

GALECTIN THERAPEUTICS INC

Form 424B3

September 25, 2018

Table of Contents

**Filed pursuant to Rule 424(b)(3)
Registration No. 333-226402**

GALECTIN THERAPEUTICS INC.

6,945,836 Shares of

Common Stock Issuable Upon Exercise of Warrants and Conversion of Series B-3 Preferred Stock

The selling stockholders identified in this prospectus may offer and sell up to 6,945,836 shares of our common stock, par value \$0.001 (Common Stock), which shares are issuable to the selling stockholders identified herein upon:

(i) up to 1,789,346 shares of Common Stock issuable upon conversion of shares of Series B-3 Preferred Stock (Series B-3 Preferred Stock) held by certain selling stockholders into Common Stock in connection with issuance of Series B-3 Shares on September 22, 2016, September 29, 2016 and December 23, 2016.

(ii) up to 1,342,009 shares of Common Stock issuable upon exercise of the Series B-3 Preferred Stock coverage warrants held by certain selling stockholders (Series B-3 Coverage Warrants) at an exercise price of \$3.00 per share in connection with the private placement of the Series B-3 Shares that closed on September 22, 2016, September 29, 2016 and December 23, 2016.

(iii) up to 1,127,033 shares of Common Stock issuable upon exercise of the Series B-3 lockup warrants held by certain selling stockholders (Series B-3 Lockup Warrants) at an exercise price of \$3.00 per share in connection with the private placements of the Series B-3 Shares that closed on September 22, 2016, September 29, 2016 and December 23, 2016.

(iv) up to 2,187,448 shares of Common Stock issuable upon exercise of the Common Stock warrants by certain selling stockholders (Common Warrants) at an exercise price of (\$5.00) per share in connection with the private placement of Common Stock that closed on December 22, 2016, December 28, 2016 and February 28, 2017.

(v) up to 500,000 shares of Common Stock issuable upon exercise of the Common Stock warrants by certain selling stockholders (Line of Credit Warrants) at an exercise price of \$5.00 per share in connection with the \$10,000,000 line of credit extended to the Company on December 19, 2017; the Series B-3 Coverage Warrants, the Series B-3 Lock-up Warrants, the Common Warrants and the Line of Credits Warrants, hereinafter sometimes collectively referred to as the Warrants.

The selling stockholders may offer the shares of Common Stock issuable upon exercise of the outstanding Warrants or from the conversion of the Series B Shares from time to time through public or private transactions at prevailing market prices, at prices related to prevailing market prices or at privately negotiated prices.

For information regarding the selling stockholders and the times and manner in which they may offer or sell the shares, see Selling Stockholder or Plan of Distribution.

We will not receive any of the proceeds from the sale of the Common Stock by the selling stockholders; however, we will receive the proceeds of any Common Stock we issue to the selling stockholders upon exercise of the Warrants. We will pay the expenses of registering the Common Stock. The selling stockholders will bear all commissions and discounts, if any, attributable to the sale of the Common Stock by the selling stockholders.

Our Common Stock is quoted on the NASDAQ Capital Market under the symbol GALT. On August 21, 2018, the last reported closing price for our Common Stock on the NASDAQ Capital Market was \$4.69 per share.

Investing in shares of our Common Stock involves certain risks. See Risk Factors beginning on page 5 of this prospectus. In addition, see Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2017 and supplemented by our Form 10-Q for the period ended March 31, 2018, and our Form 10-Q for the period ended June 30, 2018, each of which has been filed with the Securities and Exchange Commission and is incorporated by reference into this prospectus. You should carefully read and consider these risk factors before you invest in shares of our Common Stock.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is September 25, 2018.

Table of Contents

TABLE OF CONTENTS

	Page
<u>ABOUT THIS PROSPECTUS</u>	i
<u>PROSPECTUS SUMMARY</u>	1
<u>RISK FACTORS</u>	5
<u>FORWARD-LOOKING STATEMENTS</u>	5
<u>USE OF PROCEEDS</u>	6
<u>DESCRIPTION OF FINANCING TRANSACTIONS</u>	6
<u>DESCRIPTION OF WARRANTS</u>	7
<u>DIVIDEND POLICY</u>	8
<u>DESCRIPTION OF CAPITAL STOCK</u>	8
<u>SELLING STOCKHOLDERS</u>	12
<u>PLAN OF DISTRIBUTION</u>	13
<u>LEGAL MATTERS</u>	15
<u>EXPERTS</u>	15
<u>WHERE YOU CAN FIND MORE INFORMATION</u>	15
<u>IMPORTANT INFORMATION INCORPORATED BY REFERENCE</u>	15
ABOUT THIS PROSPECTUS	

This prospectus relates to the resale by the selling stockholders identified in this prospectus under the caption Selling Stockholders, from time to time, of up to 6,945,836 shares of our Common Stock, par value \$0.001 per share, issuable upon conversion of the Series B-3 Shares or upon the exercise of the Warrants. The Warrants are all currently exercisable, and the Series B-3 Shares are currently convertible. We are not selling any shares of Common Stock under this prospectus and will not receive any proceeds from the sale of shares of Common Stock by the selling stockholders.

