GALECTIN THERAPEUTICS INC
Form 10-K
March 06, 2019
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the fiscal year ended December 31, 2018

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

Commission File No. 001-31791

GALECTIN THERAPEUTICS INC.

Nevada	**04-3562325**
(State or other jurisdiction	**(I.R.S. Employer**
of incorporation)	**Identification No.)**
4960 Peachtree Industrial Blvd., Suite 240, Norcross, GA	**30071**
(Address of Principal Executive Offices)	**(Zip Code)**

(678) 620-3186

(Registrant s Telephone Number, Including Area Code)

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

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

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

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

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

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

Indicate by check mark whether the registrant has submitted electronically, every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

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

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

Large accelerated filer	Accelerated filer
Non-accelerated filer	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.

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was sold, or the average bid and asked price of such common equity, as of June 30, 2018 was $213 million.

The number of shares outstanding of the registrant s common stock as of February 20, 2019 was 45,550,226.

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FOR THE YEAR ENDED DECEMBER 31, 2018

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PART I

Item 1. *Business*

Overview

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, patented 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 fibrosis, immune cell function and immunity, cell differentiation, cell growth, and apoptosis (cell death). The importance of galectin-3 in the fibrotic process is supported by experimental evidence. Animals with the gene responsible for galectin-3 knocked-out can no longer develop fibrosis in response to experimental stimuli compared to animals with an intact galectin-3 gene. Galectin Therapeutics Inc. is using its galectin-3inhibitor 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) and results of an End of Phase 2 meeting with the FDA in May 2018which provided direction on potentially acceptable end points for a Phase 3 trial. The company with its external NASH consultants has designed a Phase 3 study which has been sent to various contract research organizations (CROs) for their input on feasibility, timing costs and other important considerations. 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

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line data in December 2017 and on planning for Phase 3 studies. 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.

Our Drug Development Programs

Galectins are a class of proteins that are made by many cells in the body, but predominantly in cells of the immune system. As a group, these proteins are able to bind to sugar molecules that are part of other proteins, glycoproteins, in and on the cells of our body. Galectin proteins act as a kind of molecular glue, bringing together molecules that have sugars on them. Galectin proteins, in particular galectin-3, are known to be markedly increased in a number of important diseases including inflammatory diseases, scarring of organs (e.g. liver, lung, kidney, and heart) and cancers of many kinds. The increase in galectin protein promotes the disease and is detrimental to the patient. Published data substantiating the importance of galectin-3 in the fibrotic process arises from gene knockout experiments in animal studies. Mice genetically altered to eliminate the galectin-3 gene, and thus unable to produce galectin-3, are incapable of developing liver fibrosis in response to toxic insult to the liver and in fatty liver disease as well as development of fibrosis in other tissues.

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, severe skin disease, 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 in treating moderate to severe plaque psoriasis, severe atopic dermatitis, 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. A second NCE, GM-CT-01 is a proprietary, patented compound that is made from a completely different starting source plant material and also binds and inhibits galectin proteins. Previously in clinical development for cancer indications, GM-CT-01 compound has been explored in limited other preclinical studies.

Our product pipeline is shown below:

Indication	Drug	Status
Fibrosis		
NASH with Advanced Fibrosis: NASH-CX trial and NASH-FX trial	GR-MD-02	IND submitted January 2013. Results from the Phase 1 clinical trial were reported in 2014, with final results reported in January 2015. End of Phase 1 meeting held with FDA in 2014. Two Phase 2 clinical trials were

designed.

The NASH FX trial was designed for patients with advanced fibrosis but not cirrhosis. The NASH FX trial top line data was reported in September 2016

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Indication	Drug	Status
		The NASH CX trial, was designed for patients with well compensated cirrhosis. The NASH CX trial top line data was reported in December 2017. End of Phase 2 (EOP2) meeting held with FDA in May 2018.
NASH RX		The NASH -RX trial, a Phase 3 trial designed for NASH patients with well compensated cirrhosis, is in planning stage based on feedback on potential endpoints received from FDA at EOP2 meeting and in consultation with our external hepatology consultants. As part of the planning related to the Phase 3 trial, the Company has had ongoing discussions with FDA regarding Galectin s proposal for the next clinical study as well as the overall development program. These ongoing conversations included a recent Type C Meeting via teleconference with the Agency on February 6, 2019, to discuss Galectin s proposal for use of progression to varices as the primary surrogate endpoint moving forward.
		In the meeting, FDA confirmed that the Agency is supportive of the use of progression to varices as a potential surrogate endpoint and progression to large varices as a component of a composite clinical benefit endpoint pending additional requested information. Galectin will address and implement additional FDA requests and considerations for the Phase 3 trial, when and where possible. Given the newness of the endpoint and the new information to be generated in the trial, some information requested may not currently be available or may not be able to be addressed fully until data from the Phase 3 trial is available to address the information requests.
Lung Fibrosis	GR-MD-02	In pre-clinical development

Kidney Fibrosis	GR-MD-02	In pre-clinical development
Cardiac and Vascular Fibrosis	GR-MD-02 and GM-CT-01	In pre-clinical development
Cancer Immunotherapy		
Melanoma, Head,Neck Squamous Cell Carcinoma (HNSCC)	GR-MD-02	Investigator IND submitted in December 2013. Phase 1B study in process. A second Phase 1B study began in Q-1 2016. Investigator IND for that study submitted in September 2015. Early data was reported in

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Indication	Drug	Status
		February 2017 and studies with the 3rd cohort were reported in September 2018. Continuation of trial is ongoing to expand the dataset of melanoma and HNSCC patients at the 4 mg/Kg dose.
Psoriasis		
Moderate to Severe Plaque Psoriasis Severe Atopic Dermatitis	GR-MD-02	IND submitted March 2015. A phase 2a trial in moderate to severe plaque psoriasis patients began in January 2016. Interim data on the first four patients were positive and were reported in May 2016. Further positive data was reported in September 2016. Investigator initiated IND submitted for treatment of three patients with severe atopic dermatitis, with positive preliminary data presented in February 2017. Further studies are dependent on finding a suitable strategic partner.

Fibrosis. 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®. An End of Phase 1 Meeting was held with FDA which, amongst other items, provided guidance on the primary endpoint for the Phase 2 clinical trial, the NASH-CX trial.

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 consisted of two separate human clinical trials. The primary clinical trial was 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 was 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

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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, is now complete. 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 that 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 was 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 (^{13}C-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).

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

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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 a 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.

Further information and details on the NASH-CX results summarized above is available in public presentations posted to our website and filed with the SEC.

NASH-RX Trial: The NASH-RX Trial is a phase 3 trial of GR-MD-02 in NASH cirrhosis patients. We have met with the FDA to discuss the results of the NASH-CX trial in an End of Phase 2 meeting as disclosed in our May 14, 2018 press release. The proposed target population of the Phase 3 clinical trial will be patients with well compensated established NASH cirrhosis and portal hypertension**.** Patients will be selected based on criteria commonly used in clinical practice to identify patients with portal hypertension who are at risk of developing esophageal varices. Ongoing conversations with FDA included a recent Type C Meeting via teleconference with the Agency on February 6, 2019, to discuss Galectin s proposal for use of progression to varices as the primary surrogate endpoint moving forward.

In the meeting, FDA confirmed that the Agency is supportive of the use of progression to varices as a potential surrogate endpoint and progression to large varices as a component of a composite clinical benefit endpoint pending additional requested information. Galectin will address and implement additional FDA requests and considerations for the Phase 3 trial, when and where possible. Given the newness of the endpoint and the new information to be generated in the trial, some information requested may not currently be available or may not be able to be addressed fully until data from the Phase 3 trial is available to address the information requests.

The focus and goal of the therapeutic program is to stop the progression of and reverse the fibrosis and/or portal hypertension 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, we believe that this goal is achievable in a significant portion of the NASH cirrhosis patient population i.e. those NASH cirrhosis patients with portal

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hypertension at risk of developing esophageal varices that may bleed and experience other decompensating events. The trial design has been refined with external consultants and sent out to potential CROs in a confidential Request for Proposal (RFP) process. We are in the process of evaluating and interviewing the CRO candidates. The final primary endpoint and the Phase 3 clinical trial design, including projected timing and costs will be announced once the planning phase is completed.

Cancer Immunotherapy. We believe there is potential for galectin inhibition to play a key role in the burgeoning area of cancer immunotherapy. For example, there have been several recent approvals of drugs that enhance a patient s immune system to fight cancer. It is our goal to use a galectin inhibitor to further enhance the immune system function to fight cancer in a way that complements other approaches to this type of therapy. This hypothesis is supported by the fact that galectin-3 is expressed at high levels in multiple types of tumors, adds to the malignant nature of the tumors, and protects the tumors from immune system attack. Our drug candidates provide a promising new therapeutic approach to enhance the activity of the immune system against cancer cells. Preclinical studies have indicated that GR-MD-02 enhances the immune response to cancer cells, increased tumor shrinkage and enhanced survival in immune competent mice with prostate, breast, melanoma and sarcoma cancers when combined with one of the immune checkpoint inhibitors, anti-CTLA-4 or anti-PD-1, or with the immune cell activator anti-OX40. These preclinical data led to the filing of two Investigator-sponsored INDs and the initiation of studies of GR-MD-02 in combination with Yervoy® (ipilimumab) and KEYTRUDA (pembrolizumab) in Phase 1B studies of patients with metastatic melanoma. The KEYTRUDA trial has also been expanded to include patients with non-small cell lung cancer and head and neck squamous cell carcinoma. These studies are being conducted under the sponsorship of Providence Portland Medical Center s Earle A. Chiles Research Institute (EACRI).

