GALECTIN THERAPEUTICS INC
Form 10-K
March 30, 2012
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

x **Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
For the fiscal year ended December 31, 2011

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

Commission File No. 000-32877

GALECTIN THERAPEUTICS INC.

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

(617) 559-0033

(Registrant s Telephone Number, Including Area Code)

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

Title of each class	Name of each exchange on which registered
Common Stock, $.001 Par Value Per Share	**The NASDAQ Capital Market**
Units, each consisting of two shares of Common Stock and one Warrant to purchase one share of Common Stock	**The NASDAQ Capital Market**
Common Stock Purchase Warrants	**The NASDAQ Capital Market**

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 x

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

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

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

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

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was sold, or the average bid and asked price of such common equity, as of June 30, 2011 was $73.7 million.

The number of shares outstanding of the registrant s common stock as of March 29, 2012 was 15,599,863.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive Proxy Statement for the 2012 Annual Meeting of Stockholders are incorporated by reference into Part III of this Report.

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FOR THE YEAR ENDED DECEMBER 31, 2011

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FORWARD-LOOKING STATEMENTS

This annual report on Form 10-K contains, in addition to historical information, forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These statements relate to future events or our future financial performance and can be identified by the use of forward-looking terminology such as project, may, could, expect, anticipate, estimate, c or other similar words. These forward-looking statements are based on management s current expectations and are subject to a number of factors and uncertainties which could cause actual results to differ materially from those described in these statements. The following are some of the important factors that could cause our actual performance to differ materially from those discussed in the forward-looking statements:

- We have incurred significant operating losses since our inception and cannot assure you that we will generate revenue or profit.
- Although we believe that we have sufficient cash on hand to fund our planned operations through 2013, if we fail to raise additional capital by the end of 2013 or fail to successfully bring our product to market, we may need to significantly curtail operations, cease operations or seek federal bankruptcy protection.
- We are subject to extensive and costly regulation by the U.S. Food and Drug Administration, or FDA, which must approve our product candidates in development and could restrict the sales and marketing of such products in development.
- We may be unable to achieve commercial viability and acceptance of our proposed products.
- We may be unable to improve upon, protect and/or enforce our intellectual property.
- We may be unable to enter into strategic partnerships for the development, commercialization, manufacturing and distribution of our proposed product candidates.
- We are subject to significant competition.
- As a public company, we 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.

PART I

Item 1. *Business*

Overview

We are a development-stage company engaged in drug development to create new therapies for cancer and fibrotic disease. Our drug candidates are based on our method of targeting galectin proteins, which are key mediators of biologic and pathologic function. We use naturally occurring plant materials to create complex carbohydrates with specific molecular weights and pharmaceutical properties. Using these unique

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carbohydrate-based candidate compounds that bind and inhibit galectin proteins, we are undertaking the 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 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 attempt to leverage our scientific and development expertise as well as established relationships with outside sources to achieve cost-effective and efficient development. 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.

DTR-Med Pharma Corp., or DTR, was incorporated in Nevada on January 26, 2001. On April 25, 2001, DTR entered into a stock exchange agreement with Pro-Pharmaceuticals, Inc., a Massachusetts corporation, 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.

Offering of Units and Reverse Stock Split

On March 22, 2012, we entered into an underwriting agreement, relating to the offer and sale of 1,159,445 units (the Units), each Unit consisting of two shares of our Common Stock and one warrant to purchase one share of our Common Stock. Pursuant to the underwriting agreement, we granted the underwriters a 45-day option to purchase up to an additional 173,916 Units to cover over-allotments, which was exercised in full 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.

On March 28, 2012, we sold 1,333,361 Units (2,666,722 shares of Common Stock and related warrants to purchase 1,333,361 shares of common stock) for gross proceeds of $12.0 million (net proceeds of approximately $10.5 million after the underwriting discount and offering costs).

On March 22, 2012, in connection with the offering, 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. On March 23, 2012, our common stock began trading on The NASDAQ Capital Market under the symbol GALT . On March 28, 2012, the units and warrants that we sold in the offering began trading on that exchange under the symbols GALTU and GALTW, respectively.