This prospectus is part of a registration statement we filed with the Securities and Exchange Commission (the SEC). Under this registration process, the selling stockholders may, from time to time, offer and sell up to 6,945,836 shares of our Common Stock, as described in this prospectus, in one or more offerings as described in the Plan of Distribution. This prospectus provides you with a general description of the securities the selling stockholders may offer. You should read this prospectus carefully before making an investment decision.

You should read this prospectus, any documents that we incorporate by reference in this prospectus and the additional information described below under Where You Can Find More Information and Important Information Incorporated By Reference before making an investment decision. You should rely only on the information contained or incorporated by reference in this prospectus. 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. 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.

You should not assume that the information in this prospectus or any documents we incorporate by reference herein or therein is accurate as of any date other than the date on the front of those documents. Our business, financial condition, results of operations and prospects may have changed since those dates.

As used in this prospectus, Galectin Therapeutics, the Company, we, our and similar terms refer to Galectin Therapeutics Inc. and its subsidiaries, unless the context indicates otherwise.

Table of Contents

PROSPECTUS SUMMARY

The following summary highlights selected information contained elsewhere in this prospectus and does not contain all of the information you should consider before investing in our securities. Before deciding to invest in our securities, you should read this entire prospectus, including the discussion of Risk Factors and our consolidated financial statements and the related notes included in our Annual Report on Form 10-K for the year ended December 31, 2017.

Our Company

We are a clinical stage biopharmaceutical company engaged in drug research and development to create new therapies for fibrotic disease and cancer. Our drug candidates are based on our method of targeting galectin proteins, which are key mediators of biologic and pathologic functions. We use naturally occurring, readily-available plant 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, a Phase 2 clinical study in NASH patients with advanced fibrosis (NASH-FX) and a second Phase 2B clinical trial in NASH patients with well compensated cirrhosis. We announced, in December 2017 top line results from our Phase 2b 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 through Galectin Sciences LLC, a discovery program aimed at the targeted development of small molecules (generally, 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 galectin-3 inhibitor compounds. We are also pursuing a development pathway to clinical enhancement and commercialization for our lead compounds in immuno-oncology for cancer therapy. However, 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 reported 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.

Description of Recent Developments

We have one new proprietary chemical entity (NCE) in development, GR-MD-02, which has shown promise in preclinical and early clinical studies in treatment of fibrosis and in cancer therapy. Currently we are focusing on development of GR-MD-02 intended to be used in the treatment of liver fibrosis associated with fatty liver disease (NASH) and more specifically in NASH cirrhosis. We have also leveraged our relationships with well-known investigators to demonstrate clinical effects of GR-MD-02

Table of Contents

and in cancer therapy in combination with immune-system modifying agent(s). GR-MD-02 is a proprietary, patented compound derived from natural, readily available, plant-based starting materials, which, following chemical processing, exhibits the properties of binding to and inhibiting galectin-3 proteins.

GR-MD-02 is our lead product candidate for treatment of fibrotic disease. Our preclinical data show that GR-MD-02 has a significant therapeutic effect on liver fibrosis as shown in several relevant animal models. In addition, in NASH animal models, GR-MD-02 has been shown to reduce liver fat, inflammation, and ballooning degeneration or death of liver cells. Therefore, we chose GR-MD-02 as the lead candidate in a development program targeted initially at fibrotic liver disease associated with non-alcoholic steatohepatitis (NASH, or fatty liver disease). In January 2013, an Investigational New Drug (IND) was submitted to the FDA with the goal of initiating a Phase 1 study in patients with NASH and advanced liver fibrosis to evaluate the human safety of GR-MD-02 and pharmacodynamics biomarkers of disease. On March 1, 2013, the FDA indicated we could proceed with a US Phase 1 clinical trial for GR-MD-02 with a development program aimed at obtaining support for a proposed indication of GR-MD-02 for treatment of NASH with advanced fibrosis. The Phase 1 trial was completed and demonstrated that GR-MD-02 up to 8 mg/kg, i.v. was safe and well tolerated. The human pharmacokinetic data defined a drug dose for use in the planned Phase 2 trials based on extrapolation from efficacy data in NASH animal models of liver fibrosis and/or cirrhosis. Additionally, there was evidence of a pharmacodynamic effect of GR-MD-02 at the 8 mg/kg dose with a decrease in alpha 2 macroglobulin, a serum marker of fibrotic activity, and a reduction in liver stiffness as determined by FibroScan[®].

Additionally, an open label drug-drug interaction study was completed in healthy volunteers during the second quarter of 2015 with GR-MD-02 and it showed that with 8 mg/kg dose of GR-MD-02 and 2 mg/kg dose of midazolam there was no drug-drug interaction and no serious adverse events or drug-related adverse events were observed. This study was required by the U.S. Food and Drug Administration (FDA) and the primary objective was to determine if single or multiple intravenous (IV) doses of GR-MD-02 affect the pharmacokinetics (PK) of midazolam. The secondary objective was to assess the safety and tolerability of GR-MD-02 when administered concomitantly with midazolam. The lack of a drug interaction in this study enabled the Company to expand the number of patients eligible for its Phase 2 clinical trial. In addition, should GR-MD-02 be approved for marketing, the success of this study supports a broader patient population for the drug label.