Data on this combination immunotherapy program was presented on February 7, 2017 at the 9th GTCBio Immunotherapeutics & Immunomonitoring Conference in San Diego, CA by Dr. William L. Redmond, Providence Cancer Center. Preclinical results in mouse models of multiple types of cancers showed important anti-tumor activity and increased survival effects of combining GR-MD-02 with different types of immune modulators, providing a case for progressing studies into human patients with cancer. Seven patients were treated in the GR-MD-02 in combination with Yervoy trial, with no safety concerns in these low dose cohorts. Due to changes in the standard of care for metastatic melanoma (i.e., approval of anti-PD-1), recruitment has been slowed significantly in this trial. Promising results were reported in the Phase 1b trial combining GR-MD-02 with pembrolizumab (KEYTRUDA). Cohort 1 was completed (n=6, 5 with melanoma, one head and neck) with one partial response and one mixed response in 5 melanoma patients. There was a rapid and marked tumor response after 3 doses of combined GR-MD-02 and pembrolizumab in the one partial response patient who had failed high-dose IL-2 and oncolytic virus + ipilimumab. The study is ongoing and progression to further development will be based on response rate as compared to historical response rates to pembrolizumab alone. In September 2018 we announced additional preliminary clinical data from cohort 3 of this investigator-initiated trial. When aggregated with cohorts previously reported, the data shows a 50% objective response rate in advanced melanoma with GR-MD-02 in combination with KEYTRUDA, and a significant decrease in the frequency of suppressive myeloid-derived suppressor cells following treatment in the responding patients (on day 85 post-treatment). Fourteen advanced melanoma patients across three dose cohorts now have Objective Response Rate (ORR) and Disease Control Rate (DCR) data. Six patients completed in cohort 3 (8 mg/Kg) have now been added to the three patients completed in cohort 2 (4 mg/Kg) and five patients completed in cohort 1 (2 mg/Kg). Cohorts 1 and 3 each had two patients with an objective response. All three patients in cohort 2 had an objective response. In addition to the fourteen advanced melanoma patients, six patients with head and neck cancer were enrolled in this trial with a 33% ORR and 67% DCR. These data, taken together with the observed favorable safety and tolerability of the combination, in the view of the principal investigator, provide compelling rationale to move forward. Given that all three melanoma patients were responders at the 4 mg/Kg dose, the investigators plan to continue the trial with the expansion of the 4 mg/Kg cohort to include additional advanced melanoma patients and additional head and neck cancer patients.

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Severe skin diseases. During our Phase 1 NASH fibrosis trial with GR-MD-02, a clinical effect on plaque psoriasis was observed in a NASH patient who also had this disease. This patient had marked improvement in her psoriasis, with improvement beginning after the third infusion. She reported that her psoriasis was completely gone and her skin was normal after the fourth infusion. Her skin remained normal for 17 months after the final infusion of study drug. The patient is convinced that the improvement in her psoriasis is related to the study drug.

This serendipitous finding, combined with galectin-3 protein being markedly upregulated in the capillary epithelia (small blood vessels) of the psoriatic dermis (plaque lesions), led to a phase 2a trial in patients with moderate to severe plaque psoriasis. GR-MD-02 inhibition of galectin-3 may attenuate capillary changes in the psoriatic dermis and inflammatory recruitment, perhaps explaining the improvements observed in the NASH fibrosis trial patient. In this open-label, unblinded trial (no placebo, all patients knowingly receive active drug), 5 patients with moderate to severe plaque psoriasis were administered GR-MD-02 every two weeks for 24 weeks. In May 2016, we reported positive results on the first four patients after 12 weeks of therapy. Based on these results, we modified the trial to include 24 weeks of therapy. In August 2016, we reported on four patients after 24 weeks of therapy and one patient after 12 weeks of therapy. The four patients who received 24 weeks of therapy experienced an average of 48% improvement in their plaque psoriasis. At this time, the average response in all five patients remains at 50% with one patient having an 82% improvement. However, there are existing drugs on the market in this disease that produce 75% and higher improvements in 60-90% of patients. While we are encouraged that this study has demonstrated clinically meaningful results in a human disease with GR-MD-02, the next steps would entail a controlled, does-ranging clinical trial which we do not expect to conduct absent a strategic partnership.

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

Liver Fibrosis: New Approach for a Significant Unmet Medical Need

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

In the liver, fibrosis is the end result of multiple inflammatory conditions and infections. Progressive liver fibrosis leads to cirrhosis, which results in reduction of liver function, multiple medical complications and ultimately death. It is estimated that one to two million patients have cirrhosis in the United States with close to 50,000 losing their lives yearly. Only a fraction of patients lives, approximately 6,200 per year, are saved by liver transplantation at a cost of at least $350,000 per transplantation with significant additional costs of care and medications after the transplant. One condition in particular that frequently leads to cirrhosis is non-alcoholic steatohepatitis, or NASH, a liver disease characterized by the accumulation of fat in the liver with associated inflammation and fibrosis, which can lead to end-stage cirrhosis requiring liver transplantation. The National Institutes of Health estimates that 9 to 15 million Americans are affected by NASH, and other sources suggest it may be as many as 30 million people have NASH, and forecasts that the number of Americans affected by this disease is growing due to obesity and diabetes, with the potential to become the leading cause of liver cirrhosis and liver transplantation in the future. Liver transplantation is currently the only therapeutic approach to NASH or other forms of liver fibrosis because, to the best of our

knowledge, there are no drug therapies on the market. Organ transplantation is a difficult, risky and costly procedure, and organ availability is scarce. There is also the

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risk of developing cirrhosis in the transplanted liver from the same disease that damaged the patient s original liver. Therefore, there is a great need for other therapeutic options. All diseases that affect the liver (viral hepatitis, alcoholic liver disease, and fatty liver as examples) lead to the development of scarring of the liver.

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

We have evaluated the ability of GR-MD-02 to block galectin-3 in animal models of liver fibrosis, the conclusions of which yielded positive results. Our pre-clinical data show that GR-MD-02 may have a therapeutic effect on liver fibrosis as shown in several relevant animal models. Therefore, we chose GR-MD-02 as the lead candidate in a development program targeted initially at fibrotic liver disease associated with NASH.

We evaluated GR-MD-02 in pre-clinical toxicology and pharmacology studies during 2013, and filed an IND with the FDA in January 2013, for initiating human studies in patients with NASH. In February 2013, we entered into an agreement with CTI Clinical Trial Services to assist with the design, development and conduct of one or more clinical research studies, specifically for services with respect to our Phase 1 clinical trials to evaluate safety of GR-MD-02 in patients with NASH. The FDA notified us in March 2013 that we may proceed with a Phase 1 clinical trial for patients with NASH, and we began enrolling patients in the Phase 1 clinical trial in the third quarter of 2013. In August 2013, GR-MD-02 was granted Fast Track designation by the FDA for NASH with hepatic fibrosis, commonly known as fatty liver disease with advanced fibrosis. In January 2014, we completed the enrollment of the first cohort of patients in the Phase 1 trial with no serious adverse events being reported. We reported initial safety and tolerability results from the first cohort of patients on June 30, 2014. The second cohort of this Phase 1 trial began, and enrollment was completed in April 2014. In July 2014, we reported the results from the second cohort of patients. Enrollment of the third cohort of Phase 1 began in July 2014, with interim results presented in November 2014 with the final report on cohort 3 presented in January 2015. The results of the Phase 1 study demonstrate that (i) GR-MD-02 was safe and well tolerated by patients with advanced NASH liver fibrosis after IV administration of four doses of 2 mg/kg, 4 mg/kg and 8mg/kg lean body weight, (ii) Pharmacokinetics in patients with advanced fibrosis, but not cirrhosis, revealed drug exposure in humans at the 8 mg/kg dose that was equivalent to the upper range of the targeted therapeutic dose determined from effective doses in NASH animal models, (iii) Disease Serum Marker Effect showed there was a statistically significant, dose-dependent reduction in FibroTest® scores due to a statistically significant reduction in alpha-2 macroglobulin (A2M) serum levels, and (iv) Liver Stiffness Effect, as measured by FibroScan® showed that there was a signal of reduced liver stiffness in patients receiving GR-MD-02. The reduction seen in A2M does *not* necessarily mean fibrosis got better in this short study but does suggest changes in the fibrogenic process that might lead to an improvement in fibrosis with longer-term therapy. These Phase 1 results in NASH patients with advanced fibrosis, in addition to completion of further toxicology and drug-drug interaction studies provided a firm foundation for entry into a Phase 2 development program (described above). Top line results of our Phase 2b in compensated NASH cirrhosis patients was reported in December 2017 and is more fully described above as well in our SEC filings.

GR-MD-02 is a proprietary, patented galactoarabino-rhamnogalacturonan polysaccharide polymer that is comprised predominantly of galacturonic acid, galactose, arabinose, rhamnose, and smaller amounts of other sugars. Structural

studies have shown that GR-MD-02 binds to galectin-1 and to galectin-3 with binding affinity to galectin-3 being significantly greater than binding to galectin-1. With respect to GR-MD-02, we currently

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have, as of December 31, 2018, 20 granted U.S. patents, and 57 foreign granted patents. These patents more fully described below, include a composition of matter patent, and methods of use including manufacture, use patient in patients with NASH, in patients with liver fibrosis, and in patients with diabetic kidney disease. Additional patent applications are pending with respect to, amongst other uses, cancer immunotherapy, lung fibrotic disease, and inflammatory disease associated with increase in inducible nitric oxide synthase. Patents have also been granted with respect to liver fibrosis, NASH, and liver fibrosis in combination with other therapeutic agents. Compounds for subcutaneous administration and oral delivery are currently under pre-clinical development.

