

GALECTIN THERAPEUTICS INC

FORM S-3

(Securities Registration Statement (simplified form))

Filed 05/19/17

Address	4960 PEACHTREE INDUSTRIAL BOULEVARD SUITE 240 NORCROSS, GA 30071
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Industry	Biotechnology & Medical Research
Sector	Healthcare
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**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM S-3
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

GALECTIN THERAPEUTICS INC.
(Exact name of registrant as specified in its charter)

Nevada
(State or other jurisdiction of
incorporation or organization)

2834
(Primary SIC
Number)

04-3562325
(I.R.S. Employer
Identification No.)

4960 Peachtree Industrial Blvd., Suite 240
Norcross, Georgia 30071
(678) 620-3186
(Address, including zip code, and telephone number, including area code, of principal executive offices)

Peter G. Traber, M.D.
Chief Executive Officer and President
Galectin Therapeutics Inc.
4960 Peachtree Industrial Blvd., Suite 240
Norcross, Georgia 30071
(678) 620-3186
(Name, address, including zip code, and telephone number, including area code, of agent for service)

With a copy to:
Robert E. Tritt
Dentons US LLP
303 Peachtree Street
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If the only securities being registered on the Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

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

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box.

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box.

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

Large accelerated filer Accelerated filer
 Non-accelerated filer (Do not check if a smaller reporting company) Smaller reporting company
 Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered(1)(2)	Proposed Maximum Offering Price Per Share(1)(2)	Proposed Maximum Aggregate Offering Price(1)(3)	Amount of Registration Fee
Primary Offering:				
Common Stock, par value \$0.001 per share				
Total Primary			\$100,000,000	\$11,590.00(4)
Secondary Offering:				
Common Stock, par value \$0.001 per share	2,994,279	\$2.39(5)	\$7,159,326.81	\$829.42
Total Primary and Secondary			\$107,156,326.81	\$12,419.42

- (1) With respect to the primary offering, such indeterminate number of shares of common stock as may from time to time be issued at indeterminate prices, with an aggregate initial offering price not to exceed \$100,000,000. This Registration Statement also relates to an indeterminate number of shares that may be issued upon stock splits, stock dividends or similar transactions in accordance with Rule 416 under the Securities Act.
- (2) With respect to the primary offering, such information is not required to be included pursuant to General Instruction II.D of Form S-3 under the Securities Act of 1933, as amended, or the Securities Act.
- (3) The proposed maximum aggregate price has been estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act.
- (4) Calculated pursuant to Rule 457(o) under the Securities Act.
- (5) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(c) under the Securities Act on the basis of the average of the high and low sale prices of the common shares on May 17, 2017, as reported on the NASDAQ Capital Market. With respect to the secondary offering, the proposed maximum offering price per share of common stock will be determined from time to time in connection with, and at the time of, the sale by the holder of such securities.

The registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until this Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

EXPLANATORY NOTE

This registration statement contains two prospectuses:

- a base prospectus which covers the offering, issuance and sale by us of up to \$100,000,000 of our common stock, and the offering and sale by selling stockholders of up to 2,994,279 shares of our common stock for resale; and
- a sales agreement prospectus covering the offering, issuance and sale by us of up to a maximum aggregate offering price of \$30,000,000 of our common stock that may be issued and sold under a sales agreement with FBR Capital Markets & Co.

The base prospectus immediately follows this explanatory note. The specific terms of any securities to be offered pursuant to the base prospectus will be specified in a prospectus supplement to the base prospectus. The sales agreement prospectus immediately follows the base prospectus. The \$30,000,000 of common stock that may be offered, issued and sold under the sales agreement prospectus is included in the \$100,000,000 of securities that may be offered, issued and sold by us under the base prospectus.

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

SUBJECT TO COMPLETION, DATED MAY 19, 2017

PROSPECTUS



Common Stock

From time to time, we may offer and sell shares of common stock in one or more offerings in amounts, at prices and on terms that we will determine at the time of the offering. The aggregate initial offering price of all securities sold by us under this prospectus will not exceed \$100,000,000. In addition, the selling stockholders may, over time, offer and sell up to 2,994,279 shares of common stock.

Each time we offer securities, we will provide you with specific terms of the securities offered in supplements to this prospectus. The prospectus supplement may also add, update or change information contained in this prospectus. You should read this prospectus, the information incorporated by reference in this prospectus, any application prospectus supplement and the additional information described below under the heading "Where You Can Find More Information" carefully before you invest in any securities.

The selling stockholders who are affiliates of the Company may be deemed to be an "underwriter" within the meaning of the Securities Act of 1933, as amended (the "*Securities Act*") and, as a result, may be deemed to be making a primary offering of securities, indirectly, on our behalf. We will not receive any of the proceeds from any sale of our shares by the selling stockholders. For a detailed discussion of the selling stockholders, please read the section captioned "Selling Stockholders" in this prospectus. The selling stockholders will be responsible for their own legal fees and expenses and for any underwriting fees, discounts and commissions due to brokers, dealers or agents. We will be responsible for all other offering expenses.

The securities offered by this prospectus may be sold directly by us or the selling stockholders to investors, through agents designated from time to time or to or through underwriters or dealers. We will set forth the names of any underwriters or agents in an accompanying prospectus supplement. For additional information on the methods of sale, you should refer to the section entitled "Plan of Distribution." The price to the public of such securities and the net proceeds we or the selling stockholders expect to receive from such sale will also be set forth in a prospectus supplement.

Our common stock is listed on The NASDAQ Capital Market under the symbol "GALT". The last reported sale price of our common stock on May 15, 2017 was \$2.73 per share.

INVESTING IN OUR SECURITIES INVOLVES A HIGH DEGREE OF RISKS. SEE "[RISK FACTORS](#)" ON PAGE 4 OF THIS PROSPECTUS AND IN THE OTHER DOCUMENTS INCORPORATED BY REFERENCE IN THIS PROSPECTUS AND THE APPLICABLE PROSPECTUS SUPPLEMENT TO READ ABOUT FACTORS YOU SHOULD CONSIDER BEFORE BUYING OUR SECURITIES.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus or the accompanying prospectus supplement is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is _____, 2017

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ABOUT THIS PROSPECTUS

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

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

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

PROSPECTUS SUMMARY

This summary highlights important features of this offering and the information included in this prospectus. This summary does not contain all of the information that you should consider before investing in our securities. You should read this prospectus carefully as it contains important information you should consider when making your investment decision. See “Risk Factors” beginning on page 7.

About Galectin Therapeutics Inc.

We are a clinical stage biopharmaceutical company engaged in drug research and development to create new therapies for fibrotic disease, severe skin disease, and cancer. Our drug candidates are based on our method of targeting galectin proteins, which are key mediators of biologic and pathologic functions. We use naturally occurring, readily-available plant products as starting material in manufacturing processes to create proprietary complex carbohydrates with specific molecular weights and other pharmaceutical properties. These complex carbohydrate molecules are appropriately formulated into acceptable pharmaceutical formulations. Using these unique carbohydrate-based candidate compounds that largely bind and inhibit galectin proteins, particularly galectin-3, we are undertaking the focused pursuit of therapies for indications where galectins have a demonstrated role in the pathogenesis of a given disease. We focus on diseases with serious, life-threatening consequences to patients and those where current treatment options are limited. Our strategy is to establish and implement clinical development programs that add value to our business in the shortest period of time possible and to seek strategic partners when a program becomes advanced and requires significant additional resources.

Our lead galectin-3 inhibitor is GR-MD-02, which has been demonstrated in preclinical models to reverse liver fibrosis and cirrhosis. GR-MD-02 has the potential to treat many diseases due to galectin-3's involvement in multiple key biological pathways such as immune cell function and immunity, cell differentiation, cell growth, and apoptosis (cell death). Galectin Therapeutics Inc. is using this inhibitor to treat advanced liver fibrosis and liver cirrhosis in NASH (non-alcoholic steatohepatitis) patients. We have completed two Phase 1 clinical studies, one Phase 2 clinical study in NASH patients with advanced fibrosis (NASH-FX) and have one ongoing Phase 2 clinical study in NASH patients with cirrhosis (NASH-CX). NASH cirrhosis is a progressive disease, currently not treatable and ultimately may result in liver failure that has poor prognosis and no effective, approved medical therapies other than liver transplant. Galectin-3 expression is highly increased in the liver of patients with liver fibrosis and liver cirrhosis. We believe that our galectin-3 inhibitor, by reducing galectin-3 at the cellular level, ultimately showing a strong anti-fibrotic potential may provide a novel treatment for various forms of liver fibrosis.

We endeavor to leverage our scientific and product development expertise as well as established relationships with outside sources to achieve cost-effective and efficient drug development. These outside sources, amongst others, provide us with expertise in preclinical models, pharmaceutical development, toxicology, clinical trial operations, pharmaceutical manufacturing, sophisticated physical and chemical characterization, and commercial development. We also have established several collaborative scientific discovery programs with leading experts in carbohydrate chemistry and characterization. These discovery programs are generally aimed at the targeted development of new carbohydrate molecules that bind galectin proteins and offer alternative options to larger market segments in our primary disease indications. We also have established a discovery program aimed at the targeted development of small molecules (non-carbohydrate) that bind galectin proteins and may afford options for alternative means of drug delivery (e.g., oral) and as a result expand the potential uses of our compounds. We are pursuing a development pathway to clinical enhancement and commercialization for our lead compounds in immune enhancement for cancer therapy and severe skin disease including moderate to severe plaque psoriasis and severe atopic dermatitis. Our clinical development efforts are focused on both liver fibrosis and fatty liver disease as represented by a Phase 2 clinical trial in NASH-cirrhosis which will report top line data in December, 2017. All of our proposed products are presently in development, including pre-clinical and clinical trials.

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

Principal Executive Offices

Our principal executive offices are located at 4960 Peachtree Industrial Blvd., Suite 240, Norcross, Georgia 30071. Our telephone number is (678) 620-3186, fax number is (770) 864-1327 and our website address is www.galectintherapeutics.com. The information on our website is not incorporated by reference into this prospectus and should not be relied upon with respect to this offering.

The Offering

Securities Offered We are offering up to \$100,000,000 in securities consisting of shares common stock. In addition, 2,994,279 shares of our common stock will be offered by selling stockholders.

Use of Proceeds We will use the net proceeds from the sale of the securities offered by this prospectus for general corporate purposes, which may include working capital, research and development, clinical trial expenditures, acquisitions of new technologies and investments. We will not receive any proceeds from the sale of shares by the selling stockholders.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

RISK FACTORS

An investment in our common stock involves a high degree of risk. You should carefully consider the risks described below and the other information before deciding to invest in our common stock. The risks described below are not the only ones facing us. 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 such risks actually occur, our business, financial condition and operating results could be materially adversely affected. In such case you may lose part or all of your investment.

Risks Related to Our Company

We have incurred net losses to date and must raise additional capital in order to continue to operate after December 31, 2017.

We have incurred net losses in each year of operation since our inception in July 2000. Our accumulated deficit as of December 31, 2016 was \$163.7 million. We had \$15.4 million of unrestricted cash as of December 31, 2016. Additionally, from January 1, 2017 through March 31, 2017, the Company raised \$1,945,000 in net proceeds from the issuance of common stock under its At the Market sales arrangement. On February 28, 2017, the Company closed a transaction with individual investors through private placements of common stock and warrants. In total, the Company issued 102,368 shares of common stock for proceeds of \$200,000. The Company also issued, to the investors, warrants to purchase 76,776 shares of common stock at \$5.00 per share. The Company believes there is sufficient cash to fund currently planned operations through December 31, 2017. We will require more cash to fund our operations after December 31, 2017. 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. If our current clinical trials are unsuccessful or do not produce positive results, it may be particularly difficult for us to raise additional capital. If we do not raise additional cash for operations after the first quarter of 2017, we may not be able to continue operations.