Our Phase 2 program in fibrotic disease consists of two separate human clinical trials. The primary clinical trial is the Phase 2b NASH-CX study for one year for patients with NASH with well compensated cirrhosis, which began enrolling in June, 2015. This study is the primary focus of our program and is a randomized, placebo-controlled, double-blind, parallel-group Phase 2b trial to evaluate the safety and efficacy of GR-MD-02 for treatment of liver fibrosis and resultant portal hypertension in NASH patients with well compensated cirrhosis. A smaller, exploratory NASH-FX trial was conducted to explore potential use of various non-invasive imaging techniques in NASH patients with advanced fibrosis but not cirrhosis.

NASH-FX Trial: The NASH-FX trial, a Phase 2a pilot trial NASH-FX for patients with NASH advanced fibrosis that explored use of three non-invasive imaging technologies, was completed in 2016. It was a short, single site, four-month trial in 30 NASH patients with advanced fibrosis, but not cirrhosis, randomized 1:1 to either 9 bi-weekly doses of 8 mg/kg of GR-MD-02 or placebo. The trial did not meet its primary biomarker endpoint as measured using multi-parametric magnetic resonance imaging (LiverMultiScan^(R), Perspectum Diagnostics). The trial also did not meet secondary endpoints that measure liver stiffness as a surrogate for fibrosis using magnetic resonance-elastography and FibroScan[®] score. We, and many experts in the field, now believe that a four-month treatment period may not be sufficient to show efficacy results in established liver fibrosis. This small study was not powered for the secondary endpoints and thus, not surprisingly did not meet the secondary endpoints. In the trial, GR-MD-02 was found to be safe and well tolerated among the patient population with no serious adverse events. Although there was no apparent improvement in the three non-invasive tests for assessment of liver fibrosis in the

four-month NASH-FX trial, the principal investigator of the NASH-FX trial has stated that the inhibition of galectin-3 with GR-MD-02 remains promising for the treatment of NASH fibrosis. Of note is that GR-MD-02 has demonstrated an improved clinical effect in moderate-to-severe psoriasis, suggesting the compound has activity in humans in an immune-mediated inflammatory human disease that can occur in association with NASH. We believe our drug candidate provides a promising new approach for the therapy of fibrotic diseases, and liver fibrosis in particular. Fibrosis is the formation of excess connective tissue (collagen and other proteins plus cellular elements such as myofibroblasts) in response to damage, inflammation or repair. When the fibrotic tissue becomes confluent, it obliterates the cellular architecture, leading to scarring and dysfunction of the underlying organ. Given galectin-3's broad biological functionality, it has been demonstrated to be involved in cancer, inflammation and fibrosis, heart disease, and renal disease. We have further demonstrated the broad applicability of the actions of our galectin-3 inhibitor's biological effect in ameliorating fibrosis involving lung, kidney, blood vessels, and cardiac tissues in a wide variety of animal models.

NASH-CX Trial: The NASH-CX trial was a larger well-designed multi-center clinical trial which explored use of GR-MD-02 for the treatment of liver fibrosis and resultant portal hypertension in patients with well-compensated NASH cirrhosis. Enrollment in this trial was completed in September, 2016, and a total of 162 patients at 36 sites in the United States were randomized to receive either 2 mg/kg of GR-MD-02, 8 mg/kg of GR-MD-02 or placebo, with approximately 54 patients in each group. The primary endpoint is a reduction in change in hepatic venous pressure gradient (HVPG). Patients received an infusion every other week for one year, total of 26 infusions, and were evaluated to determine the change in HVPG as compared with placebo. HVPG was also correlated with secondary endpoints of fibrosis on liver biopsy as well as with measurement of liver stiffness (FibroScan^(R)) and assessment of liver metabolism (¹³C-methacetin breath test, Exalenz), which are non-invasive measures of the liver that may be used in future studies. Top line data readout was reported in December 2017 demonstrating positive efficacy data and safety and clinically meaningful results in the NASH patients with well compensated cirrhosis without esophageal varices (stage 1 cirrhosis).

Table of Contents

In the total patient population, the primary endpoint HVPG showed a trend toward benefit with GR-MD-02 treatment, but the difference from placebo was not statistically significant. The mean change in HVPG of placebo from baseline to week 54 was 0.3 mm Hg. The mean change in HVPG from baseline was -0.37 and -0.42 for the 2 mg/kg dose and 8 mg/kg dose of GR-MD-02, respectively.