Galectin Inhibition in Cancer Therapy

We believe the potential exists for galectin inhibition to play an important role in cancer therapy. Galectin proteins, particularly galectin-1 and galectin-3, have been shown to be highly expressed in the majority of cancers and have multiple roles in promoting cancer progression, including tumor cell invasion, metastasis, angiogenesis, and tumor evasion of the immune system.

The role of galectins in cancer immunotherapy can be understood through the Galectin Effect , a recent discovery of how tumors avoid the body s own immune system, i.e., the tumors secrete galectin proteins that block the body s efforts to fight tumors. Our current program to block the Galectin Effect is based on the research of Dr. Pierre van der Bruggen (of the Ludwig Institute of Cancer Research in Brussels, Belgium), demonstrating that galectin-3, which is produced by the vast majority of human cancers, binds to and blocks the actions of tumor-infiltrating T-lymphocytes, the major immune cell in the body s defense against cancers. In addition, Dr. William L. Redmond of Providence Portland Medical Center s Earl A. Chiles Research Institute (EACRI) has shown that our galectin inhibitors can enhance the anti-tumor immunogenic effect of other immunotherapies based on targeting lymphocyte checkpoints such as CTLA4. Based on these results, we believe that the body s immune cells may be unable to attack and kill tumor cells in the presence of galectins. Using this approach, the mechanism of action for our drugs seeks to block galectins and, in turn, restore the ability of the T-lymphocytes to kill tumor cells.

The preclinical study found that GR-MD-02 increased tumor shrinkage and enhanced survival in immune competent mice with prostate or breast cancers when combined with one of the immune checkpoint inhibitors, anti-CTLA-4 or anti-PD-1. These findings suggest a role for GR-MD-02 in cancer immunotherapy. These preclinical observations by Dr Redmond provided scientific rationale for proceeding and lead to the filing by Providence Portland Medical Center of an Investigator-sponsored IND to conduct a Phase 1B study to determine if GR-MD-02 enhances the probability of melanoma response with ipilimumab by inducing proliferation, activation and memory function of CD8+ T cells in human patients. The company has licensed the underlying invention from Providence Portland Medical Center. This study represents a novel approach for patients with metastatic melanoma. The IND was approved by FDA in February 2014. This study is being conducted under the sponsorship of Providence Portland Medical Center s Earle A. Chiles Research Institute (EACRI) and is being supported by the Company.

The study employs a dose escalation of GR-MD-02 in conjunction with the standard therapeutic dose of ipilimumab in patients with advanced melanoma for whom ipilimumab would be considered standard of care. In addition to monitoring for toxicity and clinical response by irRECIST criteria on imaging tests, blood samples will be obtained to assess immunologic measures relevant to galectin biology and ipilimumab T-cell check-point inhibition. Galectin Therapeutics is providing its proprietary compound GR-MD-02 to EACRI researchers, as well as supplying researchers with supporting analysis of the pharmacokinetics of GR-MD-02 and the right to reference the Company s open IND on GR-MD-02. To date the first two dosing groups have been completed without serious adverse events that were determined to be related to GR-MD-02. The third dosing group is no longer enrolling due to the availability of newer agents such as the anti-PD! agents.

Similar to the agreement set forth for the ipilimumab (Yervoy®) Phase 1B study, Providence Portland Medical Center submitted an IND in September 2015 to conduct a Phase 1B study of GR-MD-02 and

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pembrolizumab (Keytruda®) in patients with metastatic melanoma. The combination of GR-MD-02 and an anti-PD1 (pembrolizumab) has been shown to enhance T-cell activation, memory, and effector function, and promote better antitumor responses in multiple mouse studies. The study will test the hypothesis that galectin-3 antagonism using GR-MD-02 with enhance the probability of melanoma response using pembrolizumab in patients by inducing proliferation, activation and memory function of CD8+ T cells that recognize melanoma antigens. Similar to the ipilimumab study, the study employs a dose escalation of GR-MD-02 in conjunction with the standard therapeutic dose of pembrolizumab in patients with metastatic melanoma who have had progression of their melanoma after ipilimumab and/or BRAF targeted therapy when a BRAF mutation is present. In addition to monitoring for toxicity and clinical response, blood and tumor samples will be obtained to assess immunologic measures relevant to galectin biology and pembrolizumab T-cell checkpoint inhibition. Top line results of the combination of the 3 dosing cohorts was reported in September 2018 and is more fully described above as well in our SEC filings and press releases. These data, taken together with the observed favorable safety and tolerability of the combination, in the view of the principal investigator, provide compelling rationale to move forward. Given that all three melanoma patients were responders at the 4 mg/Kg dose, the investigators plan to continue the trial with the expansion of the 4 mg/Kg cohort to include additional advanced melanoma patients and additional head and neck cancer patients. If these additional results should continue to be encouraging, the next step in development would entail a controlled randomized Phase 2 clinical trial.

Patents and Proprietary Rights

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

In August 2015, we received a notice of allowance from the U.S. Patent and Trademark Office for patent application number 13/726,900, titled Galactose-pronged polysaccharides in a formulation for antifibrotic therapies. This patent extends coverage of the Company s pectin-derived compounds (including broad molecular weight ranges and other sources of pectin) to include treatment of chronic kidney disease associated with the development of fibrosis, established kidney fibrosis, chronic lung disease associated with the development of fibrosis and established lung fibrosis. Claims in this patent include administering pectin-derived compound parenterally to a patient having at least one of the four aforementioned diseases where the established fibrosis or progression of the fibrosis or cirrhosis is inhibited or slowed down. Additional specific claims encompass deriving the compound from citrus pectin, apple pectin, soybean hull pectin or sugar beet pectin with a molecular weight between 2 kDa and 400kDa. Also covered is the step of administering the modified galacto-rhamnogalacturonan compound in an admixture with a therapeutic agent, where the agent is an antifibrotic compound.

In August 2014, we received a notice of allowance from the U.S. Patent and Trademark Office for patent application number 13/573,442 titled Composition of Novel Carbohydrate Drug for Treatment of Human Diseases. The patent covers composition and chemical structural claims for compounds that includes the Company s lead galectin inhibitor compound GR-MD-02 and will expire in December 2031. Claims include multiple routes of administration, including intravenous, subcutaneous and oral. The application also covers therapeutic formulations for use in the treatment of NASH (fatty liver disease), cancer and fibrotic, inflammatory and autoimmune disorders in which galectin proteins are involved, at least in part, in the pathogenesis. Additional specific claims encompass liver fibrosis, kidney fibrosis, lung fibrosis or heart fibrosis. The patent, assigned U.S. Patent No. 8,871,925, was issued October 28, 2014.

In May 2014, we received notice of allowance from the U.S. Patent and Trademark Office for patent application number 13/998,197 titled Galactose-Pronged Carbohydrate Compounds for the Treatment of

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Diabetic Nephropathy and Associated Disorders. The patent covers both composition claim for and uses of the Company s carbohydrate-based galectin inhibitor compound GR-MD-02 in patients with diabetic nephropathy, a type of progressive kidney disease that occurs in individuals with diabetes. Diabetic nephropathy is the major cause for chronic renal failure in the United States. The patent, assigned U.S. Patent No. 8,828,971, was issued September 9, 2014.

In February 2014, we received notice of issuance that the U.S. Patent and Trademark Office issued patent number 8,658,787 to the Company for its application titled Galacto-rhamnogalacturonate compositions for the treatment of non-alcoholic steatohepatitis and non-alcoholic fatty liver disease. The patent covers the Company s carbohydrate-based galectin inhibitor compound GR-MD-02 for use in patients with fatty liver disease with or without fibrosis or cirrhosis, providing patent protection through 2031. The major claims are for methods of obtaining galectin inhibitor compounds, obtaining a composition for parenteral or enteral administration in an acceptable pharmaceutical carrier and administering to a subject having at least one of the following: fatty liver, non-alcoholic fatty liver disease, non-alcoholic steatohepatitis, non-alcoholic hepatitis with liver fibrosis, non-alcoholic steatohepatitis with cirrhosis, or non-alcoholic steatohepatitis with cirrhosis and hepatocellular carcinoma. The use covers reversing or slowing the progression of disease activity or medical consequences of the disease. Applications are pending in multiple countries to extend patent protection globally.

In January 2014, we received a notice of allowance from the U.S. Patent and Trademark Office for Patent Application Number 13/550,962 titled Galactose-Pronged Polysaccharides in a Formulation for Anti-fibrotic Therapies. The patent covers both composition claim for and uses of the Company s carbohydrate-based galectin inhibitor compound GR-MD-02 for use in patients with liver fibrosis in combination with other potential therapeutic agents. The patent covers use of GR-MD-02 with agents directed at multiple targets, some of which are currently in clinical development for fibrotic disorders including monoclonal antibodies to connective tissue growth factor, integrins, and TGF-ß1. The patent, assigned U.S. Patent No. 8,722,645, was issued May 13, 2014.

In July 2012, we received a notice of issuance from the U.S. Patent and Trademark Office for the U.S. Patent number 8,236,780 issued on August 7, 2013 titled Galactose-prolonged polysaccharides in a formulation for antifibrotic therapies . This methods patent covers key methods of derivation and use for our carbohydrate-based galectin inhibitor compound for use in patients with chronic liver disease associated with the development of fibrosis, established liver fibrosis or end-stage scarring, or cirrhosis. The major claim is for a method of obtaining a galacto-rhamnogalacturan compound from an apple pectin, obtaining a composition for parenteral administration the galacto-rhamnogalacturonan compound in an acceptable pharmaceutical carrier and administering to a subject having at least one of the following: chronic liver disease associated with the development of fibrosis, established liver fibrosis or cirrhosis. The use covers inhibiting or slowing the progression of fibrosis. GR-MD-02 is covered by this patent and it provides opportunities for development of additional compounds in the class.