Drug Compounds

We have two compounds in development, one intended to be used in cancer therapy and the other intended to be used in the treatment of liver fibrosis and fatty liver disease. These two compounds are produced from completely different natural starting materials, both possessing the property which lends itself to binding to and inhibiting galectin proteins. 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 is derived from a plant source. 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 also is derived from a plant source.

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

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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.

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 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.

We believe the potential exists 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 for using the 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 produce an effective galectin inhibitor that enhances the immune system s ability to fight cancer and, most important, that complements other approaches to this type of therapy.

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. 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 (see figure of Galectin Effect below). Based on these results, we believe that the body s immune cells are 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.

We recently 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. 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. The study has been initiated and patients are beginning to be enrolled. We expect the first patient to be enrolled in March or April of 2012. We expect the first stage of this trial (involving 12 evaluable patients) to be completed within a year of enrollment of the first patient and that it will provide data that could deliver an indication of efficacy. Depending on the results of Stage 1, 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 will require funding from the Company, currently estimated at approximately $1 million. Positive results from this study could indicate that this approach of inhibiting the Galectin Effect would be an enabling technology for therapy in other tumor types. The Phase I/II clinical trial in Belgium is not being conducted under an FDA-approved IND, but there is an open IND under the FDA for GM-CT-01.

There are two 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

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chemotherapy used for treatment of various types of cancer. Three Phase II studies were conducted, but were only partially completed due to financing issues. DAVFU-003 was a Phase II, multi-center, open-label trial in end-stage, line 3/4 metastatic colorectal cancer patients, who were treated with a combination of GM-CT-01 and 5-FU. In the 20 enrolled patients, the median survival was 6.7 months and there was a notable reduction in the expected adverse events related to 5-FU therapy.

DAVFU-003 was terminated in 2007. Although only partially completed, when compared to historical controls, the data collected for DAVFU-003 suggested a favorable effect of the therapy, since the controls had an overall survival of 4.6 months. DAVFU-006 was a Phase II, open-label clinical trial in line 1 patients with locally advanced and unresectable or metastatic colorectal cancer (who were unable to tolerate intensive chemotherapy), who were treated with a regimen of GM-CT-01, 5-FU, leucovorin and Avastin®. Ten patients were enrolled in this study. DAVFU-006 was terminated in March 2010. Finally, DAVFU-007 was a Phase II, multi-center, open-label clinical trial to evaluate the efficacy and safety of GM-CT-01 in combination with 5-FU when administered as first line chemotherapy in patients with advanced biliary cancer. Seventeen patients were enrolled in this study. This study was stopped in March 2010.

It was notable in these four studies that, when the results of adverse events were pooled, there appeared to be a marked reduction in the severity of 5-FU related adverse events when compared to historical controls. To examine 5-FU related side effects in patients receiving GM-CT-01 in all of the clinical trials, a post-hoc analysis was conducted of adverse events typically related to 5-FU including, diarrhea, nausea and vomiting, mucositis and neutropenia/leukopenia. Studies for comparison to our data were culled from the literature, providing a broad spectrum of 1128 patients treated with 5-FU. Comparison of adverse events between the literature-derived patients and the 57 patients in our clinical trials that received 5-FU with full dose GM-CT-01 demonstrates that patients in our trials had a markedly lower grade: 3/4 adverse events for all of the 5-FU related toxicities. These data suggest that GM-CT-01 may ameliorate toxicities related to 5-FU, which are important limiting events in cancer chemotherapy.

Based on these completed Phase I and partially completed Phase II clinical trials, we are exploring two additional potential indicia for the use of GM-CT-01 in combination with cancer chemotherapy:

- We are seeking potential strategic partners to assist in researching the use of GM-CT-01 in the amelioration of 5-FU related side effects. Such a partnership would permit additional clinical trials in the U.S., which would not be started until a partnership was consummated; and

- We are attempting to gain regulatory approval of GM-CT-01 for use in combination with 5-FU for metastatic colorectal cancer in Colombia. This approach was recommended to the Company by key oncology opinion leaders in Colombia and by PROCAPS S.A., a Colombia-based pharmaceutical company. While Colombian marketing is not a central component of our overall corporate strategy, it could potentially help us to generate revenue in 2012 to support development programs, reduce the amount of capital we would need to raise in future equity offerings and gain additional clinical experience with GM-CT-01. There can be no assurance that we will receive regulatory approval of GM-CT-01 in Colombia, particularly since there has been no approval of GM-CT-01 in a major region such as the U.S. or Europe. Moreover, even if we receive approval in Colombia, we cannot assure you that our approach will yield successful results or that we will generate any revenue or lead to approval in any other countries, including the United States.