Further analysis showed that the drug effect was significantly dependent on dose varices in the total group of patients ($p < 0.02$). In those NASH cirrhosis patients without varices at baseline (about 50% of the total population), there was a statistically significant effect of the 2 mg/kg dose of GR-MD-02 on the absolute change in HVPG (-1.08 mm Hg, $p < 0.01$). The effect of the 8 mg/kg dose of GR-MD-02 on absolute or percent change in HVPG from baseline to week 54 was not significant. The population of patients without varices at baseline were further subdivided into those with mild portal hypertension (HVPG greater or equal to 6 mm Hg and less than 10 mm Hg). In patients with mild portal hypertension (MPH), both doses of GR-MD-02 demonstrated a statistically significant effect on change in HVPG. The mean change in HVPG in the MPH group were +1.8 mm Hg for placebo and -0.3 and -0.4 mm Hg in the 2 mg/kg and 8 mg/kg dose groups, respectively. In patients with clinically significant portal hypertension (HVPG greater than 10 mm Hg) with no varices at baseline, there was a statistically significant effect of 2 mg/kg of GR-MD-02 on the change in HVPG.

A responder analysis was performed on those patients without varices at baseline. Analysis was performed looking at two groups: those with an equal to or greater than 2 mm Hg decrease in HVPG from baseline or those with an equal to or greater than 2 mm Hg and greater than or equal to 20% decrease in HVPG from baseline. In both cases, the change observed in the GR-MD-02 2 mg/kg group was statistically significant ($p < 0.01$) while that of the 8 mg/kg group was not.

In terms of cirrhosis complications over the 54-week treatment period, in patients without varices there were statistically significantly fewer new varices that developed in the treatment groups vs placebo. We believe this may represent a useful measure of clinical outcome.

The major conclusions, to date from the NASH-CX trial results are that: i) GR-MD-02 had a statistically significant and clinically meaningful effect in improving HVPG vs placebo in patients with NASH cirrhosis who did not have esophageal varices at baseline. This effect was seen regardless of the patient's baseline portal hypertension. Furthermore, we believe that patients with esophageal varices may have masked benefits in the total patient population. ii) There was an important drug effect of GR-MD-02 in the total patient population on liver biopsy with a statistically significant improvement in hepatocyte ballooning (ie cell death), (iii) There was a statistically significant reduction ($p = 0.02$) in the development of new esophageal varices in drug-treated patients compared to placebo. We believe that this is a clinically relevant endpoint related to patient outcomes, (iv) While there was a drug effect in both the 2 mg/kg and 8 mg/kg dosage groups on liver biopsy and in the mild portal hypertension group, there was a consistently greater and statistically significant effect of the 2 mg/kg dose of GR-MD-02, (v) GR-MD-02 appears to be safe and well tolerated in this one year clinical trial and (vi) We believe this is the first large, randomized clinical trial of any drug to demonstrate a clinically meaningful improvement in portal hypertension or liver biopsy in patients with compensated NASH cirrhosis without esophageal varices.

The focus and goal of the therapeutic program is to stop the progression of and reverse the fibrosis in the liver and, thereby improve liver function and prevent the development of complications of fibrosis/cirrhosis and liver-related mortality in patients. The results of the NASH-CX trial substantiate that, subject to confirmation in later stage clinical trials, this goal is achievable in a significant portion of the NASH cirrhosis patient population i.e. those NASH cirrhosis patients without esophageal varices.

Corporate Information

Edgar Filing: GALECTIN THERAPEUTICS INC - Form 424B3

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.galactintherapeutics.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.

Table of Contents

The Offering

Common Stock offered by Selling Stockholders	Up to 6,945,836 shares of Common Stock issuable as follows: up to 1,789,346 shares of Common Stock issuable upon conversion of shares of Series B-3 Preferred Stock; up to 1,342,009 shares of Common Stock issuable upon exercise of the Series B-3 Coverage Warrants; up to 1,127,033 shares of Common Stock issuable upon exercise of the Series B-3 Lockup Warrants; up to 2,187,448 shares of Common Stock issuable upon exercise of the Common Warrants; and up to 500,000 shares of Common Stock issuable upon exercise of the Line of Credit Warrants.
Common Stock to be outstanding after the offering*	47,574,019 shares of Common Stock.
Terms of the offering	The Selling Stockholders, including their transferees, donees, pledgees, assignees and successors-in-interest, may sell, transfer or otherwise dispose of any or all of the shares of Common Stock offered by this prospectus from time to time on the NASDAQ Capital Market or any other stock exchange, market or trading facility on which the shares are traded or in private transactions. The shares of Common Stock may be sold at fixed prices, at market prices prevailing at the time of sale, at prices related to prevailing market price or at negotiated prices.
Use of proceeds	We will not receive any of the proceeds from a sale of any Common Stock offered pursuant to this prospectus that may be received by the Selling Stockholders.
NASDAQ Symbol	GALT

Risk Factors

The purchase of our Common Stock involves a high degree of risk. You should carefully review and consider the Risk Factors beginning on page 5.

*The number of shares of Common Stock to be outstanding after this offering is based on the actual number of shares outstanding as of June 30, 2018 (40,628,183 shares) and assumes the issuance of up to an additional 1,789,346 shares of Common Stock upon conversion of the Company's Series B Preferred Stock after such date and the issuance of up to an additional 5,156,490 shares of Common Stock upon exercise of each of the Warrants after such date.