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

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

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

Our ability to generate revenue from product sales and achieve profitability will depend upon our ability to successfully commercialize products, including any of our current product candidates, or other product candidates that we may in-license or acquire in the future. Even if we are able to successfully achieve regulatory approval for these product candidates, we do not know when any of these products will generate revenue from product sales for us, if at all. Our ability to generate revenue from product sales from our current or future product candidates also depends on a number of additional factors, including our ability to:

- successfully complete development activities, including the necessary clinical trials;
- complete and submit new drug applications, or NDAs, to the U.S. Food and Drug Administration, or FDA, and obtain regulatory approval for indications for which there is a commercial market;

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- complete and submit applications to, and obtain regulatory approval from, foreign regulatory authorities;
- successfully complete all required regulatory agency inspections;
- set a commercially viable price for our products;
- obtain commercial quantities of our products at acceptable cost levels;
- find suitable distribution partners to help us market, sell and distribute our approved products in other markets; and
- obtain coverage and adequate reimbursement from third parties, including government and private payers.

In addition, because of the numerous risks and uncertainties associated with product development, including that our product candidates may not advance through development or achieve the endpoints of applicable clinical trials, we are unable to predict the timing or amount of increased expenses, or when or if we will be able to achieve or maintain profitability. Even if we are able to complete the development and regulatory process for any product candidates, we anticipate incurring significant costs associated with commercializing these products.

If we are able to generate revenues from the sale of our products, we may not become profitable and may need to obtain additional funding to continue operations. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce our operations.

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

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

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

GR-MD-02 our lead product candidate for fibrosis has completed Phase 1 of the human clinical trial phase of drug development in the US and is currently in Phase 2 clinical trials in North America. GR-MD-02 is also currently in investigator sponsored, human Phase 1B clinical trials being conducted by Providence Portland Medical Center in combination with Yervoy® (ipilimumab) and Keytruda (pembrolizumab) in patients with metastatic melanoma. We cannot assure you that these trials will yield successful results, that they will lead to the generation of revenue, or that we will obtain regulatory approval in other countries.

There are currently no FDA clinical trials ongoing for GM-CT-01.

We filed for an IND with the FDA for GR-MD-02 in January 2013 for initiating human clinical trials in patients with NASH, and the FDA notified us in March 2013 that we may proceed with a Phase 1 clinical trial. Our Phase 1 clinical trial began in July 2013 and was completed in 2014. Pre-clinical studies and clinical trials are expensive, time-consuming and ultimately may not be successful. The results of pre-clinical and initial clinical testing of these products may not necessarily indicate the results that will be obtained from later or more extensive testing. Also, it is possible to suffer significant setbacks in advanced clinical trials, even after obtaining promising results in earlier trials. For example, our Phase 2a pilot trial NASH-FX for patients with advanced fibrosis, which explored three non-invasive imaging technologies, did not meet its primary endpoint. 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 GR-MD-02, GM-CT-01 and other future product candidates achieve positive results in clinical trials, we may be unable to commercialize them. The availability of government and third party payer reimbursement, and pricing, especially compared to competitor products, could affect our ability to commercialize our product candidates. Our general inability to obtain necessary regulatory approvals and, if obtained, to commercialize our products would substantially impair our viability.

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

As we develop products eligible for clinical trials, we will contract with independent parties to assist us in the design of the trial protocols, arrange for and monitor the clinical trials, collect data and analyze data. For instance, in 2015, we entered into an agreement

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with PPD Development, L.P. (PPD) for the purpose of assisting us in the design, development and conduct of one or more clinical research studies from time to time. In accordance with this agreement, PPD is conducting the Phase 2 clinical trial for GR-MD-02 to evaluate the drug's safety in subjects with NASH with advanced hepatic cirrhosis. In addition, certain clinical trials for our products may be conducted by government-sponsored agencies and will be dependent on governmental participation and funding. Additionally, GR-MD-02 is being studied by Providence Portland Medical Center in Investigator-sponsored INDs to conduct a Phase 1B studies to determine if GR-MD-02 enhances the probability of melanoma response with ipilimumab and pembrolizumab by inducing proliferation, activation and memory function of CD8+ T cells in human patients. This study represents a novel approach for patients with metastatic melanoma.

Our dependence on independent parties and clinical sites involves risks including reduced control over the timing and other aspects of our clinical trials.

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

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

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

Even if engaged, these distributors may:

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

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

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. We have agreed to reimburse many of our trial sites for certain medical expenses of clinical trial subjects if they are injured during the trial, and the expenses that could arise from such agreements are not budgeted or provided for and could result in us being able to complete our clinical trials. In addition, the use in our clinical trials of pharmaceutical formulations and products that our potential collaborators may develop and the subsequent sale of such formulations or products by us or our potential collaborators may cause us to assume a portion of or all of the product liability risks. A successful liability claim or series of claims brought against us could have a material adverse effect on our business, financial condition and results of operations.

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

We face intense competition in the biotechnology and pharmaceutical industries.

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

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

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

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

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 may 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 may engage 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 fail 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.

Our long term success is dependent not only upon the success of our current trials but also upon us being able to capitalize upon potential positive results of our trials, which is not assured.

We have marshaled our cash resources in order to increase the likelihood of having sufficient cash resources to complete our current clinical trial. We believe we have sufficient dosages of GR-MD-02 for these purposes. However, we have deferred the manufacture of additional GR-MD-02 that would be required for follow-on trials, and lead times are needed for this manufacturing. Further because of limited resources, we have curtailed most of our expenditures in research focused on the development of an oral galectin inhibitor to replace our current drug candidate that is delivered via infusion. Further, because of financial limits we have not designed follow-on trials for fibrosis, skin disease or cancer. Even if our current trials are successful, we may be adversely affected by the time needed to restart programs curtailed by financial constraints.

We are a defendant a consolidated shareholder derivative action and a state court shareholder derivative action and these lawsuits and any future such lawsuits may adversely affect our business, financial condition, results of operations and cash flows.

We and certain of our officers and directors are defendants in a consolidated shareholder derivative action and a state court shareholder derivative action. These lawsuits are described in Part I, Item 3 “Legal Proceedings” in our Annual Report on Form 10-K, which is incorporated herein by reference. These lawsuits may divert our attention from our ordinary business operations, and we may incur significant expenses associated with their defense (including, without limitation, substantial attorneys’ fees and other fees of professional advisors and potential obligations to indemnify current and former officers and directors who are or may become parties to such actions). Accordingly, the ultimate resolution of these matters could have a material adverse effect on our business, results of operations, financial condition, liquidity and ability to meet our debt obligations and, consequently, could negatively impact the trading price of our common stock. In addition, there is the potential for additional shareholder litigation and for governmental investigations and/or enforcement actions. Any existing or future shareholder lawsuits and any future governmental investigations and/or enforcement actions could adversely impact our reputation, our relationships with our customers and our ability to generate revenue.

Risks Related to the Regulation of our Products

We will need regulatory approvals to commercialize our products.

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

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 trials;
- the number of sites included in the trials;

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- the countries in which the trial are conducted;
- the length of time required and ability to enroll eligible patients;
- the number of patients that participate in the trials;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- per patient trial costs;
- third party contractors failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner;
- our drug product candidates having different chemical and pharmacological properties in humans than in lab testing;
- the need to suspend or terminate our clinical trials;
- 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.

Each of the above factors and other unanticipated factors beyond our control could prevent us from gaining approval for our drugs in a cost-effective and timely manner, which could have a material adverse impact on our business.

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 or potential replacement legislation. It is possible that the adoption of this legislation or replacement legislation could harm our business, financial condition and results of operations.

Data obtained from clinical trials are not necessarily predictive of future results, 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. Despite the results reported in some of our earlier clinical trials for GR-MD-02, 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. If later-stage clinical trials do not produce favorable results, our ability to achieve regulatory approval for any of our product candidates may be adversely impacted. 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 product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following any marketing approval.

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authority. Although we are not currently aware of any undesirable side effects caused by our product candidates, it is possible that they may be identified in the clinical trial process.

As a result of undesirable side effects or safety or toxicity issues that we may experience in our clinical trials, we may not receive approval to market any product candidates, which could prevent us from ever generating revenues or achieving profitability. Results of our trials could reveal an unacceptably high severity and prevalence of side effects. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development or deny approval of our product candidates for any or all targeted indications. These side effects could affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims.

Additionally, if any of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result, including:

- we may be forced to suspend marketing of such product;
- regulatory authorities may withdraw their approvals of such product;
- regulatory authorities may require additional warnings on the label that could diminish the usage or otherwise limit the commercial success of such products;
- we may be required to conduct post-market studies;
- we could be sued and held liable for harm caused to subjects or patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved.

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

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

Failure to obtain regulatory approval in international jurisdictions would prevent our product candidates from being marketed abroad.

In order to market and sell our products in the European Union and many other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market. If we are unable to obtain approval of any of our product candidates by regulatory authorities in the European Union or other countries, the commercial prospects of that product candidate may be significantly diminished and our business prospects could decline.

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 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.

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.

Risks Related to Our Common Stock

The market price of our common stock may be volatile and adversely affected by several factors. This could subject us to securities class action litigation and our stockholders could incur substantial losses.

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

- the results of our pre-clinical studies and clinical trials, including interim results, as well as those of our competitors;
- regulatory actions with respect to our products or our competitors' products;
- 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 may be necessary to fund our operating expenses;
- announcements of technological innovations or new products by us or our competitors;
- the success of competitive products;
- loss of any strategic relationship;
- industry developments, including, without limitation, changes in healthcare policies or practices or third-party reimbursement policies;
- regulatory or legal developments in the United States and other countries;
- the level of expenses related to any of our product candidates or clinical development programs;
- disputes or other developments related to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- economic and other external factors;
- period-to-period fluctuations in our financial results;
- sales of our common stock by us, our insiders or our other stockholders;
- whether an active trading market in our common stock develops and is maintained; and
- engagement and retention of senior management needed for our clinical trials.

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, including us, 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. As described above, we are currently defending a consolidated federal securities class action lawsuit and a consolidated shareholder derivative actions and we may become involved in additional instances of 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 capital, 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 (14,001,000 designated as of December 31, 2016), and empowers our board of directors to prescribe, by resolution and without stockholder approval, a class or series of undesignated shares, including the number of shares in the class or series and the voting powers, designations, rights, preferences, restrictions and the relative rights in each such class or series. Accordingly, we may designate and issue additional shares or series of preferred stock that would rank senior to the shares of common stock as to dividend rights or rights upon our liquidation, winding-up, or dissolution.

