAPEUTICS INC.****(A Development-Stage Company)****CONSOLIDATED STATEMENTS OF CASH FLOWS**

	Year Ended December 31,		Cumulative Period from Inception (July 10, 2000) to December 31, 2012
	2012	2011 (in thousands)	
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net loss	\$ (9,675)	\$ (10,915)	\$ (71,992)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	9	9	555
Stock-based compensation expense	2,792	3,245	12,374
Non-cash interest expense			4,279
Change in fair value of convertible debt instrument			3,426
Change in fair value of warrant liabilities		524	(9,022)
Write off of intangible assets			351
Changes in operating assets and liabilities:			
Grant receivable		234	
Prepaid expenses and other assets	(55)	(34)	(156)
Accounts payable and accrued expenses	(577)	1,273	1,626
Other long-term liabilities	6	(12)	6
Net cash used in operating activities	(7,500)	(5,676)	(58,553)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Purchases of property and equipment	(5)	(5)	(431)
Change in restricted cash and security deposit	69	(10)	
Increase in patents costs and other assets			(404)
Net cash provided by (used in) investing activities	64	(15)	(835)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Net proceeds from issuance of common stock and warrants	10,403		39,093
Net proceeds from issuance of Series A 12% convertible preferred stock and related warrants			1,691
Net proceeds from issuance of Series B-1 12% redeemable convertible preferred stock and related warrants			1,548
Net proceeds from issuance of Series B-2 12% redeemable convertible preferred stock and related warrants			3,935
Net proceeds from issuance of Series C super dividend convertible preferred stock		130	2,203
Net proceeds from issuance of convertible debt instruments			10,621
Repayment of convertible debt instruments			(1,641)
Net proceeds from exercise of common stock warrants and options		6,067	11,293
Proceeds from shareholder advances			9
Net cash provided by financing activities	10,403	6,197	68,752
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	2,967	506	9,364
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	6,397	5,891	

Edgar Filing: GALECTIN THERAPEUTICS INC - Form 10-K

CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 9,364	\$ 6,397	\$ 9,364
SUPPLEMENTAL DISCLOSURE Cash paid for interest	\$	\$	\$ 114
NONCASH FINANCING ACTIVITIES:			
Issuance of equity warrants in connection with equity offerings	\$ 4,445	\$	\$ 9,482
Conversion of accrued expenses into common stock	26		329
Cashless exercise of stock options and warrants	235	341	674
Conversion and redemptions of convertible notes and accrued interest into common stock			12,243
Conversion of extension costs related to convertible notes into common stock			171
Payment of preferred stock dividends in common stock	976	1,536	4,155
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.			

F-16

---

**Table of Contents**

**GALECTIN THERAPEUTICS INC.**

(A DEVELOPMENT-STAGE COMPANY)

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1. Nature of Business and Basis of Presentation**

Galectin Therapeutics Inc. (the Company) is a development-stage company that is applying its leadership in galectin science and drug development to create new therapies for fibrotic disease and cancer. These candidates are based on the Company's targeting of galectin proteins which are key mediators of biologic and pathologic function. These compounds also may have application for drugs to treat other diseases and chronic health conditions.

On March 23, 2012, the Company effected a one-for-six reverse stock split. All common share and per share amounts in these financial statements have been adjusted to reflect the effect of the reverse split. On March 28, 2012, the Company sold 2,666,722 shares of common stock and related \$5.63 warrants to purchase 1,333,361 shares of common stock for gross proceeds of \$12,000,000 (net proceeds of \$10,403,000). See Note 6, for further discussion of the transaction.

The Company has operated at a loss since its inception and has had no significant revenues. The Company anticipates that losses will continue for the foreseeable future. At December 31, 2012, the Company had \$9,364,000 of unrestricted cash and cash equivalents available to fund future operations. The Company believes that with the cash on hand at December 31, 2012, there is sufficient cash to fund operations through the first quarter of 2014. The Company's ability to fund operations after its current cash resources are exhausted depends on its ability to obtain additional financing or achieve profitable operations, as to which no assurances can be given. The Company has developed several plans, including cost containment efforts and potential strategic alternatives in the event that such financing cannot be realized by the Company. Accordingly, based on the forecasts and estimates underlying the Company's current operating plan, the financial statements do not currently include any adjustments that might be necessary if the Company is unable to continue as a going concern.

As shown in the consolidated financial statements, the Company incurred cumulative net losses applicable to common stockholders of \$80.3 million for the cumulative period from inception (July 10, 2000) through December 31, 2012. 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, dividend payments, and the costs related to fair value accounting for the Company's convertible debt instruments. 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, 2012, the Company had raised a net total of \$68.8 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, 2012, the Company used cash of \$58.6 million in its operations.

The Company was founded in July 2000, was incorporated in the State of Nevada in January 2001 under the name Pro-Pharmaceuticals, Inc., and changed its name to Galectin Therapeutics Inc. on May 26, 2011. On March 23, 2012, the Company began trading on The NASDAQ Capital Market under the symbol GALT. Prior to March 23, 2012, the Company was traded on the Over-the Counter Bulletin Board (OTCBB) under the symbol GALT.OB (previously PRWP.OB) from January 21, 2009 to March 22, 2012 after 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 9, 2009.

---

**Table of Contents**

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, 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.

**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 the consolidated financial statements.

*Basis of Consolidation.* The consolidated financial statements include the accounts of the Company and Galectin Therapeutics Security Corp., its wholly-owned subsidiary, which was incorporated in Delaware on December 23, 2003. Galectin Therapeutics Security 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 may affect the reported amounts of assets, liabilities, equity, revenue, expenses and related disclosure of contingent assets and liabilities. Management's estimates and judgments include assumptions used in stock option and warrant liability valuations, useful lives of property and equipment and intangible assets, accrued liabilities, deferred income taxes and various other assumptions that are believed to be reasonable under the circumstances. Actual results may differ from those estimates under different assumptions or conditions.

*Fair Value Measurements.* The Company has certain financial assets and liabilities recorded at fair value. Fair values determined by Level 1 inputs utilize observable data such as quoted prices in active markets. Fair values determined by Level 2 inputs utilize data points other than quoted prices in active markets that are observable either directly or indirectly. Fair values determined by Level 3 inputs utilize unobservable data points in which there is little or no market data, which require the reporting entity to develop its own assumptions. The estimated value of accounts payable and accrued expenses approximates their carrying value due to their short-term nature using level 3 inputs as defined above. Included in cash and cash equivalents, as of December 31, 2012 and 2011, the Company had \$583,000 and \$6,123,000, respectively, invested in money market funds which had calculated net asset values and were therefore classified as Level 2.

*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.

*Prepaid Expenses and Other Current Assets.* Prepaid expenses and other assets consist principally of prepaid insurance and prepaid rent 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 estimated useful lives of the related assets of generally three years for computers and office equipment, five years for furniture and fixtures and the shorter of the useful life or life of the lease for leasehold improvements.

## **Table of Contents**

*Restricted Cash and Security Deposit.* Restricted cash consists of security deposits principally for a real estate lease at December 31, 2011. At December 31, 2012, the Company had a security deposit of \$6,000 for leased office space.

*Intangible Assets.* Intangible assets include patent costs, consisting primarily of related capitalized legal fees, which are amortized over an estimated useful life of five years from issuance. Amortization expense in 2012 and 2011 was \$6,000 and \$3,000, respectively. Gross intangible assets at December 31, 2012 and 2011 totaled \$78,000 each year, and accumulated amortization at December 31, 2012 and 2011 totaled \$48,000 and \$42,000, respectively.

*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.

*Warrants.* The Company has issued common stock warrants in connection with the execution of certain equity and debt financings. Certain warrants were accounted for as derivative liabilities at fair value. Such warrants did not meet the accounting criteria that a contract should not be considered a derivative instrument if it is (1) indexed to its own stock and (2) classified in stockholders' equity. Changes in fair value of derivative liabilities are recorded in the consolidated statement of operations under the caption "Change in fair value of warrant liabilities." Warrants that are not considered derivative liabilities are accounted for at fair value at the date of issuance in additional paid-in capital. The fair value of warrants was determined using the Black-Scholes option-pricing model. There were no warrant liabilities as of December 31, 2012 or 2011.

*Revenue Recognition.* The Company records revenue provided that there is persuasive evidence that an arrangement exists, the price is fixed and determinable, services were rendered and collectability is reasonably assured.

*Research and Development Expenses.* Costs associated with research and development are expensed as incurred. 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 the accounting rules that 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 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.

*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.

*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

---

**Table of Contents**

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.* Stock-based compensation cost is measured at the grant date based on the fair value of the award and is recognized as expense over the service period, which generally represents the vesting period. For awards that have performance based vesting conditions the Company recognizes the expense over the estimated period that the awards are expected to be earned. The Company generally uses the Black-Scholes option-pricing model to calculate the grant date fair value of stock options. For options that only vest upon the achievement of market conditions, the Company values the options using a Monte Carlo model to calculate the grant date fair value of the stock options. The expense related to options that vest based on market conditions is not reversed should those options not ultimately vest. The expense recognized over the service period is required to include an estimate of the awards that will be forfeited.

**3. Agreement with PROCAPS S.A. and Research Grants**

*Agreement with PROCAPS S.A.*

On March 25, 2010, the Company granted PROCAPS S.A. ( PROCAPS ) (in the form of a definitive term sheet) exclusive rights to market and sell GM-CT-01 (formerly DAVANAT®) to treat cancer in Colombia, South America. PROCAPS is an international, privately held pharmaceutical company based in Barranquilla, Colombia. In October 2010, the Company received a payment of \$200,000 and shipped GM-CT-01 to PROCAPS to be used by PROCAPS to qualify its vial filling process and to replicate the Company's stability study. The \$200,000 payment from PROCAPS was included as deferred income on the condensed consolidated balance sheets as of December 31, 2011.