As of December 31, 2018, Galectin Therapeutics Inc. held 20 granted U.S. patents, 57 foreign granted, 3 Foreign patent applications allowed, 25 Foreign patent applications pending, and 3 U.S. patent applications pending. Many of our patents and patent applications cover composition of matter for complex carbohydrate drugs and/or methods of use for reducing toxicity and enhancing chemotherapeutic drugs by co-administering a polysaccharide with a chemotherapeutic agent or for use in treatment of fibrosis. The scheduled expiration dates of our United States patents span from 2020 to 2033 before considering any potential extensions. We have corresponding patent applications pending in various territories where we see potential for commercial interest. Additionally, we have patent applications in other areas to utilize our carbohydrate-based compounds to treat disease other than cancer. See Risk Factors Risks Related to Our Intellectual Property . Our competitive position, in part, is contingent upon protection of our intellectual property. Galectin Sciences LLC has 1 US patent application pending and 10 foreign applications pending; 4 PCT International applications are pending.

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Research

Our primary focus is on the design and testing of agents that target galectins in various *in vitro* and *in vivo* systems and that demonstrate efficacy in treatment of experimentally induced fibrosis or enhance immune system responsiveness in various tissues and in live animal models. We contract with independent laboratories and other facilities to conduct our research, which is designed, evaluated and managed by our scientists. While we conduct in house research related to our compounds at SBH laboratories in Massachusetts, we do not anticipate building additional in-house research or development facilities or hiring staff other than for purposes of designing and managing our out-sourced research.

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

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

In September 2014, the Company established a collaborative research program with Dr. William Redmond s laboratory located at the Providence Portland Medical Center, Portland, Oregon. This program focuses on combination immunotherapy plus galectin inhibition to augment tumor immunogenicity.

During the years ended December 31, 2018 and 2017, our expenditures for research and development were $6.5 million and $11.7 million, respectively. We expense all research and development costs as they are incurred.

In January 2014 we created, with SBH Sciences, Inc. (Natick, Ma), Galectin Sciences, LLC, a collaborative joint venture to research and develop small organic molecule inhibitors of galectin-3 for oral administration.

Using computer molecular modeling techniques coupled with *in vitro* screening of a variety of compound libraries, SBH Sciences had identified several small organic molecules with promising galectin-3 inhibitory activity *in vitro*. Galectin Sciences LLC will further develop these unique organic molecule inhibitors of galectin-3 as drug candidates as well as develop additional candidates. Subject to availability of funding, Galectin Sciences LLC will build on the scientific body of knowledge amassed by SBH Sciences, coupled with Galectin Therapeutics knowledge and expertise of galectins pathological role and mechanism of action in inflammation, fibrosis and many cancers. The long-term goal of this effort is to identify and develop drug candidates that are highly specific galectin inhibitors which may be formulated for oral administration. The intermediate term goal is the development of small molecule inhibitors of galectin-3 which exhibit activity in *in vivo* preclinical disease models of fibrosis and cancer in which galectins play a key role. Several patent applications have been filed to protect the various series of compounds discovered by these efforts.

Because, increased levels of galectin proteins have been implicated in a very large number of inflammatory, fibrotic and neoplastic diseases; the discovery and development of orally active galectin inhibitors would be a major step towards expanded treatment approaches for these disorders. This early drug discovery effort may lead to drugs that would expand our pipeline as follow on compounds to our first in class galectin inhibitors, GR-MD-02 and GM-CT-01. These efforts have identified several potential compounds which are continuing to be explored to identify lead molecules that may be identified for clinical development.

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Manufacturing and Marketing

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

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

Competition

Many biotechnology and pharmaceutical companies are developing new technologies for the treatment of cancer, fibrotic diseases and other diseases. Technologies such as monoclonal antibodies could be competitive with our galectin therapeutic platforms. Other companies are trying to improve the therapeutic profile of widely used protein-based drugs. While these companies may broaden the market for our products they may also provide competitive alternatives to our products. We expect increased competition in the area of galectins will be fueled by a nearly exponential increase in the publication rate of research papers on galectins.

See Risk Factors Risks Related to Our Company We face intense competition in the biotechnology and pharmaceutical industries for additional discussion related to our current and potential competition.

Government Regulation

The research, development, testing, manufacture, labeling, promotion, advertising, distribution, and marketing, among other things, of our products are extensively regulated by governmental authorities in the United States and other countries. The FDA regulates drugs under the federal Food, Drug, and Cosmetic Act and its implementing regulations. Failure to comply with the applicable U.S. requirements may subject us to administrative or judicial sanctions, such as FDA refusal to approve pending New Drug Applications (NDAs), warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, and/or criminal prosecution.

Drug Approval Process

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

1. Pre-clinical laboratory tests, animal studies, and formulation studies,

2. Submission to the FDA of an IND for human clinical testing, which must become effective before human clinical trials may begin,

3. Adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug for each indication,

4. Submission to the FDA of a NDA,

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5. Satisfactory completion of an FDA inspection of the manufacturing facility or facilities, at which the drug is produced to assess compliance with current good manufacturing procedures (cGMP) established by the FDA,

6. FDA review and approval of the NDA, and

7. FDA review and approval of a trademark used in connection with a pharmaceutical.

Pre-clinical tests include laboratory evaluation of product chemistry, toxicity, and formulation, as well as numerous in vitro and in vivo animal studies. The results of the pre-clinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND, which must become effective before human clinical trials may begin and the Company must resolve any outstanding FDA concerns or questions before clinical trials can proceed. There is no certainty that submission of an IND will result in the FDA allowing clinical trials to begin.

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

Clinical trials typically are conducted in three sequential phases, but the phases may overlap or be combined. Each trial must be reviewed and approved by an independent Institutional Review Board (IRB), before it can begin. Study subjects must sign an informed consent form before participating in a clinical trial. Phase 1 usually involves the initial introduction of the investigational drug into patients to evaluate its safety, dosage tolerance, pharmacodynamics, and, if possible, to gain an early indication of its effectiveness. Phase 2 usually involves trials in a limited patient population to (i) evaluate dosage tolerance and appropriate dosage; (ii) identify possible adverse effects and safety risks; and (iii) evaluate preliminarily the efficacy of the drug for specific indications. Phase 3 trials usually further evaluate clinical efficacy and test further for safety by using the drug in its final form in an expanded patient population. There is no assurance that these trials will be completed within a specified period of time, if at all.

Assuming successful completion of the required clinical testing, the results of the pre-clinical studies and of the clinical studies, together with other detailed information, including information on the manufacture and composition of the drug, are submitted to the FDA in an NDA requesting approval to market the product for one or more indications. Before approving an NDA, the FDA usually will inspect the facilities at which the drug is manufactured and will not approve the product unless compliance with cGMP is satisfactory. If the FDA evaluates the NDA and the manufacturing facilities as acceptable, the FDA will generally issue an approval letter. If the FDA evaluates the NDA submission or the manufacturing facilities as not acceptable, the FDA will generally outline the deficiencies in the submission and often will request additional testing or information. Even if an applicant submits the requested additional information, the FDA ultimately may decide that the NDA does not satisfy the regulatory criteria for approval. The testing and approval process require substantial time, effort, and financial resources, and there is no assurance that any approval will be granted on a timely basis, if at all. After approval, certain changes to the approved product, such as adding new indications, manufacturing changes, or additional labeling claims are subject to further FDA review and approval.

See Risk Factors Risks Related to the Regulation of Our Products We will need regulatory approvals to commercialize our products for additional discussion of regulatory risks related to our drug development program.

FDA Priority Review

FDA procedures provide for priority review of an NDA submitted for drugs that, compared to currently marketed products, offer a significant improvement in the treatment, diagnosis, or prevention of a disease. NDAs

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that are granted priority review are acted upon more quickly than NDAs given standard review. If we were to seek priority review, there can be no guarantee that the FDA will grant priority review status, that priority review status will affect the time of review, or that the FDA will approve the NDA submitted for any of our product candidates, whether or not priority review status is granted.

Post-Approval Requirements

If FDA approval of one or more of our products is obtained, we will be required to comply with a number of post-approval requirements. For example, holders of an approved NDA are required to report certain adverse reactions to the FDA and to comply with certain requirements concerning advertising and promotional labeling for their products. Also, quality control and manufacturing procedures must continue to conform to current Good Manufacturing Practices (cGMP) after approval, and the FDA periodically inspects manufacturing facilities to assess compliance with cGMP. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. In addition, discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved NDA, including withdrawal of the product from the market. Also, new government requirements may be established that could delay or prevent regulatory approval of our products under development.

Regulation Outside the United States

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

Environmental Regulation

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

Employees

We currently have six full-time employees, four of whom are involved primarily in management of our pre-clinical research and development and clinical trials and three who were involved primarily in management and administration of our Company. We also utilize contractors and consultants who provide product development, manufacture, analytical testing, clinical trial expertise, and clinical trial support.

Available Information

The Company is required to file annual, quarterly and current reports, proxy statements and other information with the Securities and Exchange Commission (SEC), including Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to reports filed pursuant to

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Sections 13(a) and 15(d) of the Securities Exchange Act of 1934. The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC at http://www.sec.gov. The Company s website is www.galectintherapeutics.com. The information contained on, or hyperlinked from, our website is not a part of, nor is it incorporated by reference into, this Annual Report on Form 10-K.