Table of Contents

RISK FACTORS

Investing in shares of our Common Stock involves risk. Before making any investment decision, you should carefully consider the risk factors under the caption "Risk Factors" in our most recent annual report on Form 10-K for the year ended December 31, 2017, and our subsequent quarterly reports on Form 10-Q, which are incorporated by reference in this prospectus, as well as in any applicable prospectus supplement, as updated by our subsequent filings under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These risks could materially affect our business, results of operation or financial condition and affect the value of our Common Stock. Additional risks and uncertainties that are not yet identified may also materially harm our business, operating results and financial condition and could result in a complete loss of your investment. You could lose all or part of your investment. For more information, see "Where You Can Find More Information."

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," 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 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, 2017, 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 our annual report on Form 10-K for the year ended December 31, 2017. 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.

Table of Contents

USE OF PROCEEDS

We will receive the exercise price with respect to any Common Stock we issue to the Selling Stockholders upon exercise of the Warrants. If all of the Warrants are exercised, we will receive proceeds of approximately \$25.5 million. We, however, will not receive any of the proceeds from a sale of any Common Stock offered pursuant to this prospectus that is issued upon exercise of the Warrants that may be received by the Selling Stockholders. We also will not receive any cash upon the conversion of the Series B Preferred Stock into Common Stock. We currently intend to use all proceeds received upon a cash exercise of the Warrants for working capital and general corporate purposes.

We cannot predict when the Warrants will be exercised, and it is possible that exercise of the Warrants may not result in the issuance of any Common Stock.

DESCRIPTION OF FINANCING TRANSACTIONS

September and December 2016 Series B-3 Convertible Preferred Stock Private Placement

On September 22, 2016, the Company entered into a Securities Purchase Agreement (the Purchase Agreement) with 10X Fund, L.P., a Delaware limited partnership (10X Fund). Pursuant to the Purchase Agreement, the Company agreed to issue and sell to 10X Fund, and 10X Fund agreed to purchase from the Company (i) shares of the Company's Series B-3 Convertible Preferred Stock (the Series B-3 Preferred Stock) convertible into such number of shares of the Company's common stock, par value \$0.001 per share (Common Stock) as determined thereunder and (ii) warrants to purchase 0.75 shares of Common Stock for every share of Common Stock into which the Series B-3 Preferred Stock is convertible (the Series B-3 Coverage Warrants). The terms and conditions of the Series B-3 Preferred Shares and the Series B-3 Coverage Warrants are more fully described in the Company's Current Report on Form 8-K, filed on September 27, 2016.

On September 22, 2016, the initial closing date under the Purchase Agreement, the Company issued and sold to 10X Fund: 375,000 shares of Series B-3 Preferred Stock convertible into 139,211 shares of Common Stock and Series B-3 Coverage Warrants exercisable to purchase 104,408 share of Common Stock. Subsequently, on September 22, 2016 the Company issued and sold to 10X Fund 1,125,000 shares of Series B-3 Preferred Stock convertible into 753,138 shares of Common Stock and Series B-3 Coverage Warrants exercisable to purchase 564,854 share of Common Stock. Finally, on December 23, 2016 the Company issued and sold to 10X Fund 1,008,000 shares of Series B-3 Preferred Stock convertible into 896,997 shares of Common Stock and Series B-3 Coverage Warrants exercisable to purchase 672,747 share of Common Stock.

In addition, pursuant to the Purchase Agreement and a separate Lock Up Letter Agreement entered into between the Company and Purchaser, as consideration for the Purchaser's agreement not to sell any shares of the Company's Series B Preferred Stock for a period of 18 months, subject to certain exceptions, the Company issued to the Purchaser the following warrants all exercisable at \$3.00 per share (collectively, the Lock Up Warrants): In September, 2016, warrants for 875,000 shares, and in December, 2016 warrants for 252,033 shares.

The foregoing description of the Series B-3 Warrants is not complete and is qualified in its entirety by reference to the full text of the form of Series B-3 Warrants, a copy of which is filed as Exhibit 4.1 to the Company's Current Report on Form 8-K filed on September 27, 2016, and is incorporated herein by reference.

December 2016 and February 2017 Common Stock Private Placement

On December 22, 2016, December 28, 2016, and February 28, 2017, the Company completed private placements of Common Stock and warrants to purchase Common Stock (the Common Warrants) to certain accredited investors pursuant to subscription agreements (the Subscription Agreements) entered into between the Company and such investors. The Company issued (i) 1,954,939 shares of Common Stock together with Common Stock Warrants to purchase 1,466,204 shares of Common Stock at \$5.00 per share on December 22, 2016, to a single investor for an aggregate purchase price of \$2,000,000, (ii) 859,291 shares of Common Stock together with Common Stock Warrants to purchase an aggregate of 644,468 shares of Common Stock at \$5.00 per share on December 28, 2016, to four investors for an aggregate purchase price of \$1,000,000, and (iii) 102,368 shares of Common Stock together with Common Stock Warrants to purchase an aggregate of 76,776 shares of Common Stock at \$5.00 per share on February 28, 2017, to five investors for an aggregate purchase price of \$200,000.