Liver Fibrosis: New Approach for an Unmet Medical Need

The second main initiative in our development strategy is the application of galectin inhibition in connection with liver fibrosis, a condition that leads to cirrhosis. Currently, nearly 500,000 patients have cirrhosis with nearly 50,000 losing their lives yearly in the United States, while only 6,200 were saved by liver transplantation at a cost of $350,000 per transplantation. In addition, the National Institute of Health estimates that 9 million to 15 million Americans are affected by a form of liver fibrosis known as non-alcoholic steatohepatitis, or NASH.

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NASH (also known as fatty liver disease) is a liver disease characterized by the accumulation of fat in the liver with associated inflammation and fibrosis that can lead to end-stage cirrhosis requiring a liver transplantation. The NIH forecasts that the number of Americans affected by NASH is growing due to obesity and diabetes, and that NASH is an epidemic which has the potential to become the leading cause of liver cirrhosis and liver transplantation in the future. To the best of our knowledge, there are currently no therapies on the market for NASH or other forms of liver fibrosis.

We believe that GR-MD-02 has the potential to treat 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. These experiments, along with several others that include human liver cells, have identified what we believe to be the mechanism of action for the creation of fibrotic scar tissue in the liver.

Recently, we presented pre-clinical data at the European Society for the Study of the Liver in Lisbon, Portugal, which data demonstrated that GR-MD-02 reversed NASH-induced fibrosis in the liver of mice. The animal model used was analogous to that of humans, in that the mice were given diabetes and then subsequently fed a high-fat diet, both conditions associated with the human disease. The data show that there is a reduction in fat accumulation, hepatocyte degeneration and inflammation in the liver histology on the left after 4 weeks of treatment with GR-MD-02, which was administered twice a week. The significant improvement is confirmed using a standard NASH grading system.

The percent of collagen in the livers (fibrotic tissue as demonstrated by percent Sirius red staining) was reduced by treatment with GR-MD-02 to levels equivalent to normal levels irrespective of whether treatment was started early (before fibrosis developed) or late (after the development of fibrosis). These effects in the NASH mice were independent of serum glucose and lipid levels, which were elevated in all animals. In addition, the galectin-3 levels in the liver tissue were markedly reduced by the therapy, indicating the proposed mechanism of inhibiting galectin-3 is likely operative.

In summary, 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. GR-MD-02 is currently being evaluated in pre-clinical toxicology and pharmacology studies with the aim of obtaining an IND from the FDA by the end of 2012 for initiating human studies in patients with NASH. We will seek to gain FDA approval for Phase I and Phase II studies of GR-MD-02 in NASH as well as other indications in diseases with liver fibrosis.

Agreement with PROCAPS S.A.

On October 18, 2011, we entered into a Collaboration, Supply, Marketing and Distribution Agreement (which supersedes a March 2010 definitive term sheet) which granted PROCAPS S.A., or PROCAPS, exclusive rights to market and sell GM-CT-01 to treat cancer in Colombia, South America. PROCAPS is a large, international, privately held pharmaceutical company based in Barranquilla, Colombia. Under terms of the agreement, PROCAPS is responsible for obtaining regulatory and pricing approval in Colombia. PROCAPS also will be responsible for the vial filling, packaging, marketing and distribution of GM-CT-01 in the region. In October 2010, we 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 our stability study.

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Patents and Proprietary Rights

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

As of December 31, 2011, we held six 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. The scheduled expiration dates of our United States patents begin in 2020 through 2028. 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 is contingent upon protection of our intellectual property.