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

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

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

The 10X Fund owns all of our issued and outstanding Series B Preferred Stock, which are convertible into 3,789,346 shares of our common stock. The 10X Fund owns related warrants exercisable to purchase an aggregate of 6,469,038 shares of our common stock. As of March 31, 2017, we have issued 2,054,149 shares of our common stock as dividends on the Series B Preferred Stock and 2,000,000 shares of our common stock on the exercise of warrants by 10X Fund. In addition, James C. Czirr, a managing member of 10X Capital Management, LLC, the general partner of the 10X Fund and one of our directors, owns or controls approximately 904,000 shares of our common stock, including shares of Series A on an as converted basis, and has the right to acquire 653,250 additional shares of our common stock upon the exercise of outstanding stock options (622,000 of which are exercisable as of March 31, 2017). As of March 31, 2017, 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 25% of our then outstanding shares of common stock, which, together with the shares of our common stock that would be owned by Mr. Czirr (assuming exercise of all options at that date), would constitute approximately 28% of the then fully diluted shares.

As holder of Series B Preferred Stock, the 10X Fund is entitled to elect two directors in a separate class vote, nominate three directors for election by all shares entitled to vote, and provide or withhold consent to a range of fundamental corporate actions 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, such as sales of additional securities of the Company needed to fund the ongoing clinical trial program of the Company. In addition to the conversion rights and the right to elect and nominate directors noted above, the 10X Fund, as holder of the Series B Preferred Stock, has certain approval rights, including the right to approve certain financing transactions, as well as the right to participate in certain financing transactions. These rights could negatively impact our ability to raise capital in the future, which could materially and adversely affect our business.

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

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

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

Finance transactions resulting in a large amount of newly issued shares that become readily tradable, or other events that cause current stockholders to sell shares, could place downward pressure on the trading price of our stock. Some of our shareholders have registration rights to facilitate sales of large blocks of our common stock. We have filed a shelf registration statement to allow registered sales of up to 9.7 million shares by these shareholders. We may consider additional capital raising transactions within the next twelve months, which would likely result in issuances of additional shares which would be dilutive to current shareholders. In addition, the lack of a robust resale market may require a stockholder who desires to sell a large number of shares of common stock to sell the shares in increments over time to mitigate any adverse impact of the sales on the market price of our stock.

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If our stockholders sell, or the market perceives that our stockholders intend to sell for various reasons 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.

At times, our shares of common stock and warrants have been 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, 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 be sustained, or that current trading levels will be sustained or not diminish.

We may not meet the continued listing standards of The NASDAQ Capital Market, which requires a minimum closing bid price of \$1.00 per share, which could result in our delisting and negatively impact the price of our common stock and our ability to access the capital markets.

We may not meet the continued listing standards of The NASDAQ Capital Market, which requires a minimum closing bid price of \$1.00 per share, which could result in our delisting and negatively impact the price of our common stock and our ability to access the capital markets.

Our common stock is listed on The NASDAQ Capital Market. NASDAQ provides various continued listing requirements that a company must meet in order for its stock to continue trading on the NASDAQ Capital Market. Among these requirements is the requirement that the Company's stock trades at a minimum bid price of \$1.00 per share. Our stock has recently traded below \$1.00 per share, including closing bid prices below \$1.00 per share. Between October 7, 2016 and November 11, 2016, our stock closed with a bid price below \$1.00 for 26 consecutive trading days. If our stock price closes with a bid price below \$1.00 per share for 30 consecutive trading days, we expect to receive a notice from NASDAQ providing us with 180 calendar days to regain compliance with the rule. After this 180 day period is up, if we still do not comply with the minimum \$1.00 bid price we may be eligible for an additional 180 day period to regain compliance. However, if we fail to comply with the minimum stock price of \$1.00 per share or any other continued listing standards of NASDAQ, our common stock may be delisted. If that were to occur, our stock would be subject to rules that impose additional sales practice requirements on broker-dealers who sell our securities. The additional burdens imposed upon broker-dealers by these requirements could discourage broker-dealers from effecting transactions in our common stock. This would significantly affect the ability of investors to trade our securities and would significantly negatively affect the value and liquidity of our common stock. These factors could contribute to lower prices and larger spreads in the bid and ask prices for our common stock. Also, if we seek to implement a reverse stock split in order to remain listed on The NASDAQ Capital Market, the announcement and/or implementation of a reverse stock split could significantly negatively affect the price of our common stock.

USE OF PROCEEDS

Except as otherwise provided in the applicable prospectus supplement, we intend to use the net proceeds from the sale of the securities offered by this prospectus for general corporate purposes, which may include working capital, research and development, clinical trial expenditures, acquisitions of new technologies and investments, and the repayment or redemption of preferred stock. We will not receive any proceeds from any sale of securities by the Selling Stockholder. Additional information on the use of net proceeds from the sale of securities offered by this prospectus may be set forth in the prospectus supplement relating to that offering.

DESCRIPTION OF SECURITIES

Common Stock

We currently have authorized 50,000,000 shares of common stock, par value \$0.001 per share. As of March 31, 2017, there were 34,670,684 shares of common stock outstanding. Holders of our common stock have no preemptive rights and no right to convert their common stock into any other securities. There are no redemption or sinking fund provisions applicable to the common stock. All outstanding shares of our common stock are fully paid and non-assessable.

The following summary of the terms of our common stock is subject to and qualified in its entirety by reference to our Articles of Incorporation and by-laws, copies of which are on file with the SEC as exhibits to previous SEC filings. Please refer to the section entitled “Where You Can Find More Information” for directions on obtaining these documents.

Voting Rights. The holders of our common stock are entitled to one vote for each share held of record on all matters submitted to a vote of stockholders, including, without limitation, the election of our board of directors. Our stockholders have no right to cumulate their votes in the election of directors.

Dividends. Subject to preferences that may apply to shares of preferred stock outstanding at the time, the holders of our common stock are entitled to receive ratably those dividends declared from time to time by the board of directors. We have never declared or paid any cash dividends on our common stock, and we do not currently intend to pay any cash dividends on our common stock for the foreseeable future. We expect to retain future earnings, if any, to fund the development and growth of our business. Any future determination to pay dividends on our common stock will be at the discretion of our board of directors and will depend upon, among other factors, our financial condition, operating results, current and anticipated cash needs, plans for expansion and other factors that our board of directors may deem relevant.

Rights Upon Liquidation. Subject to preferences that may apply to shares of preferred stock outstanding at the time, in the event of liquidation, dissolution or winding up, holders of our common stock, pari passu with the holders, if any, of Common Stock (Class W) are entitled to share ratably in assets remaining after payment of liabilities.

Anti-Takeover Effects of Certain Provisions of Nevada Law

Effect of Nevada Anti-takeover Statute. We are subject to Section 78.438 of the Nevada Revised Statutes, an anti-takeover law. In general, Section 78.438 prohibits a Nevada corporation from engaging in any business combination with any interested stockholder for a period of three years following the date that the stockholder became an interested stockholder, unless prior to that date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder. Section 78.439 provides that business combinations after the three year period following the date that the stockholder becomes an interested stockholder may also be prohibited unless approved by the corporation’s directors or other stockholders or unless the price and terms of the transaction meet the criteria set forth in the statute.

Section 78.416 defines “business combination” to include the following:

- any merger or consolidation involving the corporation and the interested stockholder or any other corporation which is an affiliate or associate of the interested stockholder;
- any sale, transfer, pledge or other disposition of the assets of the corporation involving the interested stockholder or any affiliate or associate of the interested stockholder if the assets transferred have a market value equal to 5% or more of all of the assets of the corporation or 5% or more of the value of the outstanding shares of the corporation or represent 10% or more of the earning power of the corporation;
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation with a market value of 5% or more of the value of the outstanding shares of the corporation;

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- the adoption of a plan of liquidation proposed by or under any arrangement with the interested stockholder or any affiliate or associate of the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder or any affiliate or associate of the interested stockholder; or
- the receipt by the interested stockholder or any affiliate or associate of the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 78.423 defines an interested stockholder as any entity or person beneficially owning, directly or indirectly, 10% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by any of these entities or persons.

Control Share Acquisitions. Sections 78.378 through 78.3793 of the Nevada Revised Statutes limit the voting rights of certain acquired shares in a corporation. The provisions apply to any acquisition of outstanding voting securities of a Nevada corporation that has 200 or more stockholders, at least 100 of which are Nevada residents, and conducts business in Nevada (an “issuing corporation”) resulting in ownership of one of the following categories of an issuing corporation’s then outstanding voting securities: (i) twenty percent or more but less than thirty-three percent; (ii) thirty-three percent or more but less than fifty percent; or (iii) fifty percent or more. The securities acquired in such acquisition are denied voting rights unless a majority of the security holders approve the granting of such voting rights. Unless an issuing corporation’s articles of incorporation or bylaws then in effect provide otherwise: (i) voting securities acquired are also redeemable in part or in whole by an issuing corporation at the average price paid for the securities within 30 days if the acquiring person has not given a timely information statement to an issuing corporation or if the stockholders vote not to grant voting rights to the acquiring person’s securities, and (ii) if outstanding securities and the security holders grant voting rights to such acquiring person, then any security holder who voted against granting voting rights to the acquiring person may demand the purchase from an issuing corporation, for fair value, all or any portion of his securities. These provisions do not apply to acquisitions made pursuant to the laws of descent and distribution, the enforcement of a judgment, or the satisfaction of a security interest, or made in connection with certain mergers or reorganizations.

Undesignated Stock

We are currently authorized to issue 20,000,000 shares of undesignated stock, par value \$0.01 per share, the rights and privileges of which may be established from time to time by our board of directors. As of the date of this prospectus, our board of directors has designated:

- 1,742,500 as Series A 12% Convertible Preferred Stock, or Series A Preferred Stock, 1,377,500 of which are issued and outstanding as of the date of this prospectus;
- 900,000 as Series B-1 Convertible Preferred Stock, or Series B-1 Preferred Stock, 2,100,000 as Series B-2 Convertible Preferred Stock, 2,508,000 as Series B-3 Convertible Preferred Stock, referred to together as the Series B Preferred Stock, all of which are issued and outstanding as of the date of this prospectus;
- 1,000 as Series C Super Dividend Convertible Preferred Stock, or Series C Preferred Stock, of which 176 are issued and outstanding as of the date of this prospectus; and
- 12,748,500 as Common Stock (Class W), of which no shares are issued and outstanding as of the date of this prospectus.

Series A 12% Convertible Preferred Stock

The shares of Series A Preferred Stock accrue interest at 12% per annum payable at our option in cash or shares of common stock valued per share at the higher of \$6.00 or 100% of the value weighted average price of our shares of common stock for the 20 consecutive trading days prior to the applicable dividend payment date. Holders are entitled to vote as a class with the common stock and each share of Series A Preferred Stock is convertible at any time to one-sixth share of common stock, subject to adjustment in the event of a stock dividend, stock split or combination, reclassification or similar event. We may require conversion if the closing price of the common stock exceeds \$18.00 for 15 consecutive trading days and a registration statement covering the resale of the shares of common stock issuable upon conversion of the Series A Preferred Stock is then in effect.

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Series B Redeemable Convertible Preferred Stock

On February 12, 2009, the Company entered into a securities purchase agreement (the “10X Agreement”) pursuant to which it agreed to issue and sell to 10X Fund LP, at two or more closings, up to: (i) 3,000,000 shares its Series B-1 and B-2 convertible preferred stock with an aggregate stated value of \$6.0 million and convertible into 2,000,000 shares of common stock at December 31, 2011 and (ii) warrants to purchase 6,000,000 shares of common stock.