The issuances of Common Stock and Common Warrants, including the issuance of shares of Common Stock upon exercise of the Common Warrants, as described above were issued in reliance upon the exemption from registration under Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D promulgated thereunder. Upon issuance the shares of Common Stock and Common Stock Warrants were not registered under the Securities Act of 1933, as amended, and were restricted securities as such term is defined by Rule 144 under the Securities Act.

The foregoing description of the Subscription Agreements and the warrants is not complete and is qualified in its entirety by reference to the Form 8-K filed by the Company on December 22, 2016 and the Form 10-Q filed by the Company on June 30, 2017.

Table of Contents

Line of Credit Transaction

On December 19, 2017, the Company and Richard E. Uihlein entered into a Line of Credit Agreement (the Credit Agreement). The Credit Agreement provided the Company a line of credit of up to \$10.0 million. Borrowings under the credit line are at the Company's discretion through December 31, 2018. Advances under the line of credit bear interest at the Applicable Federal Rate for short term loans. Principal and interest are due on December 31, 2019 unless sooner prepaid in the discretion of the Company. In connection with the Credit Agreement, the Company issued a Common Stock purchase warrant (the Line of Credit Warrant) to Mr. Uihlein to purchase one million shares of the Company's Common Stock, exercisable at \$5.00 per share. The Warrant vested with respect to 500,000 shares of Common Stock upon signing of the Credit Agreement, which vested shares are included in the shares being registered pursuant to this registration statement, and will vest with respect to the remaining underlying shares of Common Stock, ratably upon borrowings under the Credit Agreement, if any, which unvested shares are not being registered pursuant to this registration statement. As of the date of this prospectus, there have been no advances under the Credit Agreement and, as a result, the Line of Credit Warrant is currently only vested with respect to 500,000 shares of Common Stock.

The foregoing description of the Credit Agreement and the Warrant is not complete and is qualified in its entirety by reference to the Form 8-K filed by the Company on December 19, 2017.

This prospectus covers the following shares of Common Stock:

- (i) up to 1,789,346 shares of Common Stock issuable upon conversion of shares of Series B-3 Preferred Stock;
- (ii) up to 1,342,009 shares of Common Stock issuable upon exercise of the Series B-3 Coverage Warrants;
- (iii) up to 1,127,033 shares of Common Stock issuable upon exercise of the Series B-3 Lockup Warrants;
- (iv) up to 2,187,448 shares of Common Stock issuable upon exercise of the Common Warrants; and
- (v) up to 500,000 shares of Common Stock issuable upon exercise of the Line of Credit Warrants.

DESCRIPTION OF WARRANTS

The following is a brief description of the terms of the Warrants. This summary does not purport to be complete in all respects. This description is subject to and qualified in its entirety by reference to the Warrants, a form of which has been filed with the SEC and is also available upon request from us, and the agreements underlying the Financing Transactions, which have also been filed with the SEC and are also available upon request from us.

The Series B-3 Coverage Warrants are exercisable for an aggregate of 1,324,009 shares of our Common Stock at an exercise price of \$3.00 per share. The Series B-3 Coverage Warrants became exercisable beginning on the six month anniversary of the date of issuance and will expire on the seventh anniversary of the issuance date and must be exercised prior to such expiration date; thereafter, we will amend the registration statement of which this prospectus is a part to withdraw from registration any shares not issued upon exercise of the Series B-3 Coverage Warrants.

The Series B-3 Lock Up Warrants are exercisable for an aggregate of 1,127,033 shares of our Common Stock at an exercise price of \$5.00 per share. The Series B-3 Lock Up Warrants became exercisable on the six month anniversary of the date of issuance and will expire on the seventh anniversary of the issuance date and must be exercised prior to such expiration date; thereafter, we will amend the registration statement of which this prospectus is a part to

withdraw from registration any shares not issued upon exercise of the Common Warrants.

The Common Warrants are exercisable for an aggregate of 2,187,448 shares of our Common Stock at an exercise price of \$5.00 per share. The Common Warrants became exercisable on the six month anniversary of the date of issuance and will expire on the seventh anniversary of the issuance date and must be exercised prior to such expiration date; thereafter, we will amend the registration statement of which this prospectus is a part to withdraw from registration any shares not issued upon exercise of the Common Warrants.

The Line of Credit Warrants are exercisable for an aggregate of 1,000,000 shares of our Common Stock at an exercise price of \$5.00 per share. The Warrant vested with respect to 500,000 shares of Common Stock upon signing of the Credit Agreement and will vest with respect to the remaining underlying shares of Common Stock, ratably upon borrowings under the Credit Agreement, if any. The Line of Credit Warrants became exercisable on June 19, 2018 and will expire on December 19, 2024 and must be exercised prior to such expiration date; thereafter, we will amend the registration statement of which this prospectus is a part to withdraw from registration any shares not issued upon exercise of the Common Warrants.