Research

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

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

Our research and development expenditures totaled $23.1 million for the cumulative period from inception (July 10, 2000) through December 31, 2011. During the years ended December 31, 2011 and 2010, our expenditures for research and development were $3.6 million and $1.1 million, respectively.

Manufacturing and Marketing

We are a development stage company at this time and do not intend to establish internal facilities for the manufacture of our products for clinical or commercial production. To have our products manufactured, we have developed and will continue to develop relationships with third-parties that have established manufacturing capabilities. We are not a party to any long-term agreement with any of our suppliers and, accordingly, we have our products manufactured on a purchase-order basis from one of two primary suppliers.

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

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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 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.

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 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 Investigational New Drug Application (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 New Drug Application (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 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 FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed. There is no certainty that submission of an IND will result in the FDA allowing clinical trials to begin.

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

Clinical trials typically are conducted in three sequential phases, but the phases may overlap or be combined. Each trial must be reviewed and approved by an independent Institutional Review Board (IRB),

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

Assuming successful completion of the required clinical testing, the results of the pre-clinical studies and of the clinical studies, together with other detailed information, including information on the manufacture and composition of the drug, are submitted to the FDA in an NDA requesting approval to market the product for one or more indications. Before approving an NDA, the FDA usually will inspect the facilities at which the drug is manufactured, and will not approve the product unless compliance with cGMP is satisfactory. If the FDA evaluates the NDA and the manufacturing facilities as acceptable, the FDA will issue an approval letter. If the FDA evaluates the NDA submission or the manufacturing facilities as not acceptable, the FDA will outline the deficiencies in the submission and often will request additional testing or information. Even if an applicant submits the requested additional information, the FDA ultimately may decide that the NDA does not satisfy the regulatory criteria for approval. The testing and approval process requires substantial time, effort, and financial 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,

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

Environmental Regulation

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

Employees

As of December 31, 2011, we had seven full-time employees, three of whom were involved primarily in management of our pre-clinical research and development and clinical trials and four who were involved primarily in financial management and administration of our company. We also had one contractor who provides 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 2013 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, 2011 was $69.1 million and our cumulative net loss applicable to common stockholders as of December 31, 2011 was $69.4 million. Based on $6.4 million of unrestricted cash as of December 31, 2011, and approximately $10.5 million received on March 28, 2012, from the sale of 2,666,722 shares of common stock and related warrants to purchase 1,333,361 shares of common stock, we believe that we have sufficient cash to meet our financial and operating obligations through 2013. 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 2013, or we may not be able to continue operations and may be forced to seek bankruptcy protection.

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

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

We are a development stage company and have not generated any revenues to date. We granted PROCAPS, S.A. exclusive rights to market and sell GM-CT-01 to treat cancer patients in Colombia, South America, which we refer to as the PROCAPS Channel. In addition, there is no assurance that we will obtain FDA approval of 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, GM-CT-01 and GR-MD-02 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.

GM-CT-01, our lead product candidate, is currently in human clinical trials in Belgium for use in combination with peptide vaccine for therapy of metastatic melanoma. We are attempting to gain regulatory approval in Colombia of GM-CT-01 for use in combination with 5-FU for metastatic colorectal cancer. While Colombian marketing is not a central component of our overall corporate strategy, it could help us to obtain revenue in 2012 to support development programs, reduce the amount of capital we would need to raise in future equity offerings and gain additional clinical experience with GM-CT-01. There can be no assurance that we will receive regulatory approval of GM-CT-01 in Colombia, particularly since there has been no approval of GM-CT-01 in a major region such as the U.S. or Europe. Moreover, even if we receive approval in Colombia, we cannot assure you that our approach will yield successful results or that we will generate any revenue, or that we will obtain approval in other countries.

There are currently no FDA clinical trials underway for GM-CT-01. We are seeking strategic partners to explore possible FDA clinical trials to study the use of GM-CT-01 in the amelioration of 5-FU related side effects. The Phase I/II clinical trial in Belgium is being conducted under an IMPD from the EMA, under an FDA-approved IND,

GR-MD-02 is currently being evaluated in pre-clinical toxicology and pharmacology studies with the aim of obtaining an IND from the FDA by the end of 2012 for initiating human clinical trials in patients with NASH. 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

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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), 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.