On October 18, 2011, the Company entered into a Collaboration, Supply, Marketing and Distribution Agreement (the Agreement ) with PROCAPS. The Agreement granted PROCAPS first negotiation rights to enter into similar agreements in other Central and South American countries. The Company was to be the sole manufacturer and supplier of GM-CT-01 to PROCAPS. The Agreement obligated PROCAPS to procure regulatory approvals necessary for the marketing and sale of GM-CT-01 naming the Company as the owner of such approvals to the extent permitted by law, or alternatively hold the approvals for the Company's benefit. PROCAPS was to pay the Company a stated fee for each dose it purchased and royalties at an incremental rate determined by annual net sales of GM-CT-01. The Company retains all intellectual property rights to GM-CT-01 and related products and PROCAPS may not produce, modify, reverse engineer, or otherwise interfere with the GM-CT-01 compound. PROCAPS was not able to manufacture or sell products that compete with GM-CT-01 during the term of the Agreement and for five years thereafter.

PROCAPS had not obtained approval to sell GM-CT-01 in Columbia as required by the Agreement and, as they were in material breach of the Agreement, the Company terminated the Agreement, effective September 29, 2012. With no further obligations, the Company recognized the \$200,000 payment as Other Income in the Statements of Operations during the year ended December 31, 2012.

*Qualifying Therapeutic Discovery Project*

In October 2010, the Company was notified that it was awarded \$489,000 total in two federal grants under the Qualifying Therapeutic Discovery Project ( QTDP ) Program for its GM-CT-01 anti-cancer compound and for its GR/GM-Series of anti-fibrotic, cirrhosis compounds for work performed during 2010 and 2009. The Company recognized this grant in other income in the statement of operations for the year ended December 31, 2010. The Company received \$255,000 of the grant in 2010 and the remaining \$234,000 was received in 2011.

**Table of Contents****4. Property and Equipment**

Property and equipment consists of the following at December 31:

	2012	2011
	(in thousands)	
Leasehold improvements	\$ 2	\$ 15
Computer and office equipment	13	199
Furniture and fixtures	59	107
Total	74	321
Less accumulated depreciation	(66)	(315)
Property and equipment net	\$ 8	\$ 6

Depreciation expense for the years ended December 31, 2012 and 2011 was \$3,000 and \$6,000, respectively.

**5. Accrued Expenses**

Accrued expenses consist of the following at December 31:

	2012	2011
	(in thousands)	
Legal and accounting fees	\$ 109	\$ 69
Accrued compensation	42	385
Severance agreement (Note 11)	1,000	1,000
Other	10	97
Total	\$ 1,161	\$ 1,551

**6. Stockholders Deficit**

At December 31, 2012, the Company had 50,000,000 shares of common stock and 20,000,000 undesignated shares authorized. As of December 31, 2012, 5,000,000 shares have been designated for Series A 12% Convertible Preferred Stock, 900,000 shares have been designated for Series B-1 Convertible Preferred Stock, 2,100,000 shares have been designated for Series B-2 Convertible Preferred Stock, 1,000 shares have been designated for Series C Super Dividend Convertible Preferred Stock and 11,999,000 remain undesignated.

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

**2001 Private Placement**

During 2001, the Company sold a total of 114,884 shares of common stock for proceeds of \$2,221,000, net of \$17,000 of issuance costs through a private placement of securities. In connection with this issuance, the Company issued 56,534 and 58,350 warrants to purchase common stock at \$39.00 and \$30.00 per share, respectively. The Company valued the warrants at \$886,000, based on a fair market value of the Company's common stock of \$13.68 per share. These warrants expired unexercised in 2005.

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 \$1,126,000 of the outstanding





## **Table of Contents**

principal and accrued interest chose to convert at a conversion price of \$12.00 per share and received 99,705 common shares and 93,801 warrants. These warrants have an exercise price of \$39.00 per share and were immediately exercisable. The Company valued the warrants at \$503,000 based on a fair market value of the Company's common stock of \$13.68 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 18,334 warrants to the agents in connection with the 2001 offering. The warrants were exercisable immediately at an exercise price of \$21.00 per share and have a 10 year life. The Company valued these warrants at \$236,000 based on a deemed fair value of the Company's common stock of \$21.00 per share and recorded such value as interest expense in the statement of operations for the year ended December 31, 2002. These warrants expired unexercised in 2012.

### ***Public Offering***

On December 13, 2001, the Company commenced a public offering of common stock, at a price to the public of \$21.00 per share. The Company concluded the offering on June 30, 2002. During 2002, the Company sold 31,000 shares of common stock in this offering for proceeds of \$602,000, net of \$49,000 of issuance costs.

### ***2002 Private Placement***

In September 2002, the Company began a private placement (the 2002 Private Placement) of up to 1,666,667 shares of common stock at \$6.00 per share. As of December 31, 2002, the Company had sold 537,227 shares for proceeds of \$2,861,000, net of issuance costs of \$212,000 and stock subscription receivable of \$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 181,334 shares for additional proceeds of \$1,070,000, net of \$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 28,917 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 125 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 417 shares, and the finder and its other agent an aggregate of 1,625 additional shares and \$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 \$6.00 per share, consistent with the price paid for the shares placed in the offering. Such offering costs were netted against the proceeds of the 2002 Private Placement. Since none of the 29,042 shares had been issued as of December 31, 2002, the Company recorded the obligation to issue such shares as offering costs payable. The additional 2,042 shares issued in January 2003 were also valued at \$6.00 per share and included in the \$18,000 offering costs recorded at the closing. These shares were subsequently issued in 2003.

During 2002, the Company also agreed to issue 350 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 \$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 1,167 shares in connection with shares sold subsequent to

## **Table of Contents**

December 31, 2002 and through the closing date. The Company recorded an additional obligation of \$27,000 to general and administrative expenses in 2003 representing the fair value of the additional 1,167 shares.

### ***2002 Related Party Transaction***

The Company agreed to issue 4,226 shares of common stock as payment for 2002 scientific advisory services. These shares were issued in 2003.

### ***May 2003 Private Placement***

In May 2003, the Company began a private placement of up to 416,667 shares of common stock at \$12.00 per share. As of the closing on July 15, 2003, the Company had sold 399,917 shares of common stock for proceeds of \$4,671,000, net of issuance costs of \$128,000. In connection with this offering the Company issued 18,269 common stock warrants (exercisable at \$32.40 per share) to its placement agents. The Company valued the warrants at \$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 219,096 of the 238,096 offered shares of common stock at \$21.00 per share for proceeds of \$4,041,000, net of issuance costs of \$559,000. In connection with this offering, the Company issued 109,549 warrants with an initial exercise price of \$31.74 per share to the investors and 10,955 warrants with an initial exercise price of \$41.16 per share to its placement agent. The exercise price of the warrants was subject to adjustment pursuant to anti-dilution and other provisions. The investor warrants and placement agent Warrants were valued at \$2,531,000 and \$191,000, respectively, using the relative fair value, and allocated to additional paid-in-capital. The Company used the Black-Scholes pricing model to value these warrants. The warrants were originally accounted for as freestanding derivative instruments. The investor warrants expired unexercised in 2008 and the placement agent warrants expired unexercised in 2007.

### ***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 206,019 shares of common stock at \$21.60 per share for proceeds of \$3,983,000, net of cash issuance costs of \$466,000. In connection with this offering, the Company issued 103,010 warrants to investors and 10,301 warrants to a placement agent with an initial exercise price of \$31.80 per share. The exercise price of the warrants was subject to adjustment pursuant to anti-dilution and other provisions. The investor warrants and the placement agent warrants were valued at \$1,931,000 and \$154,000, respectively, using the relative fair value, and allocated to additional paid-in-capital. The Company used the Black-Scholes pricing model to value these warrants. The warrants were originally accounted for as freestanding derivative instruments. The investor warrants expired unexercised in 2009 and the placement agent warrants expired unexercised in 2007.

### ***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 333,334 shares of common stock at \$18.00 per share for proceeds of \$5,515,000, net of cash issuance costs of \$485,000. In connection with this offering the Company issued

---

**Table of Contents**

333,334 warrants to the investors and 16,667 warrants to the placement agent with an exercise price of \$4.20 per share. The exercise price of the warrants was subject to adjustment solely as a result of stock splits, recapitalizations and similar events. The investor warrants and placement agent warrants were valued at \$4,786,000 and \$239,000, respectively, and allocated to additional paid-in-capital. The Company used the Black-Scholes pricing model to value these warrants. The warrants were originally accounted for as freestanding derivative instruments. These warrants expired unexercised in 2009.

***February 25, 2008 Offering***

On February 25, 2008, the Company closed an offering in which it sold to investors (i) an aggregate of 1,250,000 shares of the Company's common stock at \$3.00 per share, (ii) warrants, which expire on August 25, 2013, to purchase an aggregate of 1,250,000 share of the Company's common stock at an exercise price of \$3.50 per share, and (iii) warrants, which expired on December 26, 2008, to purchase an aggregate of 500,000 shares of the Company's common stock at an exercise price of \$3.78 per share. In addition, the Company issued to a placement agent warrants, which expire on August 25, 2013, to purchase 34,375 shares of the Company's common stock at an exercise price of \$4.20 per share. 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.

The Company received proceeds of \$3,381,000, net of cash transaction costs of \$369,000. In addition the Company incurred \$56,000 of costs for warrants issued to a placement agent. Proceeds of \$1,044,000 were allocated to common stock and \$2,281,000 were allocated to investor warrants using the Black-Scholes method with a fair market value of the Company's common stock of \$2.40 and the following assumptions as of February 25, 2008: for the 5 year warrants exercisable at \$4.20 per share, a risk-free interest rate of 2.94% and volatility of 95% and for the 4 month warrants exercisable at \$3.78 per share, a risk-free interest rate of 2.13% and volatility of 95%. The warrants were determined to have the characteristics of derivative liabilities and were originally accounted for as liabilities prior to the Company increasing the authorized number of shares. Changes in fair value were recognized as either a gain or loss in the consolidated statement of operations. In the second quarter of 2008 the warrants were reclassified 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 \$356,000. The remaining fair value of \$2,160,000 was credited to additional paid-in capital in the balance sheet. On December 26, 2008 the 500,000 warrants exercisable at \$3.78 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.

***Cork Investments***

On July 2, 2008, the Company issued 50,000 warrants to Cork Investments in exchange for \$20,000. The warrants were exercisable for common stock at \$6.00 per share for a period of three years and expired unexercised in 2011. The \$20,000 was credited to additional paid in capital.