All of the Warrants are outstanding, and no additional Warrants will be issued. We will deliver shares of our Common Stock upon exercise of a Warrant, in whole or in part. We will not issue fractional shares. Each Warrant contains instructions for exercise. With respect to cash exercises of the Warrants, the holders of the Warrants may exercise the Warrants at any time by

Table of Contents

delivering to us a written notice of exercise and payment of an amount equal to the exercise price multiplied by the number of shares of Common Stock as to which the Warrant is being exercised. Upon receipt of the notice of exercise and payment, we will issue and deliver to the holder the number of shares of our Common Stock to which the holder is entitled pursuant to the exercise.

Subject to the exclusions and limitations set forth in the applicable Warrants, the exercise prices are subject to adjustment in the event we, at any time after the issuance date of the Warrants, pay a stock dividend on, subdivide or combine one or more classes of our then-outstanding shares of Common Stock. To date, none of the Warrants have been subject to any such price adjustment.

DIVIDEND POLICY

We have never declared or paid 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.

DESCRIPTION OF CAPITAL STOCK

General

The following is a summary of our capital stock and certain provisions of our Amended and Restated Articles of Incorporation, as amended, and Amended and Restated Bylaws, as amended, copies of which are on file with the SEC as exhibits to previous SEC filings. See *Where You Can Find More Information* elsewhere in this prospectus for information on where you can obtain copies of our Amended and Restated Articles of Incorporation and Amended and Restated Bylaws, which have been filed with and are publicly available from the SEC. This summary does not purport to be complete and is qualified in its entirety by the provisions of our Amended and Restated Articles of Incorporation, our Amended and Restated Bylaws and applicable provisions of the Nevada Revised Statutes.

Common Stock

We currently have authorized 100,000,000 shares of Common Stock, par value \$0.001 per share. As of June 30, 2018 there were 40,628,183 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.

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 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 two years following the date that the stockholder became an interested stockholder, unless the combination meets all of the requirements of the corporation's articles of incorporation, and, 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 two 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.

Table of Contents

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;

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.

Preferred 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, of which 1,377,500 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, and 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 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.

Table of Contents

Series B Preferred Stock

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 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, 2017, the 176 outstanding shares of Series C were convertible into a total of approximately 293,340 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

Table of Contents

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.

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%

250%

before the second anniversary of the date of issuance;

	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.

Table of Contents*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

The Common Stock being offered by the Selling Stockholders are those issuable to the Selling Stockholders upon exercise of the Warrants or upon the conversion of the Series B Preferred Stock. For additional information regarding the issuances of those shares of Common Stock and Warrants, see Description of Private Placement and Line of Credit Transaction above. We are registering the shares of Common Stock in order to permit the Selling Stockholders to offer the shares for resale from time to time.

The table below lists the Selling Stockholders and other information regarding the beneficial ownership of the shares of Common Stock by each of the Selling Stockholders. The second column lists the number of shares of Common Stock beneficially owned by each Selling Stockholder, based on its ownership of the shares of Common Stock and Warrants, as of June 30, 2018, assuming conversion of shares of Series B-3 Preferred Stock and exercise of the Warrants held by the Selling Stockholder on that date, without regard to any limitations on exercises.

The third column lists the shares of Common Stock being offered by this prospectus by the Selling Stockholders.

This prospectus generally covers the resale of the maximum number of shares of Common Stock issuable upon exercise of the related Warrants, determined as if the outstanding Warrants were exercised in full as of the trading day immediately preceding the date this registration statement was initially filed with the SEC, each as of the trading day immediately preceding the applicable date of determination and all subject to adjustment as provided in the Registration Rights Agreement (in the case of the holders of Series B-3 Shares), without regard to any limitations on the exercise of the Warrants. The fourth column assumes the sale of all of the shares offered by the Selling Stockholders pursuant to this prospectus.

Name of Selling Stockholder (1)	Number of shares of Common Stock Owned Prior to	Maximum Number of shares of Common Stock to be	Number of shares of Common Stock Owned After	Percentage of Ownership After Offering
--	--	---	---	---

	Offering	Sold Pursuant to this Prospectus	Offering (3)	
Richard Uihlein (1)	4,519,492	1,966,204	2,553,288	5.9%
Living Rock Foundation	150,376	64,447	85,929	*
Living Stones Foundation Charitable Trust	563,910	241,676	322,234	*
Kary Eldred	55,993	16,111	39,382	*
Kenneth & Roberta Eldred Revocable Trust	751,880	322,234	429,646	1%
Steven J. Labovitz	17,097	9,597	7,500	*
Loren S. Kendis	22,393	9,597	12,796	*
Ronna Fisher	22,393	9,597	12,796	*
Robert E. Tritt (2)	9,597	9,597	0	*
Stanley M. Marks	89,572	38,388	51,184	*
10X Fund, L.P.	6,939,780	4,258,388	2,681,392	6.0%

* less than one percent.

Percentage calculations are based on 40,628,183 shares of our common stock issued and outstanding as of June 30, 2018.

(1) Does not include (i) 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, or (ii) shares issuable under the Line of Credit Warrant that have not yet vested.

(2) Robert E. Tritt serves as outside legal counsel to the Company.

(3) Assumes all offered shares are sold.