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

Even if GM-CT-01, GR-MD-02 and other anticipated product candidates achieve positive results in clinical trials, we may be unable to commercialize them. Although we anticipate receipt of regulatory approvals in connection with the PROCAPS Channel, there is no assurance that such approvals will be obtained. 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.

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

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

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

As we develop products eligible for clinical trials, including GM-CT-01, we will contract with independent parties to assist us in the design of the trial protocols, arrange for and monitor the clinical trials, collect data and analyze data. In addition, certain clinical trials for our products may be conducted by government-sponsored agencies and will be dependent on governmental participation and funding. Our dependence on independent parties and clinical sites involves risks including reduced control over the timing and other aspects of our clinical trials.

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

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

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

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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.

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.

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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.

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

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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.

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;

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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;

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.

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

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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 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

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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.

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.

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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 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.

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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;
- industry developments, including, without limitation, changes in healthcare policies or practices or third-party reimbursement policies;
- economic and other external factors;
- 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 (8,000,000 designated as of December 31, 2011), 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.

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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. We have issued approximately 549,000 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 general partner of the 10X Fund and Executive Chairman of our board of directors, owns or controls approximately 832,000 shares of our common stock and has the right to acquire approximately 667,000 additional shares (approximately 217,000 of which are exercisable as of December 31, 2011) of our common stock upon the exercise of outstanding stock options; and (ii) Rod D. Martin, a general partner of the 10X Fund and Vice Chairman of our board of directors, owns or controls approximately 87,000 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 90,000 of which are exercisable as of December 31, 2011). As of December 31, 2011, 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 43% 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 48% 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. 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.

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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. 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 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 may 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.

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Item 2. ***Properties***

We lease 9,400 square feet for our executive offices located at 7 Wells Avenue, Newton, Massachusetts. Upon termination of the initial five-year term of the lease, we extended it for one year to September 30, 2012. We believe this space is suitable for our present operations.

Item 3. ***Legal Proceedings***

In January 2003, Custom Equity Research, Incorporated (d/b/a Summer Street Research Partners) filed a lawsuit against the Company alleging breach of contract, among other claims, based on an engagement letter in which Summer Street agreed to provide investment services to us. We denied the claims and believed they were without merit. In January 2011, the Company learned that Maxim Group, which the Company had previously engaged as a placement agent, had been named respondent in an arbitration matter with the Financial Industry Regulatory Authority (FINRA) initiated by Summer Street, for which the Company was obligated to indemnify Maxim Group. After consideration of the continued costs of litigation, the Company settled both matters for an amount that is not material to our balance sheet or our cash position.

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.

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

Not applicable.

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PART II

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

Price Range of Common Stock

Our common stock began trading on The NASDAQ Capital Market under the symbol GALT effective March 23, 2012. Our common stock had been quoted on the OTC Bulletin Board 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, for the periods indicated. All share prices reflect the one-for-six reverse split, which was effective March 23, 2012.

	High	Low
Fiscal Year Ended December 31, 2011		
First Quarter	$ 8.64	$ 5.22
Second Quarter	$ 9.42	$ 5.88
Third Quarter	$ 7.80	$ 4.56
Fourth Quarter	$ 6.78	$ 3.84
Fiscal Year Ended December 31, 2010		
First Quarter	$ 3.00	$ 1.56
Second Quarter	$ 5.34	$ 2.46
Third Quarter	$ 4.92	$ 2.88
Fourth Quarter	$ 6.24	$ 3.72

Holders of Common Stock

As of February 29, 2012, there were 272 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 federal securities laws and is subject to the safe harbor created therein for forward-looking statements. Such statements include, but are not limited to, statements concerning our anticipated operating results, research and development, clinical trials, regulatory proceedings, and financial resources, and can be identified by use of words such as, for example, anticipate, estimate, expect, project, intend, plan, believe and would, should, could or may. Forward-looking statements are based on current expecta and projections about the industry and markets in which 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

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uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Such risks and uncertainties are related to, without limitation, our early stage of development, our dependence on outside capital, uncertainties of our technology and clinical trials, intellectual property litigation, uncertainties of regulatory approval requirements for our products, competition and stock price volatility in the biotechnology industry, limited trading volume for our stock, concentration of ownership of our stock, and other risks detailed herein and from time to time in our SEC reports. The following discussion should be read in conjunction with the accompanying consolidated financial statements and notes thereto of Galectin Therapeutics appearing elsewhere herein.