Item 1A. ***Risk Factors***

An investment in our common stock involves a high degree of risk. You should carefully consider the risks described below and the other information before deciding to invest in our common stock. The risks described below are not the only ones facing our Company. Additional risks not presently known to us or that we currently consider immaterial may also adversely affect our business. We have attempted to identify below the major factors that could cause differences between actual and planned or expected results, but we cannot assure you that we have identified all of those factors.

If any of the following risks actually happen, our business, financial condition and operating results could be materially adversely affected. In this case, the trading price of our common stock could decline, and you could lose all or part of your investment.

Risks Related to Our Company

We have incurred net losses to date and must raise additional capital in order to continue to operate after December 31, 2019.

We have incurred net losses in each year of operation since our inception in July 2000 and have no revenues. Our accumulated deficit as of December 31, 2018 was $196.2 million. We had $8.3 million of unrestricted cash as of December 31, 2018. In December 2018, the Company announced an extension of its $10 million unsecured line of credit facility with stockholder and director, Richard E. Uihlein. The Company has not drawn under the line of credit. Additionally, the Company generated approximately $1.87 million in net proceeds via sale of common stock under its At Market Sales Agreement in January and February 2019. The Company believes there is sufficient cash, including availability of the line of credit, to fund currently planned operations at least through March 31, 2020. We will require more cash to fund our operations after March 31, 2020 and believe we will be able to obtain additional financing. The currently planned operations do not include costs related to a planned Phase 3 clinical trial. While the costs of the trial and general overhead during the Phase 3 trial are expected to be approximately $100 million, the costs and timing of such trial are not yet finalized. The Company has not made commitments for such trial that cannot be covered with available cash. The costs of a Phase 3 clinical trial will require additional funding. However, there can be no assurance that we will be successful in obtaining such new financing or, if available, that such financing will be on terms favorable to us.

We 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 or postpone the commencement of our Phase 3 clinical trial. 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 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.

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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;
- 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 unable 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 dependent on the success of our lead product candidate, GR-MD-02, and we cannot be certain that these product candidates will receive regulatory approval or be successfully commercialized.

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

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

GR-MD-02 our lead product candidate for fibrosis completed its Phase 2 of the human clinical trial phase in 2017, and during 2018 we have been designing a Phase 3 clinical trial. 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 (pembrolizmab) in patients with metastatic melanoma.

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To obtain FDA approval, we will need to conduct one or more Phase 3 clinical trial for GR-MD-02; however, we cannot assure you that we will be able to finance Phase 3 trials. Additionally, we cannot assure you that future our trials will yield successful results, that they will lead to the generation of revenue, or that we will obtain regulatory approval in other countries.

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, although there was positive data from our NASH-CX Phase 2 trial for GR-MD-02, which we believe will allow us to conduct a Phase 3 trial, it did not meet its primary endpoint. Similarly, 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 may engage others to conduct our clinical trials, including clinical research organizations and, possibly, government-sponsored agencies. Additional 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 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, for our NASH-CX trial we engaged the services of PPD Development, L.P. (PPD) for the purpose of assisting us in the design, development and conduct of the trial. 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. As with our Phase 2 trial, to undertake Phase 3 trials for GR-MD-02, we will need to contract with a third party for assistance with the design and conduct of the trial. We cannot be certain that the terms of any such agreement will be favorable to the company.

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

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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. 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

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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. Some 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 our current base of employees and external hepatology consultants. These individuals, among other things, design and lead our pre-clinical and clinical studies, as well as our U.S. and European regulatory processes. The loss of any personnel or failure to attract or retain other key personnel and consultants could prevent us

from developing our products and core technologies and pursuing collaborative relationships.

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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 trials but also upon us being able to capitalize upon potential positive results of our trials, which is not assured.

To conduct Phase 3 clinical trials or other clinical trials we will need sufficient cash resources to conduct those undertakings. We will also need to obtain sufficient dosages of GR-MD-02 for such trials. Manufacturing of GR-MD-02 is performed by third parties on a contract basis and production is ongoing to generate what we believe is sufficient quantities of GR-MD-02 for planned Phase 3 clinical trials. Manufacturing could become delayed due to circumstances beyond our control which could delay any planned Phase 3 clinical trials. 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.

We have been a defendant in a shareholder derivative action, 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 were defendants in a state court shareholder derivative action. This lawsuit, nor concluded, is described in Part I, Item 3 Legal Proceedings in this Form 10-K. In addition, there is the potential for additional shareholder litigation and for governmental investigations and/or enforcement actions. Similar lawsuits in the future 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). If similar lawsuits do arise in the future, we may be required to pay material damages and fines, consent to injunctions on future conduct and/or suffer other penalties, remedies or sanctions. 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. 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. FDA may change, at any time, its requirements for approval of new drugs based on information and data received from others and ourselves potentially resulting in product approval delays or non-approvals. 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

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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;
- 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;

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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. 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.

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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

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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.

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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

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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;

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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 and the cost of our clinical trials;

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 have recently defended 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 (all have been designated as of December 31, 2018), and empowers our board of directors to

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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.

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 the holders of warrants, whether currently outstanding or subsequently granted, 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 by us of up to $100 million. We may consider additional or other capital raising transactions within the next twelve months, which would likely result in issuances of additional shares that would be dilutive to current shareholders. In addition, the lack of a robust resale market may require a stockholder who desires to sell a large number of shares of common stock to sell the shares in increments over time to mitigate any adverse impact of the sales on the market price of our stock.

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

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We have not paid cash dividends on our common stock in the past and do not expect to pay cash dividends in the foreseeable future.

We have never paid cash dividends on our common stock and do not anticipate paying cash dividends on our common stock in the foreseeable future. The payment of dividends on our common 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 to raise money or otherwise desire to liquidate your shares.

We cannot predict the extent to which an active public market for our common stock 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 that 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 that 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.

Concentration of ownership by our principal stockholders may limit your ability to influence the outcome of director elections and other transactions requiring stockholder approval.

A significant percentage of our outstanding stock is held by a limited number of investors, including Richard E. Uihlein. Mr. Uihlein, the chairman of our board of directors, who beneficially owns approximately 5.7% of our outstanding common stock as of February 20, 2019 (which does not include any shares issuable upon exercise of options and warrants) and the 10X Fund, LP , which now owns 14.3% of the issued and outstanding shares of common stock of the Company as of February 20, 2019 (which does not include any shares issuable upon exercise of options and warrants). Mr. Uihlein is also an investor in the 10X Fund as a limited partner but is not deemed to be a beneficial owner of, or have a reportable interest in, any shares owned by 10X Fund. As a result of their ownership of shares of common stock, Mr. Uihlein and 10X Fund have and will have significant influence over corporate actions requiring stockholder approval, including the following actions:

to elect or defeat the election of our directors;

to amend or prevent amendment of our certificate of incorporation or bylaws;

to effect or prevent a merger, sale of assets or other corporate transaction; and

to control the outcome of any other matter submitted to our stockholders for vote.

Such persons stock ownership may discourage a potential acquirer from making a tender offer or otherwise attempting to obtain control of our company, which in turn could reduce our stock price or prevent our stockholders from realizing a premium over our stock price.

Richard E. Uihlein s and 10X Fund s significant ownership positions may deter or prevent efforts by other companies to acquire us, which could prevent our stockholders from realizing a control premium.

As a result of Mr. Uihlein s and 10X Fund s significant ownership and Mr. Uihlein s position as chairman of the board of directors, other companies may be less inclined to pursue an acquisition of us or we may not have the opportunity to be acquired in a transaction that stockholders might otherwise deem favorable, including transactions in which our stockholders might realize a substantial premium for their shares.

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Richard E. Uilhlein and/or 10X Fund could sell or transfer a substantial number of shares of our common stock, which could depress the price of our securities or result in a change in control of our company.

Although Mr. Uihlein has held common stock of the Company since 2012 and has not sold any of the shares of common stock that he has acquired during this time period, and although 10X Fund has been a long-time investor in the Company, neither Mr. Uihlein nor 10X Fund are subject to any contractual restrictions with us on their ability to sell or transfer our common stock on the open market, in privately negotiated transactions or otherwise, and these sales or transfers could create substantial declines in the price of our securities or, if these sales or transfers were made to a single buyer or group of buyers, could contribute to a transfer of control of our company to a third party. Sales by Mr. Uihlein or 10X Fund of a substantial number of shares, or the expectation of such sales, could cause a significant reduction in the market price of our common stock.

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

None.

Item 2. ***Properties***

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

Item 3. ***Legal Proceedings***

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

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

Not applicable.

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PART II

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

Our common stock began trading on The NASDAQ Capital Market under the symbol GALT effective March 23, 2012.

Holders of Common Stock

As of February 20, 2019, there were 279 shareholders of record of our common stock. Because shares of our common stock are held by depositaries, brokers and other nominees, the number of beneficial holders of our shares is substantially larger than the number of record holders. Based on information available to us, we believe there are approximately 12,500 non-objecting beneficial owners of our shares of our common stock in addition to the record holders.

Dividends

As we have never paid cash dividends on our common stock and do not anticipate paying cash dividends on our common stock in the foreseeable future. The payment of dividends on our common 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.

Item 6. *Selected Financial Data*

Not applicable.