Through a series of closings from February 2009 through May 2010, the Company issued and sold, pursuant to the 10X Agreement, a total of (i) 900,000 shares of Series B-1 convertible preferred stock (“Series B-1 convertible preferred stock” or “Series B-1”) and related common stock warrants for 1,800,000 shares of common stock and (ii) 2,100,000 shares of Series B-2 convertible preferred stock (“Series B-2 convertible preferred stock” or “Series B-2”) and related warrants for 4,200,000 shares of common stock for total net proceeds of \$5,483,000.

On September 22, 2016, the Company entered into a securities purchase agreement (the “B-3 Agreement”) pursuant to which it agreed to issue and sell to 10X Fund LP: (i) 1,500,000 shares its Series B-3 convertible preferred stock (“Series B-3 preferred stock” or “Series B-3”) with an aggregate stated value and proceeds of \$1.5 million and convertible into 892,349 shares of common stock, and (ii) warrants to purchase up to 669,262 shares of common stock. Also, pursuant to agreements signed on September 22, 2016 with 10X Fund LP, the Company issued 875,000 warrants to purchase common stock in exchange for the 10X Fund LP agreeing not to sell any shares of common or preferred stock in the Company for 18 months, except in limited circumstances.

On December 23, 2016, the Company and 10X Fund LP amended the B-3 Agreement whereby the Company agreed to issue and sell to 10X Fund LP an additional (i) 1,008,000 shares of its B-3 preferred stock with an aggregate stated value and proceeds of \$1.0 million and convertible into 896,997 shares of common stock, and (ii) warrants to purchase up to 924,780 shares of common stock.

The terms of the Series B are as follows:

Dividends . Holders of the Series B will be entitled to receive cumulative dividends at the rate of 12% for Series B-1 and B-2 and 8% for Series B-3 per annum (compounding monthly) payable quarterly which may, at the Company’s option, be paid in cash or common stock valued at 100% of the volume weighted average price of the Common Stock for the 20 consecutive trading days prior to the dividend payment date on and after September 30, 2011. If the Company does not pay any dividend on the Series B, dividends will accrue at the rate of 15% per annum (compounding monthly).

Conversion Rights . Each share of Series B-1 and B-2 is convertible into two-thirds (approximately 0.667) shares of common stock at the conversion price of \$3.00 per share at the option of the holder, at any time. The shares of Series B-3 are convertible into 1,789,346 shares of common stock at the option of the holder, at any time.

Liquidation Rights . In the event of any liquidation, dissolution or winding up of the Company, either voluntarily or involuntarily, the holders of Series B-1 and B-2 will receive \$2 per share and holders of B-3 will receive \$1 per share plus accrued and unpaid dividends, payable prior and in preference to any distributions to the holders of Common Stock but pari passu with the holders of the Series A 12% Convertible Preferred Stock.

Voting Rights . Except as noted below, the holder of each share of Series B-3 shall be entitled to the number of votes equal to the number of shares of Common Stock into which such share of Series B-3 would be convertible, and shall otherwise have voting rights and powers equal to the voting rights and powers of the Common Stock. With respect to the election of directors, the holders of the Series B-3, together with the holders of Series B-1 and Series B-2, shall vote together as a separate class to elect two (2) members of the Board of Directors (the “Series B Directors”), and the Company shall take all reasonably necessary or desirable actions within its control (including, without limitation, calling special meetings of the Board of Directors, nominating such persons designated by the holders of the Series B as directors on the applicable proxy statements and recommending their election) to permit the holders of the Series B to appoint three additional (3) members of the Board of Directors (the “Series B Nominees”), who shall be subject to election by all shares of voting stock of the Company voting together as a single group, until there are no longer any shares of Series B outstanding. The holders of Series B shall vote together with the holders of Common Stock and other voting capital stock of the Company to elect all other members of the Board of Directors.

Other Restrictions . So long as any shares of the Series B remain outstanding, the Company may not, without the approval of the holders of a majority of the shares of Series B outstanding, among other things, (i) change the size of the Company’s Board of Directors; (ii) amend or repeal the Company’s Articles of Incorporation or Bylaws or file any articles of amendment designating the preferences, limitations and relative rights of any series of preferred stock, that would alter or change the preferences, rights, privileges or powers of, or restriction provided for the benefit of the Series B; (iii) create or increase the authorized amount of any additional class or series of shares of stock that is equal to or senior to Series B; (iv) increase or decrease the authorized number of shares of the Series B; (v) purchase, redeem or otherwise acquire for value any shares of any class of capital stock; (vi) merge or consolidate the Company into or with any other corporation or sell, assign, lease, pledge, encumber or otherwise dispose of all or

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substantially all of the Company's assets or those of any subsidiary; (vii) voluntarily or involuntarily liquidate, dissolve or wind up the Company or the Company's business; (viii) pay or declare dividends on any capital stock other than the Preferred Stock, unless the Series B share ratably in such dividend and all accrued dividends payable with respect to the Series B have been paid prior to the payment or declaration of such dividend; (ix) acquire an equitable interest in, or the assets or business of any other entity in any form of transaction; (x) create or commit us to enter into a joint venture, licensing agreement or exclusive marketing or other distribution agreement with respect to the Company's products, other than in the ordinary course of business; (xi) permit the Company or any subsidiary to sell or issue any security of such subsidiary to any person or entity other than the Company; (xii) enter into, create, incur, assume or guarantee any indebtedness for borrowed money of any kind (other than indebtedness existing on the initial closing date and approved by Series B shareholders); (xiii) enter into, create, incur or assume any liens of any kind (other than certain permitted liens); (xiv) issue any common stock or common stock equivalents; (xv) increase the number of shares of the Company's common stock that may be issued pursuant to options, warrants or rights to employees, directors, officers, consultants or advisors above the number of shares that were authorized for issuance under our 2001 Stock Incentive Plan, 2003 Non-Employee Director Stock Incentive Plan and 2009 Incentive Compensation Plan as of September 9, 2016.

Series C Super Dividend Preferred Stock

Conversion Rights . Each holder of Series C may convert all, but not less than all, of his Series C shares plus accrued and unpaid dividends into Common Stock at the price of \$6.00 per share of Common Stock ("Conversion Price"), such that approximately 1,667 shares of Common Stock will be issued per each converted share of Series C (accrued and unpaid dividends will be issued as additional shares). At December 31, 2013, the 196 outstanding shares of Series C were convertible into a total of approximately 326,667 shares of Common Stock. Subject to the continuing obligation to pay post conversion dividends, we may convert all, but not less than all, of the Series C (plus all accrued and unpaid dividends) into Common Stock, at the Conversion Price, upon such time that the closing price of the Common Stock is no less than \$18.00 per share for 15 consecutive trading days.

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

The dividend shall be payable in arrears semiannually on March 31 and September 30, beginning with the first such date after the original issue date; provided, however, that all dividends and all other distributions shall cease, and no further dividends or other distributions shall be paid, in respect of each share of Series C from and after such time that the Maximum Payout has been paid in respect of such share of Series C. Such dividends shall be payable at the Company's option either in cash or in duly authorized, fully paid and non-assessable shares of Common Stock valued at the higher of (i) \$3.00 per share or (ii) the average of the Common Stock trading price for the ten (10) consecutive trading days ending on the trading day that is immediately prior to the dividend payment date.

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

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

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

ROI Percentage

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

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

Except for shares of Series A Preferred Stock, Series B Preferred Stock, and Series C Preferred Stock, there are no other shares of preferred stock outstanding as of the date of this prospectus.

Transfer Agent and Registrar. The transfer agent and registrar for any series or class of preferred stock will be set forth in the applicable prospectus supplement.

Common Stock (Class W)

Voting Rights. The holders of our Common Stock (Class W) are entitled to one vote for each share held of record on all matters submitted to a vote of stockholders, including, without limitation, the election of our board of directors, and shall otherwise have voting rights and powers equal to the voting rights and powers of our common stock. Our stockholders have no right to cumulate their votes in the election of directors.

Dividends. Subject to preferences that may apply to shares of preferred stock outstanding at the time, the holders of our Common Stock (Class W) are entitled to receive ratably those dividends declared from time to time by the board of directors and to the same extent that dividends are declared and paid on shares of common stock.

Rights Upon Liquidation. Subject to preferences that may apply to shares of preferred stock outstanding at the time, in the event of liquidation, dissolution or winding up, holders of our Common Stock (Class W) are entitled to share ratably with holders of common stock in assets remaining after payment of liabilities.

SELLING STOCKHOLDERS

This prospectus covers the sale by the selling stockholders from time to time of up to 2,994,279 shares of common stock.

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

We have listed below:

- the name of each selling stockholder;
- the number of shares of common stock beneficially owned by each selling stockholder as of the date of this prospectus;
- the maximum number of shares of common stock being offered by each of them in this offering; and

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- the number of shares of common stock to be owned by each selling stockholder after this offering (assuming sale of such maximum number of shares) and the percentage of the class which such number constitutes (if one percent or more).

Except as otherwise noted below, during the last three years, no selling stockholder has been an officer, director or affiliate of our company, nor has any selling stockholder had any material relationship with our company or affiliates during that period. Each selling stockholder represented at the closing of the private placement that it did not have any contract, undertaking, agreement or arrangement with any person to sell, transfer, pledge, hypothecate, grant any option to purchase or otherwise dispose of any of the securities. Based on information provided to us by the selling stockholders, the selling stockholders purchased the securities in the ordinary course of business.

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

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

We do not know when or in what amounts a selling stockholder may offer shares for sale. The selling stockholders might not sell any or all of the shares offered by this prospectus. Because the selling stockholders may offer some or all of the shares pursuant to this prospectus, and because there are currently no agreements, arrangements or understandings with respect to any of the shares, we cannot estimate the number of the shares that will be held by the selling stockholders after completion of the offering. However, for purposes of this table, we have assumed that, after completion of the offering, none of the shares covered by this prospectus will be held by the selling stockholders. The numbers of shares shown under the column “Common Stock Owned Upon Completion of this Offering” reflect the assumption solely for purpose of this table that such shares are still owned upon completion of the offering, which assumption is not intended to override the selling stockholder table in, as applicable, any other prospectus covering the resale of any other of our securities by the selling stockholder.

Name of Selling Stockholder	Common Stock Beneficially Owned Prior to Offering	Common Stock Offered Pursuant to this Prospectus	Common Stock Owned Upon Completion of this Offering		Percentage of Common Stock Owned Upon Completion of this Offering
Richard Uihlein (1)	2,529,909	1,954,939	574,970	(2)	*
Living Rock Foundation	85,929	85,929	0	(2)	*
Living Stones Foundation Charitable Trust	322,234	322,234	0	(2)	*
Kary Eldred	21,482	21,482	0	(2)	*
Kenneth & Roberta Eldred Revocable Trust	430,496	429,646	850	(2)	*
Steven J. Labovitz	12,796	12,796	0	(2)	*
Loren S. Kendis	12,796	12,796	0	(2)	*
Ronna Fisher	12,796	12,796	0	(2)	*
Robert E. Tritt (3)	17,796	12,796	5,000	(2)	*
Stanley M. Marks	51,184	51,184	0	(2)	*
SBH Sciences (4)	73,333	73,333	0	(2)	*
Luther Johnson	28,958	4,348	24,610	(2)	*

* less than one percent.

Percentage calculations are based on 34,670,684 shares of our common stock issued and outstanding as of March 31, 2017.

- Does not include shares held by 10X Fund, L.P. (“10X Fund”). Selling stockholder is a limited partner owning a minority investment in 10X Fund and as such, does not have voting or dispositive power over the shares held by 10X Fund.
- Assumes all offered shares are sold.