Overview

We are a development-stage company engaged in drug development to create new therapies for cancer and fibrotic disease. Our drug candidates are based on our method of targeting galectin proteins, which are key mediators of biologic and pathologic function. We use naturally occurring plant materials to create complex carbohydrates with specific molecular weights and pharmaceutical properties. Using these unique carbohydrate-based candidate compounds that bind and inhibit galectin proteins, we are undertaking the 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 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 attempt to leverage our scientific and development expertise as well as established relationships with outside sources to achieve cost-effective and efficient development. 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.

Recent Events

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 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 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 proceeds of approximately $10.5 million).

Our Drug Development Programs

We have two compounds in development, one intended to be used in cancer therapy and the other intended to be used in the treatment of liver fibrosis and fatty liver disease. These two compounds are produced from completely different natural starting materials, both possessing the property which lends itself to binding to and inhibiting galectin proteins. 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 is derived from a plant source. 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 also is derived from a plant source.

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

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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.

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 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.

We recently 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. We expect the first patient to be enrolled in March or April of 2012. We expect the first stage of this trial (involving 12 evaluable patients) to be completed within a year of enrollment of the first patient and that it will provide data that could deliver an indication of efficacy. Depending on the results of Stage 1, 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 will require funding from the Company, currently estimated at approximately $1 million. The Phase I/II clinical trial in Belgium is not being conducted under an FDA-approved IND, but there is an open IND under the FDA for GM-CT-01.

There are two 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. DAVFU-003 was terminated in 2007. Although only partially completed, when compared to historical controls, the data collected for DAVFU-003 suggested a favorable effect of the therapy, since the controls had an overall survival of 4.6 months. DAVFU-006 was a Phase II, open-label clinical trial in line 1 patients with locally advanced and unresectable or metastatic colorectal cancer (who were unable to tolerate intensive chemotherapy), who were treated with a regimen of GM-CT-01, 5-FU, leucovorin and Avastin®. Ten patients were enrolled in this study. DAVFU-006 was terminated in March 2010. Finally, DAVFU-007 was a Phase II, multi-center, open-label clinical trial to evaluate the efficacy and safety of GM-CT-01 in combination with 5-FU when administered as first line chemotherapy in patients with advanced biliary cancer. Seventeen patients were enrolled in this study. This study was stopped in March 2010.

Based on these completed Phase I and partially completed Phase II clinical trials, we are exploring two additional potential indicia for the use of GM-CT-01 in combination with cancer chemotherapy:

We are seeking potential strategic partners to assist in researching the use of GM-CT-01 in the amelioration of 5-FU related side effects. Such a partnership would permit additional clinical trials in the U.S., which would not be started until a partnership was consummated; and

We are attempting to gain regulatory approval of GM-CT-01 for use in combination with 5-FU for metastatic colorectal cancer in Colombia. This approach was recommended to the Company by key oncology opinion leaders in Colombia and by PROCAPS S.A., a Colombia-based pharmaceutical company. While Colombian marketing is not a central component of our overall corporate strategy, it could potentially help us to generate revenue in 2012 to support development programs, reduce the amount of capital we would need to raise in future equity offerings and gain additional clinical experience with GM-CT-01. There can be no assurance that we will receive regulatory approval of

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GM-CT-01 in Colombia, particularly since there has been no approval of GM-CT-01 in a major region such as the U.S. or Europe. Moreover, even if we receive approval in Colombia, we cannot assure you that our approach will yield successful results or that we will generate any revenue or lead to approval in any other countries, including the United States.

GR-MD-02 Liver Fibrosis

The second 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 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. These experiments, along with several others that include human liver cells, have identified what we believe to be the mechanism of action for the creation of fibrotic scar tissue in the liver. 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. GR-MD-02 is currently being evaluated in pre-clinical toxicology and pharmacology studies with the aim of obtaining an IND from the FDA by the end of 2012 for initiating human studies in patients with NASH. We will seek to gain FDA approval for Phase I and Phase II studies of GR-MD-02 in NASH as well as other indications in diseases with liver fibrosis.