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

Forward-Looking Statements

In addition to historical information, the following Management s Discussion and Analysis of Financial Condition and Results of Operations contains forward-looking statements as defined under Section 21E of the Securities Exchange Act of 1934, as amended, and is subject to the safe harbor created therein for forward-looking statements. Such statements include, but are not limited to, statements concerning our anticipated operating results, research and development, clinical trials, regulatory proceedings, and financial resources, and can be identified by use of words such as, for example, anticipate, estimate, expect, project, intend, 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: plans and expectations regarding clinical trials; plans and expectations regarding regulatory approvals; our strategy and expectations for clinical development and commercialization of our products; potential strategic partnerships; expectations regarding the effectiveness of our products; plans for research and development and related costs; statements about accounting assumptions and estimates; expectations regarding liquidity and the sufficiency of cash to fund currently planned operations through at least March 31, 2020; our commitments and contingencies; and our market risk exposure. Forward-looking statements are based on current expectations, estimates

and projections about the industry and markets in which Galectin Therapeutics operates, and management s beliefs and assumptions. These statements are not guarantees of future performance and involve certain known and unknown risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Such risks and uncertainties are related to and include, without limitation,

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,

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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, including expected dates of availability of clinical data,

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

We caution investors that actual results or business conditions may differ materially from those projected or suggested in forward-looking statements as a result of various factors including, but not limited to, those described above and in the Risk Factors section of this annual report on Form 10-K. We cannot assure you that we have identified all the factors that create uncertainties. Moreover, new risks emerge from time to time and it is not possible for our management to predict all risks, nor can we assess the impact of all risks on our business or the extent to which any risk, or combination of risks, may cause actual results to differ from those contained in any forward-looking statements. Readers should not place undue reliance on forward-looking statements. We undertake no obligation to publicly release the result of any revision of these forward-looking statements to reflect events or circumstances after the date they are made or to reflect the occurrence of unanticipated events.

Results of Operations from the Years Ended December 31, 2018 and 2017

Research and Development Expense

2018 as Compared to 2017

	Year ended December 31,			
	2018	2017	$ Change	% Change
	(in thousands, except %)			
Research and development	$ 6,471	$ 11,721	$ (5,250)	(45)%

We generally categorize research and development expenses as either direct external expenses, comprised of amounts paid to third party vendors for services, or all other research and development expenses, comprised of employee payroll and general overhead allocable to research and development. We consider a clinical program to have begun upon acceptance by the FDA, or similar agency outside of the United States, to commence a clinical trial in humans, at which time we begin tracking expenditures by the product candidate. Clinical program expenses comprise payments to vendors related to preparation for, and conduct of, all phases of the clinical trial, including costs for drug manufacture, patient dosing and monitoring, data collection and management, oversight of the trials and reports of results. Pre-clinical expenses comprise all research and development amounts incurred before human trials begin, including payments to vendors for services related to product experiments and discovery, toxicology, pharmacology, metabolism and efficacy studies, as well as manufacturing process development for a drug candidate. We have two product candidates, GR-MD-02 and GM-CT-01; however only GR-MD-02 is in active development.

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Our research and development expenses were as follows:

	Year Ended December 31,	
	2018	2017
	(in thousands)	
Direct external expenses:		
Clinical programs	$ 2,296	$ 9,362
Pre-clinical activities	208	194
Other research and development expenses:		
Payroll and other including stock-based compensation	3,967	2,165
	$ 6,471	$ 11,721

Clinical programs expenses decreased primarily due to costs related to our Phase 2 clinical trials during the year ended December 31, 2018 as compared to the same period in 2017. Because we completed our NASH-CX Phase 2 trial in 2017, we expected our clinical activities costs to decrease in 2018 absent additional clinical trials commencing. Other research and development expenses increased during the year ended December 31, 2018 compared to 2017 primarily due to non-cash stock-based compensation expense.

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

General and Administrative Expense

	Year ended December 31,		2018 as Compared to 2017	
	2018	2017	$ Change	% Change
	(in thousands, except %)			
General and administrative	$ 7,131	$ 4,526	$ 2,605	58%

General and administrative expenses consist primarily of salaries including stock-based compensation, legal and accounting fees, insurance, investor relations, business development and other office related expenses. The primary reasons for the increase for the year ended December 31, 2018, as compared to the same period for 2017, are due to increased non-cash stock-based compensation of $1,922,000 and increased investor relations/business development expenses of $540,000.

Other Income and Expense

During the year ended December 31, 2018, other income and expense consisted of $38,000 of interest income offset by amortization of the warrants issued with a line of credit entered into in December 2017 of $336,000 which is classified as interest expense.

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Results of Operations from the Years Ended December 31, 2017 and 2016

Research and Development Expense

	Year ended December 31,		2017 as Compared to 2016	
	2017	2016	$ Change	% Change
	(in thousands, except %)			
Research and development	$ 11,721	$ 15,325	$ (3,604)	(24)%

We generally categorize research and development expenses as either direct external expenses, comprised of amounts paid to third party vendors for services, or all other research and development expenses, comprised of employee payroll and general overhead allocable to research and development. We consider a clinical program to have begun upon acceptance by the FDA, or similar agency outside of the United States, to commence a clinical trial in humans, at which time we begin tracking expenditures by the product candidate. Clinical program expenses comprise payments to vendors related to preparation for, and conduct of, all phases of the clinical trial, including costs for drug manufacture, patient dosing and monitoring, data collection and management, oversight of the trials and reports of results. Pre-clinical expenses comprise all research and development amounts incurred before human trials begin, including payments to vendors for services related to product experiments and discovery, toxicology, pharmacology, metabolism and efficacy studies, as well as manufacturing process development for a drug candidate. We have two product candidates, GR-MD-02 and GM-CT-01; however only GR-MD-02 is in active development.

Our research and development expenses were as follows:

	Year Ended December 31,	
	2017	2016
	(in thousands)	
Direct external expenses:		
Clinical programs	$ 9,362	$ 11,994
Pre-clinical activities	194	856
Other research and development expenses:		
Payroll and other including stock-based compensation	2,165	2,475
	$ 11,721	$ 15,325

Clinical programs expenses decreased primarily due to costs related to our Phase 2 clinical trials during the year ended December 31, 2017 as compared to the same period in 2016. As we have completed our NASH-CX Phase 2 trial in 2017, we expect our clinical activities costs will further decrease absent additional clinical trials commencing. Pre-clinical activities decreased primarily because we have completed pre-clinical work directly related to our Phase 2 clinical trial program.

Both the time required and costs we may incur in order to commercialize a drug candidate that would result in material net cash inflow are subject to numerous variables, and therefore we are unable at this stage of our development to forecast useful estimates. Variables that make estimates difficult include the number of clinical trials

we may undertake, the number of patients needed to participate in the clinical trial, patient recruitment uncertainties, trial results as to the safety and efficacy of our products, and uncertainties as to the regulatory agency response to our trial data prior to receipt of marketing approval. Moreover, the FDA or other regulatory agencies may suspend clinical trials if we or an agency believes patients in the trial are subject to unacceptable risks or find deficiencies in the conduct of the clinical trial. Delays or rejections may also occur if governmental regulation or policy changes during our clinical trials or in the course of review of our clinical data. Due to these uncertainties, accurate and meaningful estimates of the ultimate cost to bring a product to market, the timing of

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costs and completion of our program and the period during which material net cash inflows will commence are unavailable at this time.

General and Administrative Expense

	Year ended December 31,		2017 as Compared to 2016	
	2017	2016	$ Change	% Change
	(in thousands, except %)			
General and administrative	$ 4,526	$ 6,156	$ (1,630)	(26)%

General and administrative expenses consist primarily of salaries including stock-based compensation, legal and accounting fees, insurance, investor relations, business development and other office related expenses. The primary reasons for the decrease for the year ended December 31, 2017 as compared to the same period for 2016 are due to, decreased legal expenses of $251,000, decreased stock-based compensation of $1,068,000 and decreased investor relations expenses of $352,000.

Other Income and Expense

During the year ended December 31, 2017, other income and expense consisted of interest income offset by amortization of the warrants issued with a line of credit entered into in December 2017 of $12,000 which is classified as interest expense.

Liquidity and Capital Resources

As described above in the Overview and elsewhere in this Annual Report on Form 10-K, we are in the development stage and have not generated any revenues to date. Since our inception on July 10, 2000, we have financed our operations from proceeds of public and private offerings of debt and equity. As of December 31, 2018, we raised a net total of $147.4 million from these offerings. At December 31, 2018, the Company had $8.3 million of unrestricted cash and cash equivalents available to fund future operations. In December 2018, the Company announced the extension of its $10 million unsecured line of credit facility with stockholder and director, Richard E. Uihlein. The Company has not drawn under the line of credit. Additionally, in January 2019, the Company received $1.87 million in net proceeds from the ATM. The Company believes there is sufficient cash, including availability of the line of credit, to fund currently planned operations at least through March 31, 2020. We will require more cash to fund our operations after March 31, 2020 and believe we will be able to obtain additional financing. The currently planned operations do not include costs related to a planned Phase 3 clinical trial. While the costs of the trial and general overhead during the Phase 3 trial are expected to be approximately $100 million, the costs and timing of such trial are not yet finalized. The Company has not made commitments for such trial that cannot be covered with available cash. The costs of a Phase 3 clinical trial will require additional funding. However, there can be no assurance that we will be successful in obtaining such new financing or, if available, that such financing will be on terms favorable to us

2018 compared to 2017

Net cash used in operations decreased by $5,713,000 to $10,179,000 for 2018, as compared to $15,892,000 for 2017. Cash operating expenses decreased principally due to decreased research and development activities primarily related to our Phase 2 clinical programs.

There were no equipment purchases or other investing activities in 2018 or 2017.

Net cash provided by financing activities was $15,379,000 during 2018 as compared to $3,583,000 during 2017, due primarily to the transactions described below.

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In 2018, we completed sales of common stock through At the Market issuances totaling $5,603,000. Additionally, in 2018, we received proceeds totaling $6,003,000 and $3,773,000 from the exercise of common stock warrants and options, respectively. In 2017, we completed a private placement of common stock with warrants totaling $200,000 and sales of common stock through At the Market issuances totaling $3,383,000.