***2012 Offering of Units***

On March 22, 2012, the Company entered into an underwriting agreement, relating to the offer and sale of 1,159,445 units (the Units) of the Company, each unit consisted of two shares of Common Stock and one warrant to purchase one share of Common Stock. Pursuant to the underwriting agreement, the Company granted the underwriters a 45-day option to purchase up to an additional 173,916 Units to cover over-allotments, which they exercised on March 26, 2012. The public offering price for each Unit was \$9.00. Each warrant has an initial exercise price of \$5.63 per share, is exercisable upon separation of the Units and expires on March 28, 2017.

**Table of Contents**

On March 28, 2012, the Company sold and issued 1,333,361 Units (2,666,722 shares of common stock and related \$5.63 warrants to purchase 1,333,361 shares of common stock) for gross proceeds of \$12.0 million (net cash proceeds of \$10,403,000 after the underwriting discount and offering costs). The warrants were valued at \$4,445,000 as of the issuance date of March 28, 2012, using the closing price of \$4.20, a life of 5 years, a volatility of 119% and a risk free interest rate of 1.05%. Based upon the Company's analysis of the criteria contained in ASC Topic 815-40, Derivatives and Hedging - Contracts in Entity's Own Equity the Company has determined that warrants issued in connection with this financing transaction were not derivative liabilities and therefore, were recorded as additional paid-in capital.

On March 28, 2012, in connection with this underwritten financing as per the underwriting agreement, the Company issued a total of 46,378 common stock purchase warrants to the underwriters. These warrants expire May 2, 2016, have an exercise price of \$5.63 per share, and are exercisable beginning one year from March 22, 2012 (the date of the underwriting agreement). These warrants were valued at \$143,000 as of the date of issuance (March 28, 2012), using the closing price of \$4.20, life of 4.1 years, volatility of 117% and risk free interest rate of 0.78%. Based upon the Company's analysis of the criteria contained in ASC Topic 815-40, Derivatives and Hedging - Contracts in Entity's Own Equity, the Company has determined that these warrants issued in connection with this financing transaction were not derivative liabilities and therefore, were recorded as additional paid-in capital.

Effective as of March 23, 2012, and in connection with the pricing of the offering of Units, the Company effected a one-for-six reverse split of its Common Stock. Per the terms of the reverse split, all fractional shares were rounded up. Based on the effective split date of March 23, 2012, the Company issued 3,324 shares of common stock to cover fractional shares.

***Series A 12% Convertible 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) and related warrants. In this transaction, the Company sold units of securities at \$6.00 per unit, each unit comprised of (i) one share of Series A Preferred, (ii) a warrant to purchase one share of common stock for \$9.00, and (iii) a warrant to purchase one share of common stock for \$12.00. Each share of the Series A 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 \$6.00 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 shares of Series A are entitled to vote as a class with the Company's common stock and each share of Series A is convertible at any time to one-sixth of a 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 \$18.00 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 is then in effect. Each warrant is exercisable solely for cash beginning August 3, 2008 and expired 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 \$1,667,500 for Series A. In 2008, the Company received additional subscription advances of \$75,000 resulting in total gross proceeds of \$1,742,500. On February 4, 2008 the Company closed the private placement. The Company incurred \$52,000 of cash transaction costs resulting in net cash proceeds of \$1,691,000. In addition, the Company incurred \$3,000 of costs for 1,400 warrants exercisable at \$9.00 issued to placement agents. Proceeds of \$984,000 were allocated to investor warrants using the Black-Scholes method with the following

**Table of Contents**

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 \$3.54. The warrants were originally 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 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. 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 \$100,000. The remaining fair value of \$502,000 was credited to additional paid-in capital in the balance sheet.

***Series B Redeemable Convertible Preferred Stock***

On February 12, 2009, the Company entered into a securities purchase agreement (the "10X Agreement") pursuant to which it agreed to issue and sell to 10X Fund LP, at two or more closings, up to: (i) 3,000,000 shares its Series B convertible preferred stock ("Series B redeemable convertible preferred stock" or "Series B") with an aggregate stated value of \$6.0 million and convertible into 2,000,000 shares of common stock at December 31, 2011 and (ii) warrants to purchase 6,000,000 shares of common stock.

Through a series of closings from February 2009 through May 2010, the Company issued and sold, pursuant to the 10X Agreement, a total of (i) 900,000 shares of Series B-1 convertible preferred stock ("Series B-1 redeemable convertible preferred stock" or "Series B-1") and related common stock warrants for 1,800,000 shares of common stock and (ii) 2,100,000 shares of Series B-2 convertible preferred stock ("Series B-2 redeemable convertible preferred stock" or "Series B-2") and related warrants for 4,200,000 shares of common stock. During 2010, the Company received total net cash proceeds of \$1,463,000 from the issuance of 770,000 shares of Series B-2 and related warrants. During 2009, the Company received total net cash proceeds of \$1,548,000 from the issuance of 900,000 shares of Series B-1 and related warrants and \$2,472,000 from the issuance of 1,330,000 shares of Series B-2 and related warrants.

The Series B closings were as follows:

On February 12, 2009, the Company issued and sold, pursuant to the 10X Agreement: (i) 900,000 shares of Series B-1 convertible preferred stock ("Series B-1 redeemable convertible preferred stock" or "Series B-1") convertible into 600,000 shares of common stock; (ii) Class A-1 warrants exercisable to purchase 300,000 shares of common stock; (iii) Class A-2 warrants exercisable to purchase 300,000 shares of common stock; and (iv) Class B warrants exercisable to purchase 1,200,000 shares of common stock. Net proceeds from the closing were \$1,548,000.

On May 13, 2009, the Company issued and sold, pursuant to the 10X Agreement: (i) 450,000 shares of Series B-2 convertible preferred stock ("Series B-2 redeemable convertible preferred stock" or "Series B-2") convertible into 300,000 shares of common stock; (ii) Class A-1 warrants exercisable to purchase 150,000 shares of common stock; (iii) Class A-2 warrants exercisable to purchase 150,000 shares of common stock; and (iv) Class B warrants exercisable to purchase 600,000 shares of common stock. Net proceeds from the closing were \$801,000.

On June 30, 2009, the Company issued and sold, pursuant to the 10X Agreement: (i) 250,000 shares of Series B-2 convertible into 166,666 shares of common stock; (ii) Class A-1 warrants exercisable to purchase 83,333 shares of common stock; (iii) Class A-2 warrants exercisable to purchase 83,333 shares of common stock; and (iv) Class B warrants exercisable to purchase 333,333 shares of common stock. Net proceeds from the closing were \$473,000.

## **Table of Contents**

On August 12, 2009, the Company issued and sold, pursuant to the 10X Agreement: (i) 150,000 shares of Series B-2 convertible into 100,000 shares of common stock; (ii) Class A-1 warrants exercisable to purchase 50,000 shares of common stock; (iii) Class A-2 warrants exercisable to purchase 50,000 shares of common stock; and (iv) Class B warrants exercisable to purchase 200,000 shares of common stock. Net proceeds from the closing were \$287,000.

On September 30, 2009, the Company issued and sold, pursuant to the 10X Agreement: (i) 162,500 shares of Series B-2 convertible into 108,333 shares of common stock; (ii) Class A-1 warrants exercisable to purchase 54,166 shares of common stock; (iii) Class A-2 warrants exercisable to purchase 54,166 shares of common stock; and (iv) Class B warrants exercisable to purchase 216,666 shares of common stock. Net proceeds from the closing were \$305,000.

On November 4, 2009, the Company issued and sold, pursuant to the 10X Agreement: (i) 155,000 shares of Series B-2 convertible into 103,333 shares of common stock; (ii) Class A-1 warrants exercisable to purchase 51,666 shares of common stock; (iii) Class A-2 warrants exercisable to purchase 51,666 shares of common stock; and (iv) Class B warrants exercisable to purchase 206,666 shares of common stock. Net proceeds from the closing were \$296,000.

On December 8, 2009, the Company issued and sold, pursuant to the 10X Agreement: (i) 162,500 shares of Series B-2 convertible into 108,333 shares of common stock; (ii) Class A-1 warrants exercisable to purchase 54,167 shares of common stock; (iii) Class A-2 warrants exercisable to purchase 54,167 shares of common stock; and (iv) Class B warrants exercisable to purchase 216,667 shares of common stock. Net proceeds from the closing were \$310,000.

On January 29, 2010, the Company issued and sold, pursuant to the 10X Agreement: (i) 162,500 shares of Series B-2 convertible into 108,334 shares of common stock; (ii) Class A-1 warrants exercisable to purchase 54,167 shares of common stock; (iii) Class A-2 warrants exercisable to purchase 54,167 shares of common stock; and (iv) Class B warrants exercisable to purchase 216,667 shares of common stock. Net proceeds from the closing were \$308,000.

On March 8, 2010, the Company issued and sold, pursuant to the 10X Agreement: (i) 167,500 shares of Series B-2 convertible into 111,667 shares of common stock; (ii) Class A-1 warrants exercisable to purchase 55,834 shares of common stock; (iii) Class A-2 warrants exercisable to purchase 55,834 shares of common stock; and (iv) Class B warrants exercisable to purchase 223,334 shares of common stock. Net proceeds from the closing were \$322,000.

On April 30, 2010, the Company issued and sold, pursuant to the 10X Agreement: (i) 155,000 shares of Series B-2 convertible into 103,334 shares of common stock; (ii) Class A-1 warrants exercisable to purchase 51,667 shares of common stock; (iii) Class A-2 warrants exercisable to purchase 51,667 shares of common stock; and (iv) Class B warrants exercisable to purchase 206,667 shares of common stock. Net proceeds from the closing were \$297,000.

On May 10, 2010, the Company issued and sold, pursuant to the 10X Agreement: (i) 285,000 shares of Series B-2 convertible into 190,000 shares of common stock; (ii) Class A-1 warrants exercisable to purchase 95,000 shares of common stock; (iii) Class A-2 warrants exercisable to purchase 95,000 shares of common stock; and (iv) Class B warrants exercisable to purchase 380,000 shares of common stock. Net proceeds from the closing were \$536,000.

The terms of the Series B are as follows:

*Dividends.* Holders of the Series B 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

---

**Table of Contents**

cash or common stock. Pursuant to an agreement with the holder of all shares of Series B, on January 26, 2011, the Company amended and restated the Certificate of Designation of Preferences, Rights and Limitations for the Series B-1 and Series B-2, to provide that dividends are payable in cash or shares of Common Stock valued at 100% of the volume weighted average price of the Common Stock for the 20 consecutive trading days prior to the dividend payment date on and after September 30, 2011. If the Company does not pay any dividend on the Series B, dividends will accrue at the rate of 15% per annum (compounding monthly).