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 consolidated balance sheets as of December 31, 2011 and 2010 and will recognize the revenue when the remaining deliverables of the agreement have been completed.

On October 18, 2011, we entered into a Collaboration, Supply, Marketing and Distribution Agreement (the Agreement) with PROCAPS. The Agreement grants PROCAPS first negotiation rights to enter into similar agreements in other Central and South American countries. We are the sole manufacturer and supplier of GM-CT-01 to PROCAPS. The Agreement obligates 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 must 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 retain 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.

Qualifying Therapeutic Discovery Project

In October 2010, we were awarded $489,000 total in two federal grants under the Qualifying Therapeutic Discovery Project (QTDP) Program for our GM-CT-01 anti-cancer compound and GR/GM-Series of anti-fibrotic, cirrhosis compounds for work performed during 2010 and 2009. We received $255,000 of the grant in 2010 and the remaining $234,000 was received in 2011 and was included in grants receivable on the consolidated balance sheet at December 31, 2010.

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Results of Operations from the Years Ended December 31, 2011 and 2010

Research and Development Expense

	Year ended December 31,		2011 as Compared to 2010	
	2011	2010	$ Change	% Change
	(in thousands, except %)			
Research and development	$ 3,552	$ 1,066	$ 2,486	233%

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 subdivide external expenses between clinical programs and pre-clinical activities. We consider a clinical program to have begun upon acceptance by the FDA, or similar agency outside of the United States, to commence a clinical trial in humans, at which time we begin tracking expenditures by the product candidate. We have two product candidates, GM-CT-01 and GR-MD-02. GM-CT-01 is in clinical trials at this time. GR-MD-02 is currently being evaluated in pre-clinical toxicology and pharmacology studies with the aim of obtaining an IND from the FDA by the end of 2012. We will seek to gain FDA approval for Phase I and Phase II studies of GR-MD-02. Clinical program expenses comprise payments to vendors related to preparation for, and conduct of, all phases of the clinical trial, including costs for drug manufacture, patient dosing and monitoring, data collection and management, oversight of the trials and reports of results. Pre-clinical expenses comprise all research and development amounts incurred before human trials begin, including payments to vendors for services related to product experiments and discovery, toxicology, pharmacology, metabolism and efficacy studies, as well as manufacturing process development for a drug candidate.

Our research and development expenses were as follows:

	Year Ended December 31,	
	2011	2010
	(in thousands)	
Direct external expenses:		
Clinical programs	$ 666	$ 608
Pre-clinical activities	773	38
All other research and development expenses	2,113	420
	$ 3,552	$ 1,066

Clinical program and pre-clinical expenses for the year ended December 31, 2011, increased compared to the same period in 2010, due primarily to increased pre-clinical activity on our fibrosis program and clinical program activity related to GM and GR compounds. Other research and development expense increased primarily due to increased stock-based compensation ($1,261,000) and payroll expenses ($252,000) as employee salaries returned to more normal levels from the prior year.

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

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uncertainties, accurate and meaningful estimates of the ultimate cost to bring a product to market, the timing of costs and completion of our program and the period during which material net cash inflows will commence are unavailable at this time.

General and Administrative Expense

	Year ended December 31,		2011 as Compared to 2010	
	2011	2010	$ Change	% Change
	(in thousands, except %)			
General and administrative	$ 6,857	$ 3,817	$ 3,040	80%

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 increase for the year ended December 31, 2011 as compared to the same period in 2010 is due to increased payroll ($661,000) as employee salaries returned to more normal levels from the reductions during the prior periods and an additional employee starting in the second quarter of 2011 as well as the recognition of employee severance related costs, increased legal costs ($541,000) related primarily to litigation and our re-branding and name change, employee stock-based compensation costs ($772,000), and increased board of directors fees ($108,000), offset by decreased business development expenses ($367,000). Additionally, 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 in October 2011 and recognized $162,000 of related expense in 2011.