- (3) Robert E. Tritt serves as outside legal counsel to the Company.
- (4) The Company has an agreement to issue common stock and warrants monthly in 2017 in exchange for services provided by SBH Sciences in an amount up to \$100,000 for 2017. Shares are issued monthly using the closing price on the last day of the month divided into the amount of services provided for that month. Additionally, the Company issues warrants monthly to purchase 10% of the number of shares issued that month with an exercise price of \$5.00 per share. For purposes hereof, we have assumed that 73,333 shares may be issued pursuant to such agreement.

PLAN OF DISTRIBUTION

We may sell the securities covered by this prospectus in any of three ways (or in any combination):

- to or through underwriters or dealers;
- directly to a limited number of purchasers or to a single purchaser; or
- through agents.

Each time we offer and sell securities, we will provide a prospectus supplement that will set forth the terms of the offering of the securities covered by this prospectus, including:

- the name or names of any underwriters, dealers or agents and the amounts of securities underwritten or purchased by each of them;
- the purchase price of the securities and the proceeds we will receive from the sale;
- any over-allotment options under which underwriters may purchase additional securities;
- any underwriting discounts or commissions or agency fees and other items constituting underwriters' or agents' compensation;
- the initial public offering price of the securities;
- any discounts, commissions or concessions allowed or re-allowed or paid to dealers; and
- any securities exchange or market on which the securities may be listed.

Any public offering price and any discounts or concessions allowed or re-allowed or paid to dealers may be changed from time to time.

Underwriters or dealers may offer and sell the securities from time to time in one or more transactions, including negotiated transactions, at a fixed public offering price or at varying prices determined at the time of sale. If underwriters or dealers are used in the sale of any securities, the securities will be acquired by such underwriters or dealers for their own account and may be resold from time to time in one or more transaction described above. We may offer the securities to the public through underwriting syndicates represented by managing underwriters, or directly by underwriters or dealers. Subject to certain conditions, the underwriters or dealers will be obligated to purchase all the securities of the series offered by the prospectus supplement. We will describe the nature of any such relationship in the prospectus supplement, naming the underwriter or dealer.

We may use underwriters with whom we have a material relationship. We may sell the securities through agents from time to time. The prospectus supplement will name any agent involved in the offer or sale of the securities and any commissions we pay to them. Unless the prospectus supplement states otherwise, any agent will be acting on a best efforts basis for the period of its appointment.

We may authorize underwriters, dealers or agents to solicit offers by certain purchasers to purchase securities from us at the public offering price set forth in the prospectus supplement pursuant to delayed delivery contracts providing for payment and delivery on a specified date in the future. The prospectus supplement will set forth the conditions to these contracts and any commissions we pay for solicitation of these contracts.

To comply with applicable state securities laws, the securities offered by this prospectus will be sold, if necessary, in such jurisdictions only through registered or licensed brokers or dealers. In addition, securities may not be sold in some states unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

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Each selling stockholder and any of his, her or its pledgees, donees, assignees and successors-in-interest may, from time to time, sell any or all of his, her or its shares on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These sales may be at fixed or negotiated prices. A selling stockholder may use any one or more of the following methods when selling shares:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales entered into after the effective date of the registration statement of which this prospectus is a part;
- broker-dealers may agree with the selling stockholders to sell a specified number of shares at a stipulated price per share;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- a combination of any of these methods of sale; or
- any other method permitted pursuant to applicable law.

The selling stockholders may also sell shares under Rule 144 under the Securities Act of 1933, as amended, or the Securities Act, if available, rather than under this prospectus.

Broker-dealers engaged by the selling stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling stockholders (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated, but, except as set forth in a supplement to this prospectus, in the case of an agency transaction not in excess of a customary brokerage commission in compliance with FINRA/NASD Rule 2440; and in the case of a principal transaction a markup or markdown in compliance with FINRA/NASD IM-2440.

The selling stockholders may, from time to time, pledge or grant a security interest in some or all of the shares of common stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of common stock, from time to time, under this prospectus, or under an amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act amending the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus. The selling stockholders also may transfer the shares of common stock in other circumstances, in which case the transferees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

In connection with the sale of shares, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the shares in the course of hedging the positions they assume. The selling stockholders may also sell shares short and deliver these shares to close out their short positions, or loan or pledge shares to broker-dealers that in turn may sell these shares. The selling stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to that broker-dealer or other financial institution of shares offered by this prospectus, which shares that broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect that transaction).

LEGAL MATTERS

The validity of the shares of common stock being offered by this prospectus has been passed upon for Galectin Therapeutics Inc. by Dentons US LLP, Atlanta, Georgia.

EXPERTS

The consolidated financial statements incorporated in this Prospectus by reference to the Annual Report on Form 10-K for the year ended December 31, 2016, have been audited by Cherry Bekaert LLP, an independent registered public accounting firm, as stated in their report incorporated by reference herein, and have been so incorporated in reliance upon such report and upon the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We are a reporting company and file annual, quarterly and current reports, proxy statements and other information with the SEC. You may read and copy any document we file with the SEC at the Public Reference Room (Room 1580), 100 F Street, N.E., Washington, D.C. 20549. You may also obtain information on the operations of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains a website (www.sec.gov) that contains the reports, proxy and information statements, and other information that we file electronically with the SEC.

This prospectus is part of a registration statement that we filed with the SEC. The registration statement contains more information than this prospectus regarding us and the securities, including exhibits and schedules. You can obtain a copy of the registration statement from the SEC at the above address or from the SEC's Internet site.

Our internet address is www.galectintherapeutics.com. We have not incorporated by reference into this prospectus the information on our website, and you should not consider it to be a part of this document. Our web address is included in this document as an inactive textual reference only.

INFORMATION INCORPORATED BY REFERENCE

The SEC allows us to "incorporate by reference" information contained in documents that we file with the SEC, which means that we can disclose important information to you by referring you to those other documents. The information incorporated by reference is an important part of this prospectus, and information that we file later with the SEC will automatically update and supersede this information. We incorporate by reference the documents listed below and any future filings we will make with the SEC under Section 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934 as amended prior to the termination of this offering:

- our Annual Report on Form 10-K for the year ended December 31, 2016 filed on March 28, 2017;
- Amendment No. 1 to our Annual Report on Form 10-K/A filed on April 28, 2017;
- our Quarterly Report on Form 10-Q for the quarter ended March 31, 2017 filed on May 15, 2017;
- our Current Reports on Form 8-K filed on each of February 17, 2017 and May 19, 2017; and
- the description of our Common Stock contained in our registration statement on Form 8-A filed with the SEC on September 9, 2003, including any amendments or reports filed for the purpose of updating such description.

You may request, orally or in writing, a copy of these documents, which will be provided to you at no cost, by contacting:

Galectin Therapeutics, Inc.
4960 Peachtree Industrial Blvd., Suite 240
Norcross, Georgia 30071
Attention: Jack W. Callicutt, Chief Financial Officer
Tel.: (678) 620-3186
E-mail: ir@galectintherapeutics.com

The information in this prospectus is not complete and may be changed. We may not sell the securities pursuant to this prospectus until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED MAY 19, 2017

PROSPECTUS

\$30,000,000



Common Stock

We have entered into an At Market Issuance Sales Agreement, or sales agreement, with FBR Capital Markets & Co., or FBR, dated as of May 19, 2017, relating to the sale of shares of our common stock offered by this prospectus. In accordance with the terms of the sales agreement, under this prospectus we may offer and sell shares of our common stock, \$0.001 par value per share, having an aggregate offering price of up to \$30 million from time to time through FBR, acting as agent.

Our common stock is traded on The NASDAQ Capital Market, or the Exchange, under the symbol "GALT." The last reported sale price of our common stock on May 15, 2017 was \$2.73 per share.

Sales of our common stock, if any, under this prospectus will be made by any method permitted that is deemed an "at the market offering" as defined in Rule 415 under the Securities Act of 1933, as amended, or the Securities Act. FBR is not required to sell any specific amount, but will act as our sales agent using commercially reasonable efforts consistent with its normal trading and sales practices. There is no arrangement for funds to be received in any escrow, trust or similar arrangement.

FBR will be entitled to compensation at a commission rate equal to 3.0% of the gross sales price per share sold. In connection with the sale of the common stock on our behalf, FBR may be deemed to be an "underwriter" within the meaning of the Securities Act and the compensation of FBR may be deemed to be underwriting commissions or discounts. We have also agreed to provide indemnification and contribution to FBR with respect to certain liabilities, including liabilities under the Securities Act.

Investing in these securities involves a high degree of risk. Before buying shares of our common stock, you should carefully consider the risk factors described in "[Risk Factors](#)" beginning on page 5 of this prospectus and in the documents incorporated by reference into this prospectus and any free writing prospectus that we have authorized for use in connection with this offering.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities, or determined if this prospectus is accurate or complete. Any representation to the contrary is a criminal offense.

FBR

The date of this prospectus is _____, 2017

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ABOUT THIS PROSPECTUS

This prospectus relates to the offering of our common stock. Before buying any of the common stock that we are offering, we urge you to carefully read this prospectus, together with the information incorporated by reference as described under the heading “Where You Can Find More Information” and “Information Incorporated by Reference.” These documents contain important information that you should consider when making your investment decision.

We provide information to you about this offering of our common stock in two separate documents that are bound together: (i) this sales agreement prospectus, which describes the specific details regarding this offering; and (ii) the accompanying base prospectus, which provides general information, some of which may not apply to this offering. Generally, when we refer to this “prospectus,” we are referring to both documents combined. If information in this sales agreement prospectus is inconsistent with the accompanying base prospectus, you should rely on this prospectus. This prospectus describes the specific terms of the common stock we are offering and also adds to and updates information contained in the documents incorporated by reference into this prospectus. To the extent there is a conflict between the information contained in this prospectus, on the one hand, and the information contained in any document incorporated by reference in this prospectus, on the other hand, you should rely on the information in this prospectus. If any statement in one of these documents is inconsistent with a statement in another document having a later date—for example, a document incorporated by reference into this prospectus—the statement in the document having the later date modifies or supersedes the earlier statement.

You should rely only on the information contained in or incorporated by reference in this prospectus and any free writing prospectus that we may authorize for use in connection with this offering. We have not, and FBR has not, authorized anyone to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We are not, and FBR is not, making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted or in which the person making that offer or solicitation is not qualified to do so or to anyone to whom it is unlawful to make an offer or solicitation. You should assume that the information appearing in this prospectus, the documents incorporated by reference in this prospectus and any free writing prospectus that we have authorized for use in connection with this offering, is accurate only as of the date of those respective documents. Our business, financial condition, results of operations and prospects may have changed since those dates. You should read this prospectus, the documents incorporated by reference in this prospectus and any free writing prospectus that we have authorized for use in connection with this offering, in their entirety before making an investment decision.

Unless otherwise indicated in this prospectus or the context otherwise requires, all references to “we,” “us,” “our,” “the Company,” and “Galectin” refer to Galectin Therapeutics Inc. and its subsidiaries.