*Conversion Rights.* Each share of Series B is convertible into four-sixths (approximately 0.667) shares of common stock at the conversion price of \$3.00 per share 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 \$9.00 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). Pursuant to an agreement with the holder of all shares of Series B, on January 26, 2011, the Company amended and restated the Certificate of Designation of Preferences, Rights and Limitations for the Series B-1 and Series B-2, to remove the Company's right to compel conversion of the Series B Preferred Stock to shares of its Common Stock.

*Redemption Rights.* Pursuant to an agreement with the holder of all shares of Series B, on January 26, 2011, the Company amended and restated the Certificate of Designation of Preferences, Rights and Limitations for the Series B-1 and Series B-2, to provide that, upon notice of not less than 30 trading days, a holder of Series B may require the Company to redeem, in whole or in part at any time on or after the earlier of (a) February 12, 2019 or (b) the date of issuance of a promissory note to David Platt (see Note 11) in connection with the achievement of certain milestones under his separation agreement.

The redemption price will be equal to the sum of the stated value of the Series B, plus all accrued but unpaid dividends thereon, as of the redemption date. If the Company fails to pay the redemption price in cash on the redemption date, then the holders of the Series B requesting redemption may, at their sole option, automatically convert their shares of Series B 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 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.

*Voting Rights.* Except as noted below, the holder of each share of Series B shall be entitled to the number of votes equal to the number of shares of Common Stock into which such share of Series B would be convertible, and shall otherwise have voting rights and powers equal to the voting rights and powers of the Common Stock. With respect to the election of directors, the holders of the Series B shall vote together as a separate class to elect two (2) members of the Board of Directors (the "Series B Directors"), and the Company shall take all reasonably necessary or desirable actions within its control (including, without limitation, calling special meetings of the Board of Directors, nominating such persons designated by the holders of the Series B as directors on the applicable proxy statements and recommending their election) to permit the holders of the Series B to appoint two additional (2) members of the Board of Directors (the "Series B Nominees"), who shall be subject to election by all shares of voting stock of the Company voting together as a single group, until such time as all authorized shares of Series B have been issued and sold, after which the number of Series B Nominees shall be three (3), and shall remain three (3) until there are no longer any shares of Series B outstanding. The holders of Series B shall vote together with the holders of Common Stock and other voting capital stock of the Company to elect all other members of the Board of Directors.

---

**Table of Contents**

*Other Restrictions.* So long as any shares of the Series B remain outstanding, the Company may not, without the approval of the holders of a majority of the shares of Series B outstanding, among other things, (i) change the size of the Company's Board of Directors; (ii) amend or repeal the Company's Articles of Incorporation or Bylaws or file any articles of amendment designating the preferences, limitations and relative rights of any series of preferred stock; (iii) create or increase the authorized amount of any additional class or series of shares of stock that is equal to or senior to Series B; (iv) increase or decrease the authorized number of shares of the Series B; (v) purchase, redeem or otherwise acquire for value any shares of any class of capital stock; (vi) merge or consolidate the Company into or with any other corporation or sell, assign, lease, pledge, encumber or otherwise dispose of all or substantially all of the Company's assets or those of any subsidiary; (vii) voluntarily or involuntarily liquidate, dissolve or wind up the Company or the Company's business; (viii) pay or declare dividends on any capital stock other than the Preferred Stock, unless the Series B share ratably in such dividend and all accrued dividends payable with respect to the Series B have been paid prior to the payment or declaration of such dividend; (ix) acquire an equitable interest in, or the assets or business of any other entity in any form of transaction; (x) create or commit us to enter into a joint venture, licensing agreement or exclusive marketing or other distribution agreement with respect to the Company's products, other than in the ordinary course of business; (xi) permit the Company or any subsidiary to sell or issue any security of such subsidiary to any person or entity other than the Company; (xii) enter into, create, incur, assume or guarantee any indebtedness for borrowed money of any kind (other than indebtedness existing on the initial closing date and approved by Series B shareholders); (xiii) enter into, create, incur or assume any liens of any kind (other than certain permitted liens); (xiv) issue any common stock equivalents; (xv) increase the number of shares of the Company's common stock that may be issued pursuant to options, warrants or rights to employees, directors, officers, consultants or advisors above 250,000.

*Warrants.* Each Class A-1 warrant, Class A-2 warrant and Class B warrant is exercisable at \$3.00 per share of common stock 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 \$7.50 per share 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 \$10.50 per share.

The fair value of the warrants issued in connection with the Series B-1 was \$1,296,000 at the date of issuance based on the following assumptions: an expected life of 5 years, volatility of 118%, risk free interest rate of 1.79% and zero dividends. The Company allocated the gross proceeds based on the relative fair value of the Series B-1 and the related warrants, resulting in \$1,105,000 of the proceeds being allocated to additional paid-in capital. The Company analyzed the Series B-1, post-allocation of the gross proceeds, and determined that there was no beneficial conversion feature at the date of issuance. The issuance costs of the Series B-1 and the amounts allocated to warrants were recorded as a reduction to the carrying value of the Series B-1 when issued, and are accreted to the redemption value of the Series B-1 through the earliest redemption date. Due to the redemption feature, the Company has presented the Series B-1 outside of permanent equity, in the mezzanine of the consolidated balance sheet at December 31, 2012 and 2011.

The fair value of the warrants issued during the year ended December 31, 2010 in connection with the Series B-2 was \$4,148,000 at the dates of issuance based on the following assumptions: an expected life of 5 years, volatility of 126% to 129%, risk free interest rates of 2.27% to 2.43% and zero dividends. The fair value of the warrants issued during the year ended December 31, 2009 in connection with the Series B-2 was \$5,333,000 at the dates of issuance based on the following assumptions: an expected life of 5 years, volatility of 124% to 127%, risk free interest rates of 1.98% to 2.70% and zero dividends. The Company allocated the gross proceeds based on the relative fair value of the Series B-2 and the related warrants, resulting in \$1,028,000 and \$1,732,000 of the proceeds being allocated to additional paid-in capital for the



**Table of Contents**

years ended December 31, 2010 and 2009, respectively. The issuance costs of the Series B-2 and the amounts allocated to warrants were recorded as a reduction to the carrying value of the Series B-2 when issued, and are accreted to the redemption value of the Series B-2 through the earliest redemption dates. Due to the redemption feature, the Company has presented the Series B-2 outside of permanent equity, in the mezzanine of the consolidated balance sheet at December 31, 2012 and 2011.

The Company analyzed the Series B-2, post-allocation of the gross proceeds, and determined that there was a beneficial conversion feature at the dates of issuance. Because the closing price of the common stock on the closing date was greater than the effective conversion price, \$388,000 and \$628,000 of the proceeds (limited to the allocation of the proceeds) during the years ended December 31, 2010 and 2009, respectively, were allocated to an embedded beneficial conversion feature of the Series B-2. The amount allocated to the beneficial conversion feature was recorded as a discount to the Series B-2 is being accreted, with such accretion being charged through the earliest redemption dates.

***Series C 6% Super Dividend Convertible Preferred Stock***

On December 29, 2010, the Company designated and authorized the sale and issuance of up to 1,000 shares of Series C Super Dividend Convertible Preferred Stock ( Series C ) with a par value of \$0.01 and a stated value equal to \$10,000 (the Stated Value ).

On December 30, 2010, the Company sold and issued 212 shares of Series C at a price of \$10,000 per share for gross proceeds of \$2,120,000. The Company incurred \$47,000 of cash transaction costs resulting in net cash proceeds of \$2,073,000. In addition, the Company issued 500 warrants exercisable at \$7.20 to a placement agent which had a de minimis value.

The terms of the Series C are as follows:

*Conversion Rights.* Each holder of Series C may convert all, but not less than all, of his Series C shares plus accrued and unpaid dividends into Common Stock at the price of \$6.00 per share of Common Stock ( Conversion Price ), such that approximately 1,667 shares of Common Stock will be issued per each converted share of Series C (accrued and unpaid dividends will be issued as additional shares). At December 31, 2011, the 220 shares of Series C were convertible into a total of 366,676 shares of Common Stock.

Subject to the continuing obligation to pay post conversion dividends, the Company may convert all, but not less than all, of the Series C (plus all accrued and unpaid dividends) into Common Stock, at the Conversion Price, upon such time that the closing price of the Common Stock is no less than \$18.00 per share for 15 consecutive trading days.

*Dividends.* Holders of Series C shall be entitled to receive cumulative non-compounding dividends at the rate per share of Series C equal to the greater of (i) 6% per annum of the Stated Value (also defined as the Floor ) or (ii) 2.5% of net sales until the total dividends paid is equal to the initial investment and 1.25% of net sales thereafter. The maximum amount each Series C shareholder will receive in dividend payments is equal to \$100,000 (the Maximum Payout ). For purposes of this dividend calculation, net sales shall mean gross revenues actually received by the Company, from the sale or licensing of the product DAVANAT® (GM-CT-01), less chargebacks, returns, expenses attributable to product recalls, duties, customs, sales tax, freight, insurance, shipping expenses, allowances and other customary deductions.

The dividend shall be payable in arrears semi annually on March 31 and September 30, beginning with the first such date after the original issue date; provided, however, that all dividends and all other distributions shall cease, and no further dividends or other distributions shall be paid, in respect of each share of Series C from and after such time that the Maximum Payout has been paid in respect of such share of Series C. Such

**Table of Contents**

dividends shall be payable at the Company's option either in cash or in duly authorized, fully paid and non-assessable shares of Common Stock valued at the higher of (i) \$3.00 per share or (ii) the average of the Common Stock trading price for the ten (10) consecutive trading days ending on the trading day that is immediately prior to the dividend payment date.