Other Income and Expense

Other income and expense for the years ended December 31, 2011 and 2010 was a loss of $506,000 and $746,000, respectively. The loss for the year ended December 31, 2011 was due primarily to the change in fair value of warrant liabilities ($524,000). The loss for the year ended December 31, 2010 was due primarily to the change in fair value of warrant liabilities ($1,241,000) offset by other income ($489,000) related to a research grant.

We were notified in November 2010 by the Internal Revenue Service that we have been awarded a total grant of $489,000 under the Qualifying Therapeutic Discovery Project Program (Section 48D of the Internal Revenue Code of 1986) for GM-CT-01 and our GR/GM-Series of anti-fibrotic, cirrhosis compounds. Of this amount, $255,000 was received in 2010 with the remaining $234,000 received in February 2011 and included in grant receivable on the consolidated balance sheet at December 31, 2010.

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, 2011, we raised a net total of $58.3 million from these offerings. At December 31, 2011, we had $6,397,000 of unrestricted cash and cash equivalents available to fund future operations. 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 $12.0 million (net proceeds of approximately $10.5 million). We believe that with the cash on hand at December 31, 2011 and $10.5 million received on March 28, 2012, there is sufficient cash to fund operations through 2013.

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,

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that such financing will be on terms favorable to us. We are actively seeking to raise additional capital and have significantly reduced our administrative and clinical spending. If we are unsuccessful in raising additional capital before the end of 2013, we may be required to cease operations or seek bankruptcy protection.

Net cash used in operations increased by $2,574,000 to $5,676,000 for 2011, as compared to $3,102,000 for 2010. Cash operating expenses increased principally due to increased research and development activities and increased general and administrative expenses.

Cash used in investing activities during 2011 consisted of an increase in restricted cash by $10,000 and equipment purchases of $5,000 as compared to no cash used in or provided by investing activities during 2010.

Net cash provided by financing activities was $6,197,000 during 2011 as compared to $8,742,000 during 2010, due primarily to the transactions described below.

In January 2011, we issued and sold 13 shares of Series C Preferred Stock for net proceeds of $130,000.

During the year ended December 31, 2011, we issued 1,771,383 shares of common stock for the exercise of common stock warrants and 216,440 shares of common stock for the exercise of common stock options, resulting in net proceeds of $5,833,000 and $234,000, respectively.

Payments Due Under Contractual Obligations

The following table summarizes the payments due under our contractual obligations at December 31, 2011, and the effect such obligations are expected to have on liquidity and cash flow in future periods:

		Payments due by period (in thousands)			
Contractual Obligations	**Total**	**Less than 1 year**	**1-3 years**	**3-5 years**	**More than 5 years**
Operating leases	$ 200	$ 200	$	$	$
Total payments due under contractual obligations	$ 200	$ 200	$	$	$

Operating leases. On May 1, 2006, we entered into an operating lease for office space. The lease commenced on August 11, 2006 and terminated on September 30, 2011. The lease provided for annual base rental payments of $235,000 in the first year, increasing in each subsequent lease year to $244,000, $253,000, $263,000 and $273,000, respectively. In addition to base rental payments included in the contractual obligations table above, we are responsible for our pro-rata share of increases in the operating expenses for the building after calendar year 2006 and taxes for the building after fiscal year 2007. In connection with this lease, a commercial bank has issued a letter of credit collateralized by cash we have on deposit with the bank of $59,000. In July 2011, we entered into an agreement to amend this lease to extend the term for a period of one year, expiring on September 30, 2012, at a base rent of $235,000 for the period.

In July 2011, we entered into an operating lease for an apartment for Company executive use for a one-year term, ending July 2012, at a rate of $41,000 for the term.

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 remaining liability related to this severance is reflected in accrued expenses ($293,000) on the consolidated balance sheet at December 31, 2010 and was paid to Dr. Platt on February 12, 2011.

The Separation Agreement also provides for the deferral of a $1.0 million severance payment due to Dr. Platt under his employment agreement until the occurrence of any of the following milestone events: (i) the approval by the Food and Drug Administration for a new drug application (NDA) for any drug candidate or

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drug delivery candidate based on the GH-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 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 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 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, 2011.

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