FORWARD-LOOKING STATEMENTS

Certain statements made herein that look forward in time or express management's expectations or beliefs with respect to the occurrence of future events are forward-looking statements as defined under Section 21E of the Securities Exchange Act of 1934, as amended, and are 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." All statements, other than statements of historical facts, included herein that address activities, events, or developments that the Company expects or anticipates will or may occur in the future, are forward-looking statements, including statements regarding:

- our early stage of development;
- we have incurred significant operating losses since our inception and cannot assure you that we will generate revenue or profit;
- our dependence on additional outside capital;
- we may be unable to enter into strategic partnerships for the development, commercialization, manufacturing and distribution of our proposed product candidates;
- uncertainties related to any litigation, including shareholder class actions and derivative lawsuits filed;
- uncertainties related to our technology and clinical trials;
- we may be unable to demonstrate the efficacy and safety of our developmental product candidates in human trials;
- we may be unable to improve upon, protect and/or enforce our intellectual property;
- we are subject to extensive and costly regulation by the U.S. Food and Drug Administration (FDA) and by foreign regulatory authorities, which must approve our product candidates in development and could restrict the sales and marketing and pricing of such products;
- 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; and
- other risks detailed herein and from time to time in our SEC reports, including our Annual Report on Form 10-K filed with the SEC for the fiscal year ended December 31, 2016, and our subsequent SEC filings.

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 Amendment No. 1 to our Annual Report on Form 10-K/A for the year ended December 31, 2016. 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. Except as required by law, 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 of this prospectus or the respective dates of documents incorporated by reference herein or therein that include forward-looking statements.

This prospectus also contains estimates, projections and other information concerning our industry, the market and our business. Information that is based on estimates, forecasts, projections or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. We obtained the industry, market and competitive position data in this prospectus from our own internal estimates and research as well as from industry and general publications and research surveys and studies conducted by third parties.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere or incorporated by reference in this prospectus. This summary does not contain all of the information that you should consider before deciding to invest in our common stock. You should read this entire prospectus carefully, including the “Risk Factors” section contained in this prospectus, our consolidated financial statements and the related notes thereto and the other documents incorporated by reference in this prospectus.

Our Company

About Galectin Therapeutics Inc.

We are a clinical stage biopharmaceutical company engaged in drug research and development to create new therapies for fibrotic disease, severe skin disease, and cancer. Our drug candidates are based on our method of targeting galectin proteins, which are key mediators of biologic and pathologic functions. We use naturally occurring, readily-available plant products as starting material in manufacturing processes to create proprietary complex carbohydrates with specific molecular weights and other pharmaceutical properties. These complex carbohydrate molecules are appropriately formulated into acceptable pharmaceutical formulations. Using these unique carbohydrate-based candidate compounds that largely bind and inhibit galectin proteins, particularly galectin-3, we are undertaking the focused pursuit of therapies for indications where galectins have a demonstrated role in the pathogenesis of a given disease. We focus on diseases with serious, life-threatening consequences to patients and those where current treatment options are limited. Our strategy is to establish and implement clinical development programs that add value to our business in the shortest period of time possible and to seek strategic partners when a program becomes advanced and requires significant additional resources.

Our lead galectin-3 inhibitor is GR-MD-02, which has been demonstrated in preclinical models to reverse liver fibrosis and cirrhosis. GR-MD-02 has the potential to treat many diseases due to galectin-3's involvement in multiple key biological pathways such as immune cell function and immunity, cell differentiation, cell growth, and apoptosis (cell death). Galectin Therapeutics Inc. is using this inhibitor to treat advanced liver fibrosis and liver cirrhosis in NASH (non-alcoholic steatohepatitis) patients. We have completed two Phase 1 clinical studies, one Phase 2 clinical study in NASH patients with advanced fibrosis (NASH-FX) and have one ongoing Phase 2 clinical study in NASH patients with cirrhosis (NASH-CX). NASH cirrhosis is a progressive disease, currently not treatable and ultimately may result in liver failure that has poor prognosis and no effective, approved medical therapies other than liver transplant. Galectin-3 expression is highly increased in the liver of patients with liver fibrosis and liver cirrhosis. We believe that our galectin-3 inhibitor, by reducing galectin-3 at the cellular level, ultimately showing a strong anti-fibrotic potential may provide a novel treatment for various forms of liver fibrosis.

We endeavor to leverage our scientific and product development expertise as well as established relationships with outside sources to achieve cost-effective and efficient drug development. These outside sources, amongst others, provide us with expertise in preclinical models, pharmaceutical development, toxicology, clinical trial operations, pharmaceutical manufacturing, sophisticated physical and chemical characterization, and commercial development. We also have established several collaborative scientific discovery programs with leading experts in carbohydrate chemistry and characterization. These discovery programs are generally aimed at the targeted development of new carbohydrate molecules that bind galectin proteins and offer alternative options to larger market segments in our primary disease indications. We also have established a discovery program aimed at the targeted development of small molecules (non-carbohydrate) that bind galectin proteins and may afford options for alternative means of drug delivery (e.g., oral) and as a result expand the potential uses of our compounds. We are pursuing a development pathway to clinical enhancement and commercialization for our lead compounds in immune enhancement for cancer therapy and severe skin disease including moderate to severe plaque psoriasis and severe atopic dermatitis. Our clinical development efforts are focused on both liver fibrosis and fatty liver disease as represented by a Phase 2 clinical trial in NASH-cirrhosis which will report top line data in December, 2017. All of our proposed products are presently in development, including pre-clinical and clinical trials.

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

THE OFFERING

Common stock offered by us pursuant to this prospectus	Shares of our common stock having an aggregate offering price of up to \$30 million.
Manner of offering	“At the market offering” that may be made from time to time on The NASDAQ Capital Market or other market for our common stock in the U.S. through our agent, FBR Capital Markets & Co. See the section entitled “Plan of Distribution” on page 7 of this prospectus.
Use of proceeds	We intend to use the net proceeds of this offering for the continued development of our drug research and development programs, including the current clinical trial for GR-MD-02, and for general corporate purposes. See the section entitled “Use of Proceeds” on page 6 of this prospectus.
Risk factors	See “Risk Factors” beginning on page 5 of this prospectus and the other information included in, or incorporated by reference into, this prospectus for a discussion of certain factors you should carefully consider before deciding to invest in shares of our common stock.
NASDAQ Capital Market symbol	GALT

RISK FACTORS

Investment in our common stock involves risks. Before deciding whether to invest in our common stock, you should consider carefully the risk factors discussed below and those contained in the section entitled “Risk Factors” contained in Amendment No. 1 to our Annual Report on Form 10-K/A for the year ended December 31, 2016, as filed with the SEC on April 28, 2017, which is incorporated herein by reference in its entirety, as well as any amendment or update to our risk factors reflected in subsequent filings with the SEC. If any of the risks or uncertainties described in our SEC filings actually occurs, our business, financial condition, results of operations or cash flow could be materially and adversely affected. This could cause the trading price of our common stock to decline, resulting in a loss of all or part of your investment. The risks and uncertainties we have described are not the only ones facing our company. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also affect our business operations.

Risks Associated with this Offering

We have broad discretion in the use of the net proceeds of this offering and may not use them effectively.

We intend to use the net proceeds from this offering for general corporate purposes and to commence or continue clinical trials of our product candidates, including our current clinical trials for GR-MD-02. However, our management will have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. The failure by management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and delay the development of our product candidates.

You will experience immediate and substantial dilution.

The offering price per share in this offering may exceed the net tangible book value per share of our common stock outstanding prior to this offering. Assuming that an aggregate of 11,111,111 shares of our common stock are sold at a price of \$2.73 per share, the last reported sale price of our common stock on the Exchange on May 15, 2017, for aggregate gross proceeds of approximately \$30 million, and after deducting commissions and estimated offering expenses payable by us, you will experience immediate dilution of \$1.88 per share, representing the difference between our as adjusted net tangible book value per share as of December 31, 2016 after giving effect to this offering and the assumed offering price. The exercise of outstanding stock options and warrants, or the conversion of outstanding preferred stock into common stock, will result in further dilution of your investment. See the section entitled “Dilution” below for a more detailed illustration of the dilution you would incur if you participate in this offering.

You may experience future dilution as a result of future equity offerings.

In order to raise additional capital, we may in the future offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock at prices that may not be the same as the price per share in this offering. We may sell shares or other securities in any other offering at a price per share that is less than the price per share paid by investors in this offering, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders. The price per share at which we sell additional shares of our common stock, or securities convertible or exchangeable into common stock, in future transactions may be higher or lower than the price per share paid by investors in this offering.

USE OF PROCEEDS

We may issue and sell shares of our common stock having aggregate sales proceeds of up to \$30 million from time to time. Because there is no minimum offering amount required as a condition to close this offering, the actual total public offering amount, commissions and proceeds to us, if any, are not determinable at this time. We estimate that the net proceeds from the sale of the shares of common stock that we are offering may be up to approximately \$29.0 million, after deducting FBR’s commission and estimated offering expenses payable by us.

We intend to use the net proceeds of this offering for the continued development of our drug research and development programs, including the current clinical trial for GR-MD-02, and for general corporate purposes.

DIVIDEND POLICY

We have never declared or paid any cash dividends on our common stock. We currently intend to retain any future earnings and do not expect to declare or pay any cash dividends in the foreseeable future. Any future determination to pay dividends will be at the discretion of our board of directors, subject to applicable laws, and will depend on our financial condition, results of operations, capital requirements, general business conditions and other factors that our board of directors considers relevant.

DILUTION

If you invest in our common stock, your interest will be diluted to the extent of the difference between the price per share you pay in this offering and the net tangible book value per share of our common stock immediately after this offering. Our net tangible book value of our common stock as of March 31, 2017 was approximately \$9.6 million, or approximately \$0.28 per share of common stock based upon 34,670,684 shares outstanding. Net tangible book value per share is equal to our total tangible assets, less our total liabilities, divided by the total number of shares outstanding as of March 31, 2017.

After giving effect to the sale of our common stock in the aggregate amount of \$30 million at an assumed offering price of \$2.73 per share, the last reported sale price of our common stock on The NASDAQ Capital Market on May 15, 2017, and after deducting estimated offering commissions payable by us, our net tangible book value as of March 31, 2017 would have been \$38.6 million, or \$0.85 per share of common stock. This represents an immediate increase in net tangible book value of \$0.57 per share to our existing stockholders and an immediate dilution in net tangible book value of \$1.86 per share to new investors in this offering.

The following table illustrates this calculation on a per share basis:

Offering price per share	\$2.73
Net tangible book value per share	\$0.28
Increase in net tangible book value per share attributable to the offering	\$0.57
As-adjusted net tangible book value per share after giving effect to the offering	\$0.85
Dilution in net tangible book value per share to new investors	\$1.88

The number of shares of our common stock to be outstanding immediately after this offering is based on 34,670,684 shares of our common stock outstanding as of March 31, 2017. The number of shares outstanding as of March 31, 2017 excludes:

- 12,249,016 shares issuable upon exercise of outstanding warrants with a weighted average exercise price of \$3.22;
- 4,656,888 shares issuable upon exercise of outstanding options with a weighted average exercise price of \$4.30;
- 166 shares reserved for issuance under our 2009 Incentive Compensation Plan; and
- 4,312,282 shares issuable upon the conversion of preferred stock.

The foregoing table does not give effect to the exercise of any outstanding options or warrants or the conversion of preferred stock to common stock. To the extent options and warrants are exercised, or to the extent preferred stock is converted to common stock, there may be further dilution to new investors.