*Series C Post Conversion Dividend Right.* In the event that any share of Series C is converted into Common Stock before the Maximum Payout is paid in respect of such converted share of Series C, then the holder shall have the right to continue to receive dividends in respect of such converted share of Series C equal to the remaining payout (the Series C Preferred Stock Post Conversion Dividend Right) which shall be equal to the Maximum Payout less the cumulative dividends received through the conversion date. One share of Series C Preferred Stock Post Conversion Dividend Right shall be issued for each such converted share of Series C. The holder of each Series C Preferred Stock Post Conversion Dividend Right shall receive the remaining payout on an equal basis and in conjunction with the then outstanding shares of Series C and all the other then outstanding Series C Post Conversion Dividend Rights, in the same manner and subject to the same terms and conditions as applicable to the payment of dividends on each share of Series C, except that for purposes of calculating the dividend the Floor shall not apply. The Series C Preferred Stock Post Conversion Dividend Right shall have no stated value, liquidation preference or right to any dividends or distributions other than the remaining payout. The Series C Preferred Stock Post Conversion Right is subject to redemption in the same manner as outstanding Series C shares.

At the date of issuance, the Series C have an embedded dividend right to continue to receive dividend payments after conversion to common stock (the Series C Post Conversion Dividend Right) which requires bifurcation. The value of this post conversion dividend right on the date of issuance was determined to be de minimis due to the fact that the payment of a dividend stream other than the 6% dividend and conversion of Series C prior to the Company achieving sales of GM-CT-01 was deemed improbable at that time. Upon a conversion of the Series C, the Company will be required to record a liability and the related expense during the period of conversion.

In July 2011, 5 shares of Series C were converted into 8,334 shares of common stock and 5 Series C Post Conversion Dividend Rights (Dividend Rights) were issued. In January 2013, 5 shares of Series C were converted into 8,334 shares of common stock and 5 Dividend Rights were issued. Per the terms of the Series C, these Dividend Rights shall continue to participate in dividends, however the Floor shall not apply. At December 31, 2012, these Dividend Rights were determined to have a de minimis value, as the payment of a dividend is considered improbable at this time. The Company will continue to evaluate and assess the Series C Post Conversion Dividend Right for each reporting period.

*Liquidation Rights.* In the event of any liquidation, dissolution or winding up of the Company, either voluntarily or involuntarily, the holders of Series C will receive \$10,000 per share plus accrued and unpaid dividends, payable prior and in preference to any distributions to the holders of Common Stock but after and subordinate to the Series A 12% Convertible Preferred Stock (Series A), Series B-1 and Series B-2, subject to the Maximum Payout.

**Table of Contents**

**Redemption.** Upon a sale of the Company, the Company shall redeem all of the then outstanding shares of Series C and Series C Preferred Stock Post Conversion Rights within thirty (30) days after the transaction constituting the sale of the Company is closed and such closing is fully funded. The price to redeem a share of Series C and each redeemed Series C Preferred Stock Post Conversion Redemption Right shall be equal to (i) (A) the applicable return on investment ( ROI ) percentage, multiplied by (B) \$10,000, minus (ii) the cumulative dividends received through the redemption date. The redemption price shall be payable at the Company's option either in cash or in shares of common stock valued at the higher of (i) \$3.00 per share or (ii) the average market price for the ten consecutive trading days ending immediately prior to the date of redemption. The ROI Percentage shall mean the percentage that applies as of the redemption date, as follows:

**ROI Percentage**

200%	before the second anniversary of the date of issuance;
250%	on or after the second anniversary of the date of issuance, but before the third anniversary of the date of issuance;
300%	on or after the third anniversary of the date of issuance, but before the fourth anniversary of the date of issuance;
350%	on or after the fourth anniversary of the date of issuance, but before the fifth anniversary of the date of issuance;
400%	on or after the fifth anniversary of the date of issuance, but before the sixth anniversary of the date of issuance;
450%	on or after the sixth anniversary of the date of issuance, but before the seventh anniversary of the date of issuance;
500%	on or after the seventh anniversary of the date of issuance, but before the eighth anniversary of the date of issuance;
	and
550%	on or after the eighth anniversary of the date of issuance, but before the ninth anniversary of the date of issuance.

Due to the redemption feature, the Company has presented the Series C outside of permanent equity, in the mezzanine of the consolidated balance sheets at December 31, 2012 and 2011. At December 31, 2012, the Series C redemption value was \$5,204,000 and the Series C Post Conversion Dividend Right redemption value was \$123,000. At March 29, 2013, the Series C redemption value was \$5,151,000 and the Series C Post Conversion Dividend Right redemption value was \$241,000.

**Voting Rights.** The Series C shares have no voting rights.

**7. Warrants and Warrant Liabilities****Warrants**

Warrant activity is summarized as follows:

Outstanding at December 31, 2010	8,585,872
Issued	
Cancelled	(141,084)
Exercised	(1,771,383)
Outstanding at December 31, 2011	6,673,405
Issued	1,379,739
Cancelled	(616,726)
Exercised	(12,177)
Outstanding at December 31, 2012	7,424,241

**Table of Contents**

The following table summarizes information with regard to outstanding warrants issued in connection with equity and debt financings and consultants as of December 31, 2012.

Issued in Connection With	Number Issued	Exercise Price	Exercisable Date	Expiration Date
February 25, 2008 Common Stock Transaction				
\$0.70 Investor Warrants	710,834	\$ 4.20	August 25, 2008	August 25, 2013
February 12, 2009 Series B-1 Transaction				
\$0.50 Investor Warrants Class A-2	300,000	\$ 3.00	February 12, 2009	February 12, 2014
\$0.50 Investor Warrants Class B	1,200,000	\$ 3.00	February 12, 2009	February 12, 2014
May 13, 2009 Series B-2 Transaction				
\$0.50 Investor Warrants Class A-2	150,000	\$ 3.00	May 13, 2009	May 13, 2014
\$0.50 Investor Warrants Class B	600,000	\$ 3.00	May 13, 2009	May 13, 2014
June 30, 2009 Series B-2 Transaction				
\$0.50 Investor Warrants Class A-2	83,333	\$ 3.00	June 30, 2009	June 30, 2014
\$0.50 Investor Warrants Class B	333,333	\$ 3.00	June 30, 2009	June 30, 2014
April 15, 2009 Consultant Warrants	33,333	\$ 3.00	April 15, 2009	April 15, 2013
May 1, 2009 Consultant Warrants	74,000	\$ 3.00	May 1, 2009	May 1, 2014
June 30, 2009 Consultant Warrants	40,000	\$ 3.00	June 30, 2009	June 30, 2014
July 26, 2009 Consultant Warrants	16,667	\$ 3.00	July 26, 2009	July 26, 2014
August 12, 2009 Series B-2 Transaction				
\$0.50 Investor Warrants Class A-2	50,000	\$ 3.00	August 12, 2009	August 12, 2014
\$0.50 Investor Warrants Class B	200,000	\$ 3.00	August 12, 2009	August 12, 2014
September 30, 2009 Series B-2 Transaction				
\$0.50 Investor Warrants Class A-2	54,166	\$ 3.00	September 30, 2009	September 30, 2014
\$0.50 Investor Warrants Class B	216,666	\$ 3.00	September 30, 2009	September 30, 2014
November 4, 2009 Series B-2 Transaction				
\$0.50 Investor Warrants Class A-2	51,666	\$ 3.00	November 4, 2009	November 4, 2014
\$0.50 Investor Warrants Class B	206,666	\$ 3.00	November 4, 2009	November 4, 2014
December 8, 2009 Series B-2 Transaction				
\$0.50 Investor Warrants Class A-2	54,167	\$ 3.00	December 8, 2009	December 8, 2014
\$0.50 Investor Warrants Class B	216,667	\$ 3.00	December 8, 2009	December 8, 2014
January 29, 2010 Series B-2 Transaction				
\$0.50 Investor Warrants Class A-2	54,167	\$ 3.00	January 29, 2010	January 29, 2015
\$0.50 Investor Warrants Class B	216,667	\$ 3.00	January 29, 2010	January 29, 2015
March 8, 2010 Series B-2 Transaction				
\$0.50 Investor Warrants Class A-2	55,834	\$ 3.00	March 8, 2010	March 8, 2015
\$0.50 Investor Warrants Class B	223,334	\$ 3.00	March 8, 2010	March 8, 2015
April 30, 2010 Series B-2 Transaction				
\$0.50 Investor Warrants Class A-2	51,667	\$ 3.00	April 30, 2010	April 30, 2015
\$0.50 Investor Warrants Class B	206,667	\$ 3.00	April 30, 2010	April 30, 2015
May 10, 2010 Series B-2 Transaction				
\$0.50 Investor Warrants Class A-2	95,000	\$ 3.00	May 10, 2010	May 10, 2015
\$0.50 Investor Warrants Class B	380,000	\$ 3.00	May 10, 2010	May 10, 2015
May 25, 2010 Consultant Warrants	28,334	\$ 4.50	May 25, 2010	May 25, 2014
May 25, 2010 Consultant Warrants	7,500	\$ 15.00	May 25, 2010	May 25, 2014
June 15, 2010 Consultant Warrants	100,000	\$ 4.26	June 15, 2010	June 15, 2015
December 9, 2010 Consultant Warrants	33,334	\$ 3.90	December 9, 2010	December 9, 2015
December 30, 2010 Placement Agent Warrants	500	\$ 7.20	December 30, 2010	December 30, 2015
March 28, 2012 Offering Warrants	1,333,361	\$ 5.63	March 28, 2012	March 28, 2017
2012 Offering Placement Agent Warrants	46,378	\$ 5.63	March 28, 2012	May 2, 2016
<b>Total outstanding warrants</b>	<b>7,424,241</b>			



---

**Table of Contents*****Consultant Warrants***

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 6,500 warrants valued at \$3,000. The expense associated with these warrants was calculated using the Black-Scholes option-pricing model and charged to stock compensation expense. The warrants are exercisable at \$3.00 per share for a period of three years.