2017 compared to 2016

Net cash used in operations decreased by $517,000 to $15,892,000 for 2017, as compared to $16,409,000 for 2016. Cash operating expenses decreased principally due to decreased research and development activities primarily related to our Phase 2 clinical programs.

There were no equipment purchases or other investing activities in 2017 or 2016.

Net cash provided by financing activities was $3,583,000 during 2017 as compared to $5,925,000 during 2016, due primarily to the transactions described below.

In 2017, we completed a private placement of common stock with warrants totaling $200,000 and sales of common stock through At the Market issuances totaling $3,383,000. In 2016, we completed sales of Series B-3 preferred stock with warrants totaling $2,508,000, private placements of common stock and warrants totaling $3,000,000 and sales of common stock through At the Market issuances totaling $417,000.

Operating leases

Effective December 31, 2018, the Company entered into an amendment to its operating lease for office space in Norcross, GA for a term of thirty-eight months, beginning on January 1, 2019 and ending February 28, 2022 at a rate of approximately $3,800 per month. The amended lease provided for free rent for the first two months of the lease and continues the security deposit of $6,000. In addition to base rental payments included in the contractual obligations table above, the Company is responsible for our pro-rata share of the operating expenses for the building.

In October 2012, the Company entered into an operating lease for office space collocated with lab space for research and development activities. The lease is for a period of one year, beginning on October 1, 2012, for a rate of $15,000 for the term, payable in equal monthly increments. This lease was continued on a month to month basis from October 1, 2013.

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

Off-Balance Sheet Arrangements

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

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Contractual Obligations and Commitments

The following table summarizes contractual obligations and commitments as of December 31, 2018:

	Payments due by period (in thousands)				
Contractual Obligations	**Total**	**Less than 1 year**	**1-3 years**	**3-5 years**	**More than 5 years**
Operating Leases	$ 140	$ 38	$ 102		
Total	$ 140	$ 38	$ 102		

Critical Accounting Policies and Estimates

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

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

Research and Development Expenses. Costs associated with research and development are expensed as incurred. Research and development expenses include, among other costs, salaries and other personnel-related costs, and costs incurred by outside laboratories and other accredited facilities in connection with clinical trials and preclinical studies.

Stock-Based Compensation. Stock-based compensation cost is measured at the grant date based on the fair value of the award and is recognized as expense over the service period, which generally represents the vesting period. For

awards that have performance-based vesting conditions the Company recognizes the expense over the estimated period that the awards are expected to be earned. The Company generally uses the Black-Scholes option-pricing model to calculate the grant date fair value of stock options. For options that only vest upon the achievement of market conditions, the Company values the options using a Monte Carlo model to calculate the grant date fair value of the stock options. The expense related to options that vest based on market conditions is not reversed should those options not ultimately vest. The expense recognized over the service period is required

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to include an estimate of the awards that will be forfeited. Stock options issued to non-employees are accounted for in accordance with the provisions of ASC Subtopic 505-50, Equity-Based Payments to Non-employees, which requires valuing the stock options using an option pricing model (the Company uses Black-Scholes) and measuring such stock options to their current fair value when they vest.

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

Due to the nature of our operations, assets and absence of debt, we are not exposed to any significant market risks at December 31, 2018 and 2017.

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

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

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

None.

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

(a) Evaluation of Disclosure Controls and Procedures

As required by Rule 13a-15 under the Securities Exchange Act of 1934, (the Exchange Act) as of the end of the period covered by this Annual Report, we carried out an evaluation, under the supervision and with the participation of our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of our disclosure controls and procedures as of December 31, 2018. Our management has concluded, based on their evaluation, that our disclosure controls and procedures were effective as of December 31, 2018 to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission s rules and forms.

(b) Management s Annual Report on Internal Control Over Financial Reporting

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting. As defined in Rule 13a-15(f) under the Exchange Act, internal control over financial reporting is a process designed by, or under the supervision of, a company s principal executive and principal financial officers and effected by a company s board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. It includes those policies and procedures that:

a) Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company;

b) Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of a company are being made only in accordance with authorizations of management and the board of directors of the Company; and

c) Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company s assets that could have a material effect on its financial statements.

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Because of the inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

The Company s management has used the criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), or COSO, to evaluate the effectiveness of the Company s internal control over financial reporting. Management has selected the COSO 2013 framework for its evaluation as it is a control framework recognized by the SEC and the Public Company Accounting Oversight Board, that is free from bias, permits reasonably consistent qualitative and quantitative measurement of the Company s internal controls, is sufficiently complete so that relevant controls are not omitted, and is relevant to an evaluation of internal controls over financial reporting. Management conducted an evaluation of internal controls based on the COSO 2013 framework. The evaluation included a full scale, documented risk assessment, based on the principles described in the framework, and included identification of key controls. Management completed documentation of its testing to verify the effectiveness of the key controls. Based on the evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2018.

(c) Changes in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting that occurred during the fourth quarter of 2018 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. ***Other Information***

None.

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PART III

Item 10. ***Directors, Executive Officers and Corporate Governance***

Each of our directors is elected annually and holds office until his or her successor has been elected and qualified or until the earlier of his or her death, resignation or removal. Our board of directors currently consists of nine members, all of whom were elected at our 2018 Annual Meeting of Stockholders.

The following table sets for the certain biographical information about our directors as of February 20, 2019, and the qualifications, experiences and skills considered in determining that each such person should serve as a director.

Name	Age	Position	Director Since
Gilbert F. Amelio, Ph.D (2)(3)	75	Director	2009
James C. Czirr	63	Director	2009
Kary Eldred (1)	45	Director	2018
Kevin D. Freeman (1)(3)	57	Director	2011
Joel Lewis (1) (2)	49	Director	2017
Gilbert S. Omenn, M.D., Ph.D. (2)	77	Director	2014
Marc Rubin, M.D. (3)	64	Director	2011
Stephen Shulman	74	Director	2017
Richard E. Uihlein, Chairman	73	Director	2017

(1) Member of audit committee
(2) Member of compensation committee
(3) Member of nominating and governance committee

Gilbert F. Amelio, Ph.D., a director since February 2009, began his career at Bell Labs in Murray Hill, New Jersey. Since January 1, 2012, Dr. Amelio has provided consulting and advisory services through GFA, LLC, a California limited liability company. He was a Senior Partner of Sienna Ventures (a privately-held venture capital firm in Sausalito, California) from April 2001 until the fund closed per plan on December 31, 2011. Dr. Amelio was Chairman and Chief Executive Officer of Jazz Technologies, Inc. (now a wholly owned subsidiary of Tower Semiconductor Ltd., an independent specialty wafer foundry) from August 2005 until his retirement in September 2008 (when he was named Chairman Emeritus). Dr. Amelio was Chairman and Chief Executive Officer of Beneventure Capital, LLC (a full-service venture capital firm in San Francisco, California) from 1999 to 2005 and was Principal of Aircraft Ventures, LLC (a consulting firm in Newport Beach, California) from April 1997 to December 2004. Dr. Amelio was elected a Director of AT&T in February 2001 and had previously served as an Advisory Director of AT&T (then known as SBC Communications Inc.) from April 1997 to February 2001. He served as a Director of Pacific Telesis Group from 1995 until the company was acquired by AT&T in 1997. Prior to 1997, he served as Chairman, President and CEO of National Semiconductor (1991-1996) and Apple Computer (1996-1997). We believe Dr. Amelio s qualifications to sit on our Board of Directors include his executive leadership and management experience, as well as his extensive experience with global companies, his financial expertise and his years of experience providing strategic advisory services to organizations.

James C. Czirr, was nominated and elected by the holder(s) of the Series B Preferred Stock voting as a separate class to serve on our Board of Directors. Mr. Czirr served as Chairman of the Board from February 2009 until January 2016

and Executive Chairman from February 2010 until January 2016, is a co-founder of 10X Fund, L.P. and is a managing member of 10X Capital Management LLC, the general partner of 10X Fund, L.P. Mr. Czirr was a co-founder of Galectin Therapeutics in July 2000. Mr. Czirr was instrumental in the early stage development of Safe Science Inc., a developer of anti-cancer drugs; served from 2005 to 2008 as Chief Executive Officer of Minerva Biotechnologies Corporation, a developer of nano particle bio chips to determine the cause of solid tumors; and was a consultant to Metalline Mining Company Inc., now known as Silver Bull Resources, Inc., (AMEX: SVBL), a mineral exploration company seeking to become a low cost producer of zinc. Mr. Czirr

received a B.B.A. degree from the University of Michigan. We believe that Mr. Czirr is best situated to sit on our Board because he is the director who was a co-founder of the Company and is familiar with our business and industry.

Kary Eldred, is a director and Chief Investment Officer for the Living Stones Foundation since July 2015 and has been an active private equity investor for many years. In these capacities, he serves and has served on a number of corporate boards of companies with potential for and driving toward initial public offerings and is currently serving as a board member in Buy It Installed (since 2017), Babywise and Wise King Media (since 2015). Kary Eldred also served on the board and audit committee of GCT Semiconductor. From January 2011 through October 2014, Mr. Eldred was CEO & Chairman of Altadona, S.A. a software integration company based in Europe and prior to that was a principal in Parakletos Ventures, an institutional venture capital firm with several investments in companies that went on to be acquired or become publicly listed on different exchanges around the world including the NASDAQ, KOSDAQ and the GEM market. Mr. Eldred has an Executive MBA from IE Business School and a BA in Foreign Service from Baylor University. We believe that Mr. Eldred s qualifications to sit on our board include his experience serving on boards of several companies and experience in venture capital and private equity investing.