PLAN OF DISTRIBUTION

We have entered into an At Market Issuance Sales Agreement with FBR under which we may issue and sell our common stock from time to time through FBR acting as agent, subject to certain limitations, including the number of shares registered under the registration statement to which the offering relates. The form of the sales agreement is filed as an exhibit to a Form 8-K filed by the Company on May 19, 2017. The sales, if any, of shares made under the sales agreement will be made by any method that is deemed an “at the market offering” as defined in Rule 415 promulgated under the Securities Act. We may instruct FBR not to sell common stock if the sales cannot be effected at or above the price designated by us from time to time. We or FBR may suspend the offering of common stock upon notice and subject to other conditions.

Each time we wish to issue and sell common stock under the sales agreement, we will notify FBR of the number of shares to be issued, the dates on which such sales are anticipated to be made, any minimum price below which sales may not be made and other sales parameters as we deem appropriate. Once we have so instructed FBR, unless FBR declines to accept the terms of the notice, FBR has agreed to use its commercially reasonable efforts consistent with its normal trading and sales practices to sell such shares up to the amount specified on such terms. The obligations of FBR under the sales agreement to sell our common stock are subject to a number of conditions that we must meet.

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We will pay FBR commissions for its services in acting as agent in the sale of common stock. FBR will be entitled to a commission in an amount equal to 3.0% of the gross proceeds from the sale of common stock offered hereby. FBR may also receive customary brokerage commissions from purchasers of the common stock in compliance with FINRA Rule 2121. FBR may effect sales to or through dealers, and such dealers may receive compensation in the form of discounts, concessions or commissions from FBR and/or purchasers of shares of common stock for whom they may act as agents or to whom they may sell as principal. In addition, we have agreed to reimburse FBR for fees and disbursements related to its legal counsel in an amount not to exceed \$15,000, and for certain other expenses. We estimate that the total expenses for the offering, excluding compensation payable to FBR under the terms of the sales agreement, will be approximately \$100,000.

Settlement for sales of common stock will generally occur on the third business day following the date on which any sales are made, or on some other date that is agreed upon by us and FBR in connection with a particular transaction, in return for payment of the net proceeds to us. There is no arrangement for funds to be received in an escrow, trust or similar arrangement.

In connection with the sale of the common stock on our behalf, FBR may, and will with respect to sales effected in an “at the market offering,” be deemed to be an “underwriter” within the meaning of the Securities Act and the compensation of FBR may be deemed to be underwriting commissions or discounts. We have agreed to provide indemnification and contribution to FBR against certain civil liabilities, including liabilities under the Securities Act. We have also agreed to reimburse FBR for certain other specified expenses.

The offering of our common stock pursuant to the sales agreement will terminate upon the earlier of (i) the sale of all of our common stock provided for in this prospectus or (ii) termination of the sales agreement as provided therein.

FBR and its affiliates may in the future provide various investment banking and other financial services for us and our affiliates, for which services they may in the future receive customary fees. To the extent required by Regulation M, FBR will not engage in any market making activities involving our common stock while the offering is ongoing under this prospectus.

LEGAL MATTERS

The validity of the common stock offered hereby will be passed upon by Dentons US LLP, Atlanta, Georgia. Duane Morris LLP, Newark, New Jersey, is counsel for FBR in connection with this offering .

EXPERTS

The consolidated financial statements incorporated in this Prospectus by reference to the Annual Report on Form 10-K for the year ended December 31, 2016, have been audited by Cherry Bekaert LLP, an independent registered public accounting firm, as stated in their report incorporated by reference herein, and have been so incorporated in reliance upon such report and upon the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND ADDITIONAL INFORMATION ABOUT US

We file reports with the SEC on an annual basis using Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K. You may read and copy any such reports and amendments thereto at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549 on official business days during the hours of 10:00 a.m. to 3:00 p.m. Please call the SEC at 1-800-SEC-0330 for information on the Public Reference Room. Additionally, the SEC maintains a website that contains annual, quarterly, and current reports, proxy statements, and other information that issuers (including us) file electronically with the SEC. The SEC's website address is <http://www.sec.gov>. You can also obtain copies of materials we file with the SEC from our Internet website found at www.galactintherapeutics.com. Our stock is quoted on the NASDAQ Capital Market under the symbol “GALT.”

This prospectus is only part of a registration statement on Form S-3 that we have filed with the SEC under the Securities Act and therefore omits certain information contained in the registration statement. We have also filed exhibits and schedules with the registration statement that are excluded from this prospectus, and you should refer to the applicable exhibit or schedule for a complete description of any statement referring to any contract or other document. You may inspect a copy of the registration statement, including the exhibits and schedules, without charge, at the public reference room or obtain a copy from the SEC upon payment of the fees prescribed by the SEC.

INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The SEC allows us to “incorporate by reference” the information we file with them which means that we can disclose important information to you by referring you to those documents instead of having to repeat the information in this prospectus. The information

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incorporated by reference is considered to be part of this prospectus, and later information that we file with the SEC will automatically update and supersede this information. We incorporate by reference the documents listed below and any future filings made with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act between the date of this prospectus and the termination of the offering (other than, unless otherwise specifically indicated, current reports furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits filed on such form that are related to such items):

- our Annual Report on Form 10-K for the year ended December 31, 2016 filed on March 28, 2017;
- Amendment No. 1 to our Annual Report on Form 10-K/A filed on April 28, 2017;
- our Quarterly Report on Form 10-Q for the quarter ended March 31, 2017 filed on May 15, 2017;
- our Current Reports on Form 8-K filed on each of February 17, 2017 and May 19, 2017; and
- the description of our Common Stock contained in our registration statement on Form 8-A filed with the SEC on September 9, 2003, including any amendments or reports filed for the purpose of updating such description.

We also incorporate by reference all documents we file under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act until all of the common stock to which this prospectus relates has been sold or the offering is otherwise terminated.

\$30,000,000



Common Stock

PROSPECTUS



, 2017

PART II. INFORMATION NOT REQUIRED IN PROSPECTUS

Item 14. Other Expenses of Issuance and Distribution.

The following table sets forth all costs and expenses to be incurred by the Company in connection with the preparation and filing of this Registration Statement. All amounts shown are estimates except for the SEC registration fee. We will pay all expenses in connection with the distribution of the shares of common stock being registered hereby.

SEC Registration Fee	\$ 12,419
FINRA Fee	16,573
Accountants' Fees and Expenses	4,000
Legal Fees and Expenses	35,000
Transfer Agent Fees and Expenses	1,200
Miscellaneous	2,500
Total Expenses	<u>\$ 71,692</u>

Item 15. Indemnification of Directors and Officers.

The registrant's By-laws, as amended to date, provide for indemnification of officers and directors to the fullest extent permitted by Section 7502 of Chapter 78 of the Nevada Revised Statutes ("NRS") (as from time to time amended), provided such officer or director acts in good faith and in a manner which such person reasonably believes to be in or not opposed to the best interests of the registrant, and with respect to any criminal matter, had no reasonable cause to believe such person's conduct was unlawful.

NRS 78.7502 states:

"1. A corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative, except an action by or in the right of the corporation, by reason of the fact that he is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses, including attorneys' fees, judgments, fines and amounts paid in settlement actually and reasonably incurred by him in connection with the action, suit or proceeding if he:

- (a) Is not liable pursuant to NRS 78.138; or
- (b) Acted in good faith and in a manner which he reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful.

The termination of any action, suit or proceeding by judgment, order, settlement, conviction or upon a plea of *nolo contendere* or its equivalent, does not, of itself, create a presumption that the person is liable pursuant to NRS 78.138 or did not act in good faith and in a manner which he reasonably believed to be in or not opposed to the best interests of the corporation, or that, with respect to any criminal action or proceeding, he had reasonable cause to believe that his conduct was unlawful.

2. A corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor by reason of the fact that he is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against expenses, including amounts paid in settlement and attorneys' fees actually and reasonably incurred by him in connection with the defense or settlement of the action or suit if he:

- (a) Is not liable pursuant to NRS 78.138; or
- (b) Acted in good faith and in a manner which he reasonably believed to be in or not opposed to the best interests of the corporation.

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Indemnification may not be made for any claim, issue or matter as to which such a person has been adjudged by a court of competent jurisdiction, after exhaustion of all appeals therefrom, to be liable to the corporation or for amounts paid in settlement to the corporation, unless and only to the extent that the court in which the action or suit was brought or other court of competent jurisdiction determines upon application that in view of all the circumstances of the case, the person is fairly and reasonably entitled to indemnity for such expenses as the court deems proper.

3. To the extent that a director, officer, employee or agent of a corporation has been successful on the merits or otherwise in defense of any action, suit or proceeding referred to in subsections 1 and 2, or in defense of any claim, issue or matter therein, the corporation shall indemnify him against expenses, including attorneys' fees, actually and reasonably incurred by him in connection with the defense."

The registrant's By-laws also provide that to the fullest extent permitted by NRS 78.751 (as from time to time amended), the registrant shall pay the expenses of officers and directors of the Corporation incurred in defending a civil or criminal action, suit or proceeding, as they are incurred and in advance of the final disposition of such matter, upon receipt of an undertaking in form and substance acceptable to the board of directors for the repayment of such advances if it is ultimately determined by a court of competent jurisdiction that the officer or director is not entitled to be indemnified.

NRS 78.751 states:

"1. Any discretionary indemnification pursuant to NRS 78.7502, unless ordered by a court or advanced pursuant to subsection 2, may be made by the corporation only as authorized in the specific case upon a determination that indemnification of the director, officer, employee or agent is proper in the circumstances. The determination must be made:

- (a) By the stockholders;
- (b) By the board of directors by majority vote of a quorum consisting of directors who were not parties to the action, suit or proceeding;
- (c) If a majority vote of a quorum consisting of directors who were not parties to the action, suit or proceeding so orders, by independent legal counsel in a written opinion; or
- (d) If a quorum consisting of directors who were not parties to the action, suit or proceeding cannot be obtained, by independent legal counsel in a written opinion.

2. The articles of incorporation, the bylaws or an agreement made by the corporation may provide that the expenses of officers and directors incurred in defending a civil or criminal action, suit or proceeding must be paid by the corporation as they are incurred and in advance of the final disposition of the action, suit or proceeding, upon receipt of an undertaking by or on behalf of the director or officer to repay the amount if it is ultimately determined by a court of competent jurisdiction that he is not entitled to be indemnified by the corporation. The provisions of this subsection do not affect any rights to advancement of expenses to which corporate personnel other than directors or officers may be entitled under any contract or otherwise by law.

3. The indemnification pursuant to NRS 78.7502 and advancement of expenses authorized in or ordered by a court pursuant to this section:

- (a) Does not exclude any other rights to which a person seeking indemnification or advancement of expenses may be entitled under the articles of incorporation or any bylaw, agreement, vote of stockholders or disinterested directors or otherwise, for either an action in his official capacity or an action in another capacity while holding his office, except that indemnification, unless ordered by a court pursuant to NRS 78.7502 or for the advancement of expenses made pursuant to subsection 2, may not be made to or on behalf of any director or officer if a final adjudication establishes that his acts or omissions involved intentional misconduct, fraud or a knowing violation of the law and was material to the cause of action. A right to indemnification or to advancement of expenses arising under a provision of the articles of incorporation or any bylaw is not eliminated or impaired by an amendment to such provision after the occurrence of the act or omission that is the subject of the civil, criminal, administrative or investigative action, suit or proceeding for which indemnification or advancement of expenses is sought, unless the provision in effect at the time of such act or omission explicitly authorizes such elimination or impairment after such action or omission has occurred.
- (b) Continues for a person who has ceased to be a director, officer, employee or agent and inures to the benefit of the heirs, executors and administrators of such a person."