In April 2009, the Company entered into agreements with consultants that provided for the grant of warrants for the purchase of 55,000 shares of common stock at an exercise price of \$3.00 per share. Of the 55,000 warrants, 13,334 vested immediately and 41,666 will vest upon the achievement of certain milestones. The initial 13,334 warrants were valued at \$32,000 on issuance based on the following assumptions: an expected life of 4 years, volatility of 134%, risk free interest rate of 1.76% and zero dividends and the expense recognized upon issuance. During the year ended December 31, 2010, 8,334 warrants vested (valued at \$16,000 on the vesting date using the following assumptions: expected life of 3.06 years, volatility of 140%, risk free interest rates of 1.69% and zero dividends). In 2010, when it appeared probable that the remaining 33,332 warrants would vest, the Company valued the warrants at \$124,000 as of December 31, 2010 using the following assumptions: expected life of 2.29 years, volatility of 141%, risk free interest rates of 0.61% and zero dividends. The Company valued the warrants at \$104,000 as of December 31, 2011 using the following assumptions: expected life of 1.29 years, volatility of 70%, risk free interest rates of 0.12% and zero dividends. The Company recognized expense related to the 33,332 warrants of \$111,000 for the year ended December 31, 2010 and a reversal of expense of \$13,000 for the year ended December 31, 2011. During the year ended December 31, 2012, these warrants were no longer expected to vest and the Company recognized a reversal of previously recognized expense related to these warrants of \$100,000 for the year ended December 31, 2012.

In May 2009, the Company entered into agreements with consultants that provided for the grant of warrants to purchase 95,834 shares of common stock at an exercise price of \$3.00 per share of which 74,000 vested and 21,834 were forfeited. The warrants were valued at \$232,000 on issuance based on the following assumptions: an expected life of 5 years, volatility of 124%, risk free interest rate of 2.16% and zero dividends. The Company recognized expense related to these warrants of \$53,000 during the year ended December 31, 2010. As of December 31, 2010, 74,000 of these warrants were vested and 21,834 shares were forfeited.

In May 2010, the Company granted warrants to consultants for the purchase of 35,001 shares of common stock at an exercise price of \$4.50 per share. The warrants were valued at \$134,000 on issuance based on the following assumptions: an expected life of 4 years, volatility of 143%, risk free interest rate of 1.610% and zero dividends. The warrants vested immediately and the company recognized an expense of \$134,000 related to these warrants during the year ended December 31, 2010.

In May 2010, the Company entered into an agreement with a consultant that provided for the grant of warrants for the purchase of 12,000 shares of common stock at an exercise price of \$15.00 per share. The warrants were initially valued at \$40,000 on issuance based on the following assumptions: an expected life of 4 years, volatility of 143%, risk free interest rate of 1.610% and zero dividends. The warrants vest at a rate of 500 per month and the unvested warrants will be revalued as they vest. At December 31, 2011, 7,500 warrants were vested and 4,500 were forfeited upon cancellation of the agreement. The following assumptions were used to value the warrants for the year ended December 31, 2011: an expected life of 2.99 to 3.32 years, volatility of 128% to 130%, risk free interest rate of 0.79% to 1.29% and zero dividends. The following assumptions were used to value the warrants for the year ended December 31, 2010: an expected life of 3.40 to 3.99 years, volatility of 130% to 144%, risk free interest rate of 0.51% to 1.68% and zero dividends. The company recognized an expense of \$12,000 and \$15,000 related to these warrants during the years ended December 31, 2011 and 2010, respectively.

**Table of Contents**

In August 2010, the Company entered into an agreement with a consultant, who was also a board member, which provided for the grant of warrants for 100,000 shares of common stock at an exercise price of \$4.26 per share. Of the 100,000 warrants, 25,000 vested immediately on signing of the agreement, 25,000 were to vest at the end of one year and the remaining 50,000 warrants were to vest based on the achievement of certain milestones. The following assumptions were used to value the remaining unvested warrants on March 7, 2011 at the date the consultant effectively became an employee of the Company: an expected life of 4.28 years, volatility of 135%, risk free interest rate of 1.705% and zero dividends. Pursuant to an employment agreement entered into in May 2011, all remaining unvested warrants were immediately vested. The Company recognized expense of \$340,000 and \$219,000 related to these warrants during the years ended December 31, 2011 and 2010, respectively.

In December 2010, the Company granted warrants to a consultant for the purchase of 33,334 shares of common stock at an exercise price of \$3.90 per share. The warrants were valued at \$112,000 on issuance based on the following assumptions: an expected life of 5 years, volatility of 130%, risk free interest rate of 1.9% and zero dividends. The warrants vested immediately and the company recognized an expense of \$112,000 related to these warrants during the year ended December 31, 2010.

In December 2010, the Company issued warrants to a placement agent for the purchase of 500 shares of common stock at an exercise price of \$7.20 per share. These warrants were valued at \$2,000 using the following assumptions: an expected life of 5 years, volatility of 130%, risk free interest rate of 2.06% and zero dividends.

***Impact of Adopting Provisions Regarding Warrant Liabilities***

In June 2008, the Financial Accounting Standards Board ( FASB ) ratified standards related to determining whether an instrument (or an embedded feature) is indexed to an entity's own stock. The standards provide 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. The standard is effective for fiscal years beginning after December 15, 2008. The Company adopted the standard on January 1, 2009 and determined that the 1,164,929 warrants issued in connection with the February 2006 Transaction that had been classified as equity and included in additional paid-in capital at December 31, 2008, should be classified as liabilities due to repricing and anti-dilution provisions contained in the warrant agreements. The impact of adopting new accounting provisions on January 1, 2009, which required the treatment of warrants with certain features as liabilities rather than equity, was a decrease in additional paid-in-capital by \$458,000, which was the fair value recorded at the time the warrants were transferred from a liability to equity during the year ended December 31, 2008, an increase of warrant liabilities by \$204,000, the fair value of the warrants as of January 1, 2009 and a credit to accumulated deficit for the difference.

During the year ended December 31, 2011, the Company recognized a loss of \$524,000 in its consolidated statements of operations related to the change in fair value of warrant liabilities.

**8. Stock-Based Compensation*****Summary of Stock-Based Compensation Plans***

At December 31, 2012, the Company had three stock-based compensation plans where the Company's common stock has been made available for equity-based incentive grants as part of the Company's compensation programs (the Incentive Plans) as follows:

*2001 Stock Incentive Plan.* 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 833,334 shares of common stock for issuance upon

**Table of Contents**

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, 2012, 291,992 shares were available for future grant under the Incentive Plan.

*2003 Non-Employee Director Stock Option 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 166,667 shares of common stock for issuance upon exercise of grants made under the Director Plan. At December 31, 2012, 146,557 shares were available for future grant under the Director Plan.

*2009 Incentive Compensation Plan.* In February 2009, the Company adopted the 2009 Incentive Compensation Plan (the 2009 Plan) which provides for the issuance of up to 3,333,334 shares of the Company's common stock in the form of options, stock appreciation rights, restricted stock and other stock-based awards to employees, officers, directors, consultants and other eligible persons. At December 31, 2012, 979,259 shares were available for future grant under the 2009 Plan.

In addition, the Company has awarded 1,477,379 non-plan stock option grants to employees and non-employees. These non-plan grants have vesting periods and expiration dates similar to those options granted under the Incentive Plans. At December 31, 2012, 1,440,045 non-plan grants were outstanding.

**Stock-Based Compensation**

Following is the stock-based compensation expense related to common stock options, restricted common stock and common stock warrants:

	<b>Year Ended December 31,</b>	
	<b>2012</b>	<b>2011</b>
Research and development	\$ 922	\$ 1,558
General and administrative	1,870	1,687
<b>Total stock-based compensation expense</b>	<b>\$ 2,792</b>	<b>\$ 3,245</b>

The fair value of the options granted is determined using the Black-Scholes option-pricing model. The following weighted average assumptions were used:

	<b>2012</b>	<b>2011</b>	<b>Cumulative Period from Inception (July 10, 2000) to December 31, 2012</b>
Risk-free interest rate	0.90%	1.90%	1.84%
Expected life of the options	5.81 years	5.13 years	5.19 years
Expected volatility of the underlying stock	116%	131%	119%
Expected dividend rate	0%	0%	0%

As noted above, the fair value of stock options is determined by using the Black-Scholes option pricing model. For all options granted since January 1, 2006 the Company has generally used option terms of between 5 to 10 years, with 5 years representing the estimated life of options granted to employees. The volatility of the common stock is estimated using historical volatility over a period equal to the expected life at the date of grant. The risk-free interest rate used in the Black-Scholes option pricing model is determined by reference to historical U.S. Treasury constant maturity rates with terms equal to the expected terms of the awards. An expected dividend yield of zero is used in the option valuation model, because the Company





**Table of Contents**

does not expect to pay any cash dividends in the foreseeable future. At December 31, 2012, the Company does not anticipate any option 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.

Of the options granted during 2011, 166,668 vest only upon the achievement of certain market conditions (83,334 and 83,334 upon the Company achieving a market capitalization of \$5 billion and \$10 billion, respectively). These market condition stock option awards were valued at \$1,006,000 using a Monte Carlo model and will be recognized over a weighted average period of 5.5 years. Assumptions used to value these options included the following: annualized volatility of 110%, annualized drift/risk-free interest rate of 3.5% and a forecast horizon/life of 10 years.

The following table summarizes the stock option activity in the stock based compensation plans:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding, December 31, 2010	1,965,748	\$ 6.42		
Granted	1,676,712	7.02		
Forfeited/Cancelled	(334,543)	8.93		
Exercised	(216,443)	1.21		
Outstanding, December 31, 2011	3,091,474	\$ 6.83		
Granted	800,000	2.13		
Forfeited/Cancelled	(299,683)	8.93		
Exercised	(51,830)	2.31		
Outstanding, December 31, 2012	3,539,961	\$ 5.66	6.79	\$ 279
Exercisable, December 31, 2012	2,067,910	\$ 5.96	5.41	\$ 268

The aggregate intrinsic value in the table above represents the total pre-tax amount, net of exercise price, which would have been received by option holders if all option holders had exercised all options with an exercise price lower than the market price on December 31, 2012, based on the closing price of the Company's common stock of \$2.05 on that date.

The weighted-average grant-date fair values of options granted during 2012 and 2011 were \$1.77 and \$6.07, respectively. As of December 31, 2012 and December 31, 2011, there were unvested options to purchase 1,472,051 and 1,317,480 shares of common stock, respectively. Total expected unrecognized compensation cost related to such unvested options is \$5,628,000 at December 31, 2012, which is expected to be recognized over a weighted-average period of 3.7 years.