Table of Contents

PLAN OF DISTRIBUTION

Each Selling Stockholder and any of their pledgees, assignees and successors-in-interest may, from time to time, sell any or all of their securities covered hereby on the NASDAQ Capital Market or any other stock exchange, market or trading facility on which the securities 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 securities:

ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;

block trades in which the broker-dealer will attempt to sell the securities 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;

in transactions through broker-dealers that agree with the Selling Stockholders to sell a specified number of such securities at a stipulated price per security;

through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;

a combination of any such methods of sale; or

any other method permitted pursuant to applicable law.

The Selling Stockholders may also sell securities under Rule 144 under the Securities Act or any other exemptions from registration, 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 securities, 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 Rule 2440; and in the case of a principal transaction a markup or markdown in compliance

with FINRA IM-2440.

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

The Selling Stockholders and any broker-dealers or agents that are involved in selling the securities may be deemed to be underwriters within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the securities purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Each Selling Stockholder has informed the Company that it does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the securities.

The Company is required to pay certain fees and expenses incurred by the Company incident to the registration of the securities. The Company has agreed to indemnify the Selling Stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

Table of Contents

We agreed to keep this prospectus effective until the earlier of (i) the date on which the securities may be resold by the Selling Stockholders without registration and without regard to any volume or manner-of-sale limitations by reason of Rule 144, without the requirement for the Company to be in compliance with the current public information under Rule 144 under the Securities Act or any other rule of similar effect or (ii) all of the securities have been sold pursuant to this prospectus or Rule 144 under the Securities Act or any other rule of similar effect. The resale securities will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the resale securities covered hereby may not be sold 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.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the resale securities may not simultaneously engage in market making activities with respect to the common stock for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution. In addition, the Selling Stockholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of the Common Stock by the Selling Stockholders or any other person. We will make copies of this prospectus available to the Selling Stockholders and have informed them of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale (including by compliance with Rule 172 under the Securities Act).

LEGAL MATTERS

Certain legal matters relating to the issuance of the Common Stock offered by this prospectus will be passed upon for us by Dentons US LLP, Atlanta, Georgia.

EXPERTS

The consolidated financial statements of Galectin Therapeutics Inc. as of December 31, 2017 and 2016 and for each of the years in the two-year period ended December 31, 2017 have been audited by Cherry Bekaert LLP, an independent registered public accounting firm, as stated in their reports thereon, and included in this prospectus and registration statement in reliance upon such report and upon the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

This prospectus is part of a registration statement on Form S-3 we have filed with the SEC. We have not included in this prospectus all of the information contained in the registration statement and you should refer to our registration statement and its exhibits for further information.

We file annual, quarterly and current reports, proxy statements and other information with the SEC. You may read and copy any materials we file with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549, on official business days during the hours of 10 a.m. to 3 p.m. You may obtain information about the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Our filings are also available to the public from commercial document retrieval services and at the website maintained by the SEC at www.sec.gov.

Our website address is www.galectintherapeutics.com. There we make available free of charge, on or through the investor relations section of our website, annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such material with the SEC. The information on our website is not incorporated into this prospectus.

Table of Contents

IMPORTANT INFORMATION INCORPORATED BY REFERENCE

The SEC allows us to incorporate by reference the information we file with them into this prospectus. This means that we can disclose important information about us and our financial condition to you by referring you to another document filed separately with the SEC instead of having to repeat the information in this prospectus. The information 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 until this offering is completed:

our Annual Report on Form 10-K for the year ended December 31, 2017, filed on March 29, 2018;

our Quarterly Report on Form 10-Q for the quarter ended March 31, 2018, filed on May 11, 2018;

our Quarterly Report on Form 10-Q for the quarter ended June 30, 2018, filed on August 14, 2018;

the portions of our definitive proxy statement that are deemed filed pursuant to Section 14 of the Exchange Act in connection with our 2018 Annual Meeting of Stockholders filed with the SEC on April 11, 2018;

our Current Report on Form 8-K filed on April 16, 2018, May 14, 2018, May 29, 2018, June 12, 2018 and June 15, 2018; 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.

Additionally, all reports and other documents subsequently filed by us pursuant to Sections 13(a), 13(c), 14, and 15(d) of the Exchange Act after the date of this prospectus and prior to the sale of all shares of common stock registered hereunder or the termination of the registration statement, shall be deemed to be incorporated by reference in this prospectus and to be part hereof from the date of filing of such reports and other documents. Any information that we subsequently file with the SEC that is incorporated by reference as described above will automatically update and supersede any previous information that is part of this prospectus. Nothing in this prospectus shall be deemed to incorporate information furnished but not filed with the SEC.

You may request a copy of the filings incorporated herein by reference, including exhibits to such documents that are specifically incorporated by reference, at no cost, by writing or calling us at the following address or telephone number:

Galectin Therapeutics Inc.

4960 Peachtree Industrial Blvd., Suite 240

Edgar Filing: GALECTIN THERAPEUTICS INC - Form 424B3

Norcross, Georgia 30071

Attention: Jack W. Callicutt, Chief Financial Officer

Tel.: (678) 620-3186

E-mail: callicutt@galectintherapeutics.com

The information in this prospectus is not complete and may be changed. We 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 it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.