In addition, the registrant maintains directors' and officers' liability insurance which insures against liabilities that its directors and officers may incur in such capacities.

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Reference is made to “Undertakings,” below, for the registrant’s undertakings in this registration statement with respect to indemnification of liabilities arising under the Securities Act of 1933, as amended (the “Securities Act”).

Item 16. Exhibits

See the Exhibit Index attached to this registration statement and incorporated herein by reference.

Item 17. Undertakings.

Insofar as indemnification by the registrant for liabilities arising under the Securities Act, may be permitted to directors, officers and controlling persons of the registrant pursuant to the provisions referenced in this Item 17 of this registration statement, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. If a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer, or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by a director, officer or controlling person in connection with the securities being registered hereunder, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act, and will be governed by the final adjudication of such issue.

The undersigned registrant hereby undertakes:

1. To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the SEC pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the “Calculation of Registration Fee” table in the effective registration statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

provided, however, that paragraphs (i), (ii) and (iii) of this section 1 do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the Registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), that are incorporated by reference in this registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

2. That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and this offering of such securities at that time shall be deemed to be the initial bona fide offering thereof;

3. To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of this offering;

4. That, for the purpose of determining liability under the Securities Act to any purchaser, if relying on Rule 430B, each prospectus filed by the registrant pursuant to Rule 424(b)3 shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement and each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5) or (b)(7) as part of the registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii) or (x) for the purpose of providing the information required by section 10(a) of the Securities Act shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof; provided, however, that no statement made in a

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registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date. If instead the registrant is subject to Rule 430C, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness; provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use; and

5. That, for the purpose of determining liability of the registrant under the Securities Act to any purchaser in the initial distribution of the securities, the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

- (i) any preliminary prospectus or prospectus of an undersigned registrant relating to this offering required to be filed pursuant to Rule 424;
- (ii) any free writing prospectus relating to this offering prepared by, or on behalf of, the undersigned registrant or used or referred to by the undersigned registrant;
- (iii) the portion of any other free writing prospectus relating to this offering containing material information about an undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and
- (iv) any other communication that is an offer in this offering made by the undersigned registrant to the purchaser.

6. The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act, each filing of the registrant's annual report pursuant to Section 13(a) or 15(d) of the Exchange Act that is incorporated by reference in this Registration Statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

7. That, for purposes of determining any liability under the Securities Act, (i) the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective and (ii) each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

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<u>/s/ Steven Prelack</u> Steven Prelack	Director	May 19, 2017
<u>/s/ Marc Rubin, M.D.</u> Marc Rubin, M.D.	Director	May 19, 2017
<u>/s/ Theodore Zucconi</u> Theodore Zucconi	Director	May 19, 2017

EXHIBIT INDEX

Exhibit No.	Description
1.1*	Form of Underwriting Agreement
1.2	At Market Issuance Sales Agreement between Galectin Therapeutics Inc. and FBR Capital Markets &Co. (incorporated by reference to the Company's Current Report on Form 8-K as filed with the Commission on May 19, 2017)
3.1	Amended and Restated Articles of Incorporation of Galectin Therapeutics Inc. (incorporated by reference to the Company's Current Report on Form 8-K filed with the Commission on May 30, 2012).
3.2	Amended and Restated Bylaws of Galectin Therapeutics Inc. (incorporated by reference to the Company's Current Report on Form 8-K filed with the Commission on September 27, 2016).
3.3	Certificate of Designation of Preferences, Rights and Limitations of Series A 12% Convertible Preferred Stock of Pro Pharmaceuticals, Inc., as filed with the Secretary of State of the State of Nevada on October 5, 2007. (incorporated by reference to the Company's Current Report on Form 8-K filed with the Commission on October 9, 2007).
3.4	Amendment to Certificate of Designation of Preferences, Rights and Limitations of Series A 12% Convertible Preferred Stock of Pro Pharmaceuticals, Inc., as filed with the Secretary of State of the State of Nevada on May 15, 2017. (incorporated by reference to the Company's Current Report on Form 8-K filed with the Commission on May 19, 2017).
3.5	Second Amended and Restated Certificate of Designation of Preferences, Rights and Limitations of Series B-1 Convertible Preferred Stock, Series B-2 Convertible Preferred Stock and Series B-3 Convertible Preferred Stock of Galectin Therapeutics, Inc., as filed with the Secretary of State of the State of Nevada on September 22, 2016. (Incorporated by reference to the Company's Current Report on Form 8-K filed with the Commission on September 27, 2016.)
3.6	Amendment to Second Amended and Restated Certificate of Designation of Preferences, Rights and Limitations of Series B-1 Convertible Preferred Stock, Series B-2 Convertible Preferred Stock and Series B-3 Convertible Preferred Stock of Galectin Therapeutics, Inc., as filed with the Secretary of State of the State of Nevada on May 15, 2017. (incorporated by reference to the Company's Current Report on Form 8-K filed with the Commission on May 19, 2017).
3.7	Certificate of Designation of Preferences, Rights and Limitation of Series C Super Dividend Convertible Preferred Stock of Pro-Pharmaceuticals, Inc., as filed with the Secretary of State of Nevada on December 30, 2010 (incorporated by reference to the Company's Current Report on Form 8-K as filed with the Commission on January 6, 2011).
3.8	Certificate of Change as filed with the Nevada Secretary of State on March 1, 2012 (incorporated by reference to the Company's Current Report on Form 8-K as filed with the Commission on March 23, 2012).
3.9	Certificate of Designation of Preferences, Rights and Limitation of Common Stock (Class W), as filed with the Secretary of State of Nevada on February 13, 2017 (incorporated by reference to the Company's Current Report on Form 8-K as filed with the Commission on February 17, 2017).
3.9	Amendment to Certificate of Designation of Preferences, Rights and Limitation of Common Stock (Class W), as filed with the Secretary of State of Nevada on May 15, 2017 (incorporated by reference to the Company's Current Report on Form 8-K as filed with the Commission on May 19, 2017).
4.1	Specimen certificate for shares of Common Stock (incorporated by reference to Exhibit 4.1 of the Company's Form S-1 Registration Statement filed with the Commission on November 19, 2008)
5.1†	Opinion of Dentons US LLP
23.1†	Consent of Cherry Bekaert LLP (independent registered public accounting firm).
23.2†	Consent of Dentons US LLP (included in legal opinion filed as Exhibit 5.1).
24.1	Power of Attorney**

* To the extent applicable, to be filed by an amendment or as an exhibit to a document filed under the Securities Exchange Act of 1934, as amended, and incorporated by reference herein.

† Filed herewith.

** Included on signature page filed herewith.

May 19, 2017

Board of Directors
Galectin Therapeutics Inc.
4960 Peachtree Industrial Blvd., Suite 240
Norcross, Georgia 30071

Re: Registration Statement on Form S-3

Gentlemen:

We have acted as counsel to Galectin Therapeutics Inc., a Nevada corporation (the “Company”), in connection with (i) the preparation and filing with the Securities and Exchange Commission (the “Commission”) under the Securities Act of 1933, as amended (the “Securities Act”), of a registration statement on Form S-3 (the “Registration Statement”), relating to the registration of shares of Common Stock, \$0.001 par value per share (“Common Stock”), having an aggregate initial offering price of up to \$100,000,000 (collectively, the “Securities”), including 2,994,279 shares of Common Stock with respect to the resale, from time to time, of such shares of Common Stock by those certain selling stockholders named in the Registration Statement (the “Selling Stockholders”) pursuant to Rule 415 under the Securities Act; and (ii) the proposed issue and sale by Company, of the Company’s Common Stock, \$0.001 par value (the “Sales Agreement Shares”), representing a portion of the Securities registered on the Registration Statement, having an aggregate offering price of up to \$30.0 million from time to time pursuant to an At Market Issuance Sales Agreement dated May 19, 2017 (the “Sales Agreement”). Unless otherwise defined herein, capitalized terms used herein shall have the meanings assigned to them in the Registration Statement. The shares of Common Stock registered pursuant to the Registration Statement are hereinafter referred to as the “Shares.” This opinion letter is being rendered pursuant to Item 16 of Form S-3 and Item 601(b)(5) of Regulation S-K.

In connection with this opinion, we have examined such documents and considered such legal matters deemed by us to be relevant to this opinion letter and the Registration Statement, including the applicable statutory provisions and related rules and regulations of Chapter 78 of the Nevada Revised Statutes and the reported judicial decisions interpreting those laws, the Amended and Restated Articles of Incorporation of the Company, the Amended and Restated Bylaws of the Company, the authorizing resolutions of the Company’s Board of Directors and the Sales Agreement. We also have made such further legal and factual examinations and investigations as we deemed necessary for purposes of expressing the opinion set forth herein. With respect to such examination, we have assumed the genuineness of all signatures, the authenticity of all documents submitted to us as originals, the conformity to original documents of all documents submitted to us as reproduced or certified copies, and the authenticity of the originals of those latter documents. As to questions of fact material to this opinion, we have, to the extent deemed appropriate, relied upon information provided by officers of the Company and the Selling Stockholders. We have not independently verified or investigated, nor do we assume any responsibility for, the factual accuracy or competency of such factual statements.

Our opinion is limited to applicable statutory provisions of Chapter 78 of the Nevada Revised Statutes and the reported judicial decisions interpreting those laws, and federal laws of the United States of America to the extent referred to specifically herein. We do not express any opinion herein concerning any other laws. We are generally familiar with Chapter 78 of the Nevada Revised Statutes as currently in effect and the judicial decisions thereunder and have made such inquiries and review of matters of fact and law as we determined necessary to render the opinion contained herein. We assume no obligation to revise or supplement this opinion in the event of future changes in such laws or the interpretations thereof or such facts. We express no opinion regarding the Securities Act, or any other federal or state laws or regulations.

Based upon the foregoing, and in reliance thereon, it is our opinion that, as of the date hereof, the Shares registered for resale that have been previously issued have been duly authorized, are validly issued, fully paid and nonassessable and the Shares that will be issued have been duly authorized, and when issued will be validly issued, fully paid and nonassessable.

This opinion letter is provided for use solely in connection with the resale of the Common Stock covered by the Registration Statement, and except for its use in connection with such resale, may not be furnished to, quoted from or relied upon by any other person, firm, or corporation without our express written consent. No opinion may be implied or inferred beyond the opinion expressly stated in the paragraph immediately above. Our opinion expressed herein is as of the date hereof, and we undertake no obligation to advise you of any changes in applicable law or any other matters that may come to our attention after the date hereof that may affect our opinions expressed herein.

We consent to the filing of this opinion letter as an exhibit to the Registration Statement and to the use of our name under the heading "Legal Matters" in the prospectus constituting a part thereof. In giving such consent, we do not thereby admit that we are within the category of persons whose consent is required under Section 7 of the Securities Act or the rules and regulations of the Commission thereunder.

Very truly yours,

/s/ Dentons US, LLP

Dentons US, LLP

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in this Registration Statement of Galectin Therapeutics, Inc. on Form S-3 of our report dated March 28, 2017, with respect to the consolidated financial statements of Galectin Therapeutics, Inc. included in its Annual Report on Form 10-K for the year ended December 31, 2016, and to the reference to us under the heading “Experts” in the prospectus, which is part of this Registration Statement.

/s/ Cherry Bekaert LLP

Atlanta, Georgia
May 19, 2017