During the years ended December 31 2012 and 2011, 51,830 and 216,400, respectively, shares were issued upon the exercise of options valued at \$96,000 and \$253,000, respectively. During the years ended December 31, 2012 and 2011, the Company received \$0 and \$234,000, respectively, for the exercise of stock options. During 2012 and 2011, 90,253 and 83,334 options were exercised cashlessly resulting in the issuance of 51,830 and 64,273 shares, respectively. The intrinsic value of options exercised during the years ended December 31, 2012 and 2011 and from the period from inception to December 31, 2012 was \$162,000, \$1,174,000 and \$1,724,000, respectively.

During the years ended December 31, 2012 and 2011, 595,420 and 380,391 options vested, respectively. The total fair value of options vested during the years ended December 31, 2012, 2011 and the cumulative period from inception to December 31, 2012 was \$2,447,000, \$2,153,000 and \$13,056,000, respectively.

---

**Table of Contents*****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 33,334 options to purchase common stock at an exercise price of \$21.00 in consideration for services to be performed. At the time of issuance, these options were valued at \$239,000 based on a deemed fair market value of the Company's common stock of \$13.68 per share. Total expense for the years ended December 31, 2003, 2002 and 2001 related to these options was \$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 334 options a month to purchase common stock at an exercise price of \$21.00 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 4,000 options on March 1, 2002, which vest at a rate of 334 options per month, as services are performed. These options were valued at \$11,000 using the Black-Scholes option-pricing model, based on a grant date fair value of the Company's common stock of \$12.96 per share. During 2002, the Company recorded a \$41,000 charge to stock compensation expense related to the 3,334 options that vested during the year. As of December 31, 2002, the Company had deferred compensation of \$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 4,000 options effective retroactively to March 1, 2003, which vest at a rate of 334 options per month as services are performed. These options were valued at \$33,000 using the Black-Scholes option-pricing model, based on a fair market value of the Company's common stock of \$21.00 per share. The consulting arrangement was concluded on March 1, 2004. The Company recorded fair value adjustments of (\$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 \$17,000 and \$40,000, respectively.

In January 2003, the Company granted 16,667 options at an exercise price of \$21.00 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 \$156,000 using the Black-Scholes option-pricing model, based on a fair market value of the Company's common stock of \$16.80 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 \$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 \$51,000 and \$193,000, respectively.

In May 2003, the Company granted 1,667 options at an exercise price of \$21.00 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 \$16,000 using the Black-Scholes option-pricing model based on a fair market value of the Company's common stock of \$16.80 per share. The Company recorded fair value adjustments of \$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 \$5,000 and \$13,000, respectively.

In September 2003, the Company granted 4,167 options each to a Board member and to a member of the Scientific Advisory Board for consulting services. The options were exercisable immediately at \$24.30 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 \$14.64 per share. The Company recorded a \$122,000 charge to stock compensation expense in 2003 related to these awards.

## Table of Contents

In October 2003, in connection with the resignation of its former Chief Financial Officer, the Company accelerated the vesting on 16,667 options granted to such officer in September 2003 at an exercise price of \$24.30, 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 \$26.70 per share at the time the vesting was accelerated, the Company recorded a \$40,000 charge to stock compensation expense. Also, in October 2003, such officer exercised on a cashless basis 8,334 options at an exercise price of \$17.82 per share resulting in the issuance of 2,772 shares. As the fair market value of the Company's common stock on the date of exercise was \$26.70 per share, the Company recorded a charge of \$74,000 to stock compensation expense in 2003 related to the exercise of these options.

In March 2004, the Company issued 4,167 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 834 options per month, up to a maximum of 16,667 options, exercisable at \$34.80 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 \$29,000 as stock compensation expense in 2003 on the 2,500 options that vested as of December 31, 2003 and an additional stock compensation expense of \$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 834 per month up to a maximum of 10,000 options exercisable at \$30.96 per share as services are performed. During 2004, 7,500 options were earned but not issued. During 2005, 2,500 options were earned and the full 10,000 options were issued. The Company recorded \$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 834 options to a member of the Scientific Advisory Board for consulting services. The options were exercisable immediately at \$15.66 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 \$8.10 per share which was the fair market value at the date of the grant. The Company recorded a \$7,000 charge to stock compensation expense in 2005 related to this award. These options expired unexercised in 2010.

In March 2006 the Company issued 2,500 options to a consultant for consulting services, of which 834 of the options were exercisable immediately, 833 options vested in March 2008 and 833 options vested in March 2009. The options are exercisable at \$22.50 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 \$13.20 per share which was the fair market value at the date of the grant. The Company recorded a \$33,000 charge to stock compensation expense over the vesting period of the options.

In December 2007, the Company issued 834 options to a consultant for consulting services. The options were exercisable immediately at \$3.78 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 \$2.76 per share which was the fair market value at the date of the grant. The Company recorded a \$2,000 charge to stock compensation expense in 2007 related to this award.

In April 2008, the Company issued 8,000 options to a consultant for consulting services. The options were exercisable immediately at \$2.64 per share. These options were valued using the Black-Scholes option-

**Table of Contents**

pricing model based on a grant date fair value of the Company's common stock of \$2.34 per share which was the fair market value at the date of the grant. The Company recorded a \$15,000 charge to stock compensation expense in 2008 related to this award.

In February 2009, the Company issued 33,334 options to a consultant for consulting services. The options were exercisable immediately at \$0 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 \$0.72 per share which was the fair market value at the date of the grant. The Company recorded a \$24,000 charge to stock compensation expense in 2009 related to this award.

During the year ended December 31, 2012, the Company modified the terms of certain option grants for four employees to extend the exercisable period from ninety days post-employment to the remaining legal life of the option grant. During the year ended December 31, 2012, the Company modified certain cashless exercise terms for one employee. The modification of these option terms resulted in additional stock-based compensation expense of \$271,000 during the year ended December 31, 2012. During the year ended December 31, 2011, the Company modified the options of one employee to extend the exercisable period post-employment from ninety days to the remaining legal life of the option, resulting in additional stock-based compensation expense of \$63,000.

In May 2012, the Company granted 7,000 shares of common stock to a consultant for payment of past services. These shares of common stock were valued at \$16,000, based on the market value of the shares at the date of grant and are included in stock based compensation expense for the year ended December 31, 2012.

In August 2012, the Company granted 4,348 shares of common stock to a consultant for payment of services. These shares of common stock were valued at \$10,000, based on the market value of the shares at the date of grant and are included in stock based compensation expense for the year ended December 31, 2012.

**Restricted Stock**

During the year ended December 31, 2009, the Company granted 416,670 shares of restricted common stock to members of its Board of Directors. These shares were restricted and any unvested shares were subject to forfeiture upon termination and would revert back to the Company. Of the 416,670 shares, 390,628 were vested as of December 31, 2010, and the final 26,042 vested in 2011. The restricted shares were valued at \$450,000 (\$1.08 per share) at the date of grant and were recognized over the vesting period. During 2011, the Company recognized stock-based compensation of \$18,000 related to these restricted stock grants.

In 2011, the Company issued 20,834 shares of restricted common stock to a consultant. These shares were restricted until November 15, 2011 and any unvested shares were subject to forfeiture upon termination and would revert back to the Company. At December 31, 2011 there no restricted shares remaining. The restricted shares were valued at \$113,000 (\$5.40 per share) at November 15, 2011, and the Company recognized expense of \$110,000 during 2011 related to these shares.

	Number of Shares	Weighted Average Price on Grant
Unvested restricted shares outstanding, December 31, 2010	26,042	\$ 1.08
Restricted shares issued	20,834	8.04
Restricted shares vested	(46,876)	4.17
Unvested restricted shares outstanding, December 31, 2011		\$

**Table of Contents****9. Fair Value of Financial Instruments**

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

	<b>Fair Value of Warrant Liabilities (in thousands)</b>
Balance December 31, 2010	\$ 861
Change in fair value of warrant liabilities	524
Intrinsic value of liability warrants exercised	(1,385)
Balance December 31, 2011	\$

The warrant liabilities in the table above were classified as a Level 2 liability and were valued using the Black-Scholes pricing model.

**10. Loss Per Share**

Basic net loss per common share is computed by dividing the net loss available to common stockholders by the weighted average number of common shares outstanding during the period. Diluted net loss per common share is computed by dividing the net loss available to common stockholders by the weighted average number of common shares and other potential common shares then outstanding. Potential common shares consist of common shares issuable upon the assumed exercise of in-the-money stock options and warrants and potential common shares related to the conversion of the preferred stock. 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.

	<b>Year Ended December 31, (in thousands, except share and per share amounts)</b>	
	<b>2012</b>	<b>2011</b>
Basic and diluted net loss per common share:		
Net loss	\$ (9,675)	\$ (10,915)
Preferred stock dividends	(976)	(1,568)
Preferred stock accretion	(230)	(230)
Net loss applicable to common stockholders	\$ (10,881)	\$ (12,713)
Weighted average common shares outstanding basic and diluted	15,131	11,986
Net loss per common share basic and diluted	\$ (0.72)	\$ (1.06)

Dilutive shares which could exist pursuant to the exercise of outstanding stock instruments and which were not included in the calculation because their affect would have been anti-dilutive during are as follows:

	<b>December 31,</b>	
	<b>2012</b>	<b>2011</b>
	<b>(Shares)</b>	<b>(Shares)</b>
Warrants to purchase shares of common stock	7,424,241	6,673,405
Options to purchase shares of common stock	3,539,961	3,091,474
Shares of common stock issuable upon conversion preferred stock	2,627,110	2,627,110
	13,591,312	12,391,989



**Table of Contents****11. Commitments and Contingencies***Lease Commitments*

In September 2012, the Company entered into an operating lease for office space in Norcross, GA for a term of twenty-six months, beginning on October 1, 2012 and ending November 30, 2014 at a rate of \$3,000 per month. The lease provides for free rent for the first two months of the lease and required a security deposit of \$6,000. In addition to base rental payments included in the contractual obligations table above, we are responsible for our pro-rata share of the operating expenses for the building.

In October 2012, the Company entered into an operating lease for office space collocated with lab space for research and development activities. The lease is for a period of one year, beginning on October 1, 2012, for a rate of \$15,000 for the term, payable in equal monthly increments.

In July 2011, the Company entered into an agreement to amend its lease for offices in Newton, MA to extend the term for a period of one year, which expired on September 30, 2012, at a base rent of \$235,000 for the period. In addition to base rental payments, the Company was responsible for its pro-rata share of increases in the operating expenses for the building. In connection with this lease, a commercial bank issued a letter of credit collateralized by cash, which the Company had on deposit with the bank of \$59,000 at December 31, 2011 and which was released during 2012 after the lease term ended. In July 2011, the Company entered into an operating lease for an apartment for Company executive use for a one-year term, which ended in August 2012, at a rate of \$44,000 for the term.

Rent expense under the above operating leases was \$216,000 and \$293,000 for the years ended December 31, 2012 and 2011, respectively.

Future minimum payments under this lease as of December 31, 2012 are as follows (in thousands):

<b>Year ended December 31,</b>	
2013	\$ 49
2014	36
<b>Total lease payments</b>	<b>\$ 85</b>

*Separation Agreement Former Chief Executive Officer and Chairman of the Board of Directors*

In February 2009, the Company entered into a Separation Agreement in connection with the resignation of David Platt, Ph.D., the Company's former Chief Executive Officer and Chairman of the Board of Directors. The Separation Agreement provides for the deferral of a \$1.0 million separation payment due to Dr. Platt upon the earlier occurrence of any of the following milestone events: (i) the approval by the Food and Drug Administration for a new drug application ( NDA ) for any drug candidate or drug delivery candidate based on the Company's GM-CT-01 technology (whether or not such technology is patented), in which case Dr. Platt is also entitled to a fully vested 10-year cashless-exercise stock option to purchase at least 83,334 shares of common stock at an exercise price not less than the fair market value of the common stock determined as of the date of grant; (ii) consummation of a transaction with a pharmaceutical company expected to result in at least \$10.0 million of equity investment or \$50 million of royalty revenue to the Company, in which case Dr. Platt is also entitled to stock options on the same terms to purchase at least 50,000 shares of common stock; or (iii) the renewed listing of the Company's securities on a national securities exchange and the achievement of a market capitalization of \$100 million. Payment upon the events (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 obligation to pay the \$1.0 million with the result that Dr. Platt may assert a claim for such



**Table of Contents**

obligation against the bankruptcy estate. During 2011, when it became probable that the Company could be relisted on a national securities exchange and eventually reach a market capitalization of \$100 million, the Company recognized the \$1.0 million severance payment due to Dr. Platt and it is included in accrued expenses at December 31, 2012 and December 31, 2011.

On May 2, 2012, Dr. Platt instituted arbitration before the American Arbitration Association, seeking a \$1.0 million separation payment based on a claim that a milestone event in the Separation Agreement has occurred (see clause (iii) above). On March 22, 2012, the Company's common stock was listed on the NASDAQ Capital Markets, but since that date, the stock has not achieved the required market capitalization. Therefore, it is the Company's position that a milestone event has not yet occurred. The arbitration hearing was held on October 16 - 17, 2012 and on November 1, 2012, the arbitrator denied Dr. Platt's demand in all respects. Insofar as the Company does not dispute its obligations under the Separation Agreement to pay Dr. Platt upon the occurrence of a milestone event, it has recorded the payment as an accrued expense payable if and when the milestone event occurs.

On October 12, 2012, Dr. Platt commenced a lawsuit under the Massachusetts Wage Act against Dr. Traber and Mr. McGauley who in their capacities as the Company's Chief Executive Officer and Chief Financial Officer respectively can be held individually liable under the Wage Act for non-payment of wages. The lawsuit is based on the facts and issues raised in the arbitration regarding the payment of the \$1.0 million separation payment under the Separation Agreement, and other unspecified wages. The statute provides that a successful claimant may be entitled to multiple damages, interest and attorneys fees. Although the Company is not a party to the lawsuit, it plans to indemnify Dr. Traber and Mr. McGauley consistent with its obligations under the by-laws and applicable law, believes the lawsuit is without merit, and intends a vigorous defense on their behalf.

On March 29, 2013, the Company instituted arbitration before the American Arbitration Association, seeking to rescind or reform the Separation Agreement discussed above. The Company claims that Dr. Platt fraudulently induced the Company to enter into the Separation Agreement, breached his fiduciary duty to the Company, and was unduly enriched from his conduct. Along with removal of the \$1.0 million milestone payment provided for under the Separation Agreement, the Company is seeking repayment of all separation benefits paid to Dr. Platt to date. Depending on the outcome of the arbitration, the previously accrued \$1.0 million could be reversed. The timing and ultimate outcome of this arbitration, though, is uncertain and there is no guarantee that the Company will be successful in this demand.

***Series C Post Conversion Dividend Rights***

In July 2011, 5 shares of the Company's Series C Super Dividend Convertible Preferred Stock (Series C) were converted into 8,334 shares of common stock which also resulted in the issuance of 5 Series C post-conversion dividend rights (Dividend Rights). Under the terms of the Series C, the Dividend Rights entitle the holder only to dividend payments based on a percentage of actual sales of GM-CT-01 but not, following a conversion to common stock, the 6% dividend payable on outstanding shares of Series C. At December 31, 2012, the outstanding Dividend Rights were determined to have a de minimis value, because payment of a dividend for the Dividend Rights is considered improbable at this time and the Company has not recorded a liability related to the Dividend Rights. The Company will continue to evaluate and assess the Dividend Rights for each reporting period.

***Other Legal Proceedings***

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. There are no other pending legal proceedings except as noted above.

**Table of Contents****12. Income Taxes**

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

	2012	2011
	(in thousands)	
Operating loss carryforwards	\$ 21,753	\$ 19,119
Tax credit carryforwards	317	330
Other temporary differences	2,921	2,070
	24,991	21,519
Less valuation allowance	(24,991)	(21,519)
Net deferred tax asset	\$	\$

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

	2012	2011
Tax benefit at U.S. statutory rates	(34%)	(34%)
State tax benefit	(5.3%)	(5.3%)
Credit	(0.2%)	(1.0%)
Permanent differences	1.4%	3.5%
Expiring state NOLs	3.3%	3.4%
Changes in valuation allowance	34.8%	33.4%
	0%	0%

As of December 31, 2012, the Company has federal and state net operating loss carryforwards totaling \$60,886,000 and \$25,160,000 respectively, which expire through 2032. The net operating losses include Federal and State excess benefits related to stock options of \$707,000 that will be charged to additional paid-in capital when utilized. In addition, the Company has federal and state research and development credits of \$223,000 and \$143,000, respectively, which expire through 2032. Ownership changes, as defined by Section 382 of the Internal Revenue Code, may have limited the amount of net operating loss carryforwards that can be utilized annually to offset future taxable income. Subsequent ownership changes could further affect the limitation in future years. Because of the Company's limited operating history and its recorded losses, management has provided, in each of the last two years, a 100% valuation allowance against the Company's net deferred tax assets.

On January 3, 2013, the American Taxpayer Relief Act of 2012 was signed into law reinstating the federal research and development credit for the 2012 and 2013 years. Under ASC 740-10-25 the effects are recognized as a component of income tax expense or benefit from continuing operations in the financial statements for the interim or annual period that includes the enactment date. The benefit related to the 2012 federal research and development credit \$61,000 will be recorded during 2013.

At December 31, 2012 the Company has \$1,082,000 of unrecognized tax benefits, \$923,000 of which would affect the effective tax rate. The Company has not recognized an adjustment to the deficit accumulated during the development stage for unrecognized tax benefits because a full valuation allowance has been recorded against net operating loss carry forwards. Since the Company's net deferred tax assets and the unrecognized tax benefits 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.

**Table of Contents**

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**

The Company has evaluated all events or transactions that occurred through the date on which the financial statements were issued, noting the following:

***Agreement with CTI for Phase I Clinical Trial***

On February 1, 2013, the Company entered into an Amended and Restated Master Services Agreement (the *Agreement*) with CTI Clinical Trial Services, Inc. and CTI Clinical Consulting Services, Inc. (individually and collectively, *CTI*), whereby CTI will assist the Company in the design, development and conduct of one or more clinical research studies from time to time. All work performed by CTI for the Company will be conducted pursuant to the terms of work orders that describe the specific obligations undertaken by CTI with respect to any particular clinical research study sponsored or conducted by the Company. Unless otherwise terminated sooner in accordance with the terms of the Agreement, the Agreement will be effective until January 31, 2018.

On February 1, 2013, the Company entered into a work order (the *Work Order*) with CTI in accordance with the terms of the Agreement. The Work Order provides that CTI will provide services with respect to the Company's Phase I Clinical Trial to evaluate the safety of the Company's drug GR-MD-02 in subjects with Non-Alcoholic Steatohepatitis ( *NASH* ) with advanced hepatic fibrosis. CTI will provide the following services, amongst others, with respect to the Work Order: reviewing and providing notices regarding IND safety reports, selecting investigators and monitors for the study, informing investigators of new observations, monitoring the progress of the study and reviewing ongoing investigations, keeping certain records, inspecting the Company's records and reports, and disposing of any unused supply of the investigational drug.

The Work Order provides for CTI's anticipated involvement in the study from February 1, 2013 until March 31, 2014. The estimated budget for the Work Order is \$2,155,000, which is subject to change as necessary, with payments made throughout the term of the project as the work is performed.

The Agreement or any work order may be terminated for any reason by any party upon ninety (90) days prior written notice to the other party. In addition, the Agreement may be terminated by either party immediately if the other party becomes insolvent, is dissolved or liquidated, makes a general assignment for the benefit of its creditors, files or has filed against it (and does not obtain a dismissal within ninety (90) days) a petition of bankruptcy, or has a receiver appointed for it or a substantial part of its assets, among other reasons. Further, the Agreement or any relevant work order may be terminated immediately by written notice from the Company, in the following circumstances: (1) the FDA withdraws authorization and approval to conduct a study; or (2) the Company reasonably determines that for medical, clinical or patient safety reasons, a study should terminate immediately. In addition, either party may terminate the Agreement or any work order for material breach upon thirty (30) days' written notice specifying the nature of the breach, if such breach has not been substantially cured within the thirty (30) day period.

***Drug Discovery Program with the University of Georgia***

In February 2013, the Company established a collaborative drug discovery program at the Complex Carbohydrate Research Center at the University of Georgia. This program is focused on the discovery of new carbohydrate molecules that can be used in the therapy of diseases where galectin proteins play a major role, including cancer and inflammatory and fibrotic disorders. The term of the agreement is effective through December 31, 2013, for which the Company will provide funding of \$154,000.