Kevin D. Freeman, a director since May 2011, holds the Chartered Financial Analyst designation and is Chief Executive Officer of Cross Consulting and Services, LLC, an investment advisory and consulting firm founded in 2004. He is also author of a New York Times best-selling book about the stock market and economy and the host of television segments (Economic War Room with Kevin Freeman) that airs nationally during local newscasts on 200 stations. Formerly he was Chairman of Separate Account Solutions, Inc. and held several offices at Franklin Templeton Investment Services from 1991 to 2000. He holds a B.S. in business administration from University of Tulsa, Tulsa, Oklahoma. We believe Mr. Freeman s qualifications to sit on our Board of Directors includes his extensive financial expertise and his years of experience providing financial advisory services.

Joel Lewis, a director since 2017, is the Managing Director of Shareholder Services at Uline, Inc. (a distributor of shipping, packaging and industrial supplies), a position he has held since 2007. Mr. Lewis is a financial executive with over 25 years of experience started his career in public accounting in 1992. Prior to his employment with Uline Inc., Mr. Lewis served as a Tax and Accounting Manager for Century America LLC from 2001 to 2006 and a Tax Manager for Deloitte & Touche from 1998 to 2001. After spending a decade in public accounting where he specialized in both financial reporting and taxation, Mr. Lewis migrated to privately held companies focusing on high net worth family businesses. Mr. Lewis has a wide range of expertise including working in a variety of industries and disciplines including taxation, restructuring, acquisition and private equity ventures. Mr. Lewis is a registered CPA in the state of Illinois. He holds a B.S. in Accountancy from the University of Illinois and a Masters in Taxation from DePaul University. We believe that Mr. Lewis qualifications to sit on our Board include his business and financial expertise and his service as a board observer on our Board during 2017.

Gilbert S. Omenn, M.D., Ph.D., a director since September 2014, served on the board of directors of Amgen Inc. for 27 years and of Rohm & Haas Company for 22 years. He currently serves on the boards of Esperion Therapeutics Inc., and Oncofusion. Dr. Omenn is Professor of Computational Medicine & Bioinformatics, Internal Medicine, Human Genetics, and Public Health and Director of the university-wide Center for Computational Medicine and Bioinformatics at the University of Michigan where he leads major research programs in proteomics and integrative biomedical informatics. Dr. Omenn served as executive vice president for medical affairs and as chief executive officer of the University of Michigan Health System from 1997 to 2002. Prior to this, he was the dean of the School of Public Health and Community Medicine and professor of medicine at the University of Washington. Earlier he was Associate Director of the White House Office of Science and Technology and of the Office of Management and Budget. He is the author of more than 563 research papers and scientific reviews and author/editor of 18 books. Dr. Omenn received his B.A. summa cum laude from Princeton University, M.D. magna cum laude from Harvard Medical School, and Ph.D. in genetics from the University of

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Washington. We believe Dr. Omenn s qualifications to sit on our Board of Directors include his extensive executive leadership and management experience in the medical industry and his continuing cutting-edge research.

Marc Rubin, M.D, a director since October 2011 and Chairman of the Board since January 2016, is Executive Chairman of the Board of Directors of Titan Pharmaceuticals, Inc. (TTNP: OTC BB) and served as its President and Chief Executive Officer from October 2007 to January 2009. Until February 2007, Dr. Rubin served as Head of Global Research and Development for Bayer Schering Pharma, as well as a member of the Executive Committee of Bayer Healthcare and the Board of Management of Bayer Schering Pharma. Prior to the merger of Bayer Pharmaceuticals and Schering AG in June 2006, Dr. Rubin was a member of the Executive Board of Schering AG since joining the company in October 2003, as well as Chairman of Schering Berlin Inc. and President of Berlex Pharmaceuticals, a division of Schering AG. From 1990 until August 2003, Dr. Rubin was employed by GlaxoSmithKline where he held positions of responsibility in global clinical and commercial development overseeing programs in the United States, Europe, Asia and Latin America. From 2001 through 2003 at GlaxoSmithKline, he was Senior Vice President of Global Clinical Pharmacology & Discovery Medicine. Dr. Rubin holds an M.D. from Cornell University Medical College and is board certified in internal medicine with subspecialties in medical oncology and infectious diseases. Dr. Rubin is a member of the Board of Directors of Curis Inc. (Nasdaq: CRIS) and formerly served on the Board of Directors of Medarex, Inc., now a subsidiary of Bristol-Myers Squibb Company. We believe Dr. Rubin s qualifications to sit on our Board of Directors include his extensive executive leadership and management experience in the pharmaceutical industry.

Stephen Shulman, a director since 2017, is the Chief Executive Officer of Medical Devices Inc. (MDI), a position he has held since 1982. MDI is responsible for numerous medical device startups such as defibrillator electrodes, Fiberoptic pressure sensors, occlusive dressings, surgical glue, non-invasive body temperature control and end stage renal care. Prior to the formation of MDI, he was Director of Sales and Marketing/Asia Pacific for Medtronic from 1970 to 1981. Mr. Shulman received a B.S.C. in microbiology and physics from Wayne State University. We believe that Mr. Shulman is best situated to sit on our Board because of his extensive executive leadership and management experience in the medical device industry.

Richard E. Uihlein, a director since 2017, co-founded Uline, Inc. (a leading distributor of shipping, packaging and industrial supplies) in 1980, and has served as its Chief Executive Officer and Chairman since its founding. Prior to founding Uline Inc., Mr. Uihlein was employed at General Bindings Corp., Northbrook, IL from 1967 to 1980. Mr. Uihlein graduated from Stanford University, Palo Alto, CA. with a BA degree in history in 1967. We believe Mr. Uihlein s qualifications to sit on our Board includes his extensive executive leadership and management experience.

Code of Ethics

We have adopted a Code of Ethics that applies to all our directors, officers and employees. The Code of Ethics is publicly available on our website at www.galectintherapeutics.com. Amendments to the Code of Ethics and any grant of a waiver from a provision of the Code of Ethics requiring disclosure under applicable SEC rules will be disclosed on our website.

Director Nominations

No material changes have been made to the procedures by which security holders may recommend nominees to our board of directors.

Audit Committee

The members of this committee are Joel Lewis (chair), Kary Eldred and Kevin D. Freeman. The Audit Committee is responsible for oversight of the quality and integrity of the accounting, auditing and reporting

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practices of Galectin Therapeutics. More specifically, it assists the Board of Directors in fulfilling its oversight responsibilities relating to (i) the quality and integrity of our financial statements, reports and related information provided to stockholders, regulators and others, (ii) our compliance with legal and regulatory requirements, (iii) the qualifications, independence and performance of our independent registered public accounting firm, (iv) the internal control over financial reporting that management and the Board have established, and (v) the audit, accounting and financial reporting processes generally. The Committee is also responsible for review and approval of related-party transactions. The Board has determined that Mr. Lewis is an audit committee financial expert within the meaning of SEC rules. The Audit Committee has the authority to obtain advice and assistance from, and receive appropriate funding from the Company for, outside legal, accounting or other advisors as it deems necessary to carry out its duties.

Risk Management

The Board has an active role, as a whole and also at the committee level, in overseeing management of our risks. The Board regularly reviews information regarding our credit, liquidity and operations, as well as the risks associated with each. The Compensation Committee of our Board is responsible for overseeing the management of risks relating to our executive compensation plans and arrangements. The Audit Committee of our Board oversees management of financial risks. The Nominating and Corporate Governance Committee of our Board manages risks associated with the independence of the Board members and potential conflicts of interest. While each committee is responsible for evaluating certain risks and overseeing the management of such risks, the entire Board of Directors is regularly informed through committee reports about such risks.

We believe that any risks arising from our policies and programs are not reasonably likely to have a material adverse effect on the Company. Our programs reflect sound risk management practices including:

Use of multiple compensation vehicles that provide a balance of long- and short-term incentives with fixed and variable components; and

Equity incentive awards that generally vest over several years, so while the potential compensation payable for equity incentive awards is tied directly to appreciation of our stock price, taking excessive risk for a short term gain is discouraged because it would not maximize the value of equity incentive awards over the long-term.

Executive officers, key employees and key consultants:

Harold H. Shlevin, Ph.D., age 69, became our Chief Operating Officer and Secretary on October 1, 2012 and was named Chief Executive Officer and President effective July 6, 2018. Dr. Shlevin previously had been employed at the Georgia Institute of Technology s Advanced Technology Development Center as Principal and Manager of bioscience commercialization efforts since November 2009, where he has assisted faculty in identifying technology worthy of commercialization, catalyzed formation of new start-up bioscience companies, and mentored new company management. From October 2008 to November 2009, he served as Head of Operations and Commercial Development for Altea Therapeutics Corporation, an advanced drug delivery company focused on the delivery of therapeutic levels of water-soluble biotherapeutics and small drugs through the skin. At Altea, he was responsible for pharmaceutical research and development, clinical research, regulatory affairs, engineering, clinical and commercial manufacturing, quality assurance, information technology, facility operations and finance. From July 2006 to September 2008, Dr. Shlevin served as the President and Chief Executive Officer of Tikvah Therapeutics, Inc., a start-up

pharmaceutical enterprise focused on later-stage development of neuroscience therapeutics. From May 2000 to December 2005, he served as President and CEO of Solvay Pharmaceuticals, Inc. (US). In January 2006, he was promoted to a global senior Vice President role within Solvay Pharmaceuticals, SA and member of the Board of Solvay Pharmaceuticals, SA, until his resignation in June 2006.

Jack W. Callicutt, age 51, became our Chief Financial Officer on July 1, 2013 and was appointed Secretary on July 6, 2018. From August 2012 through June 2012, Mr. Callicutt was the Chief Financial Officer of REACH

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Health, Inc., a telemedicine technology company headquartered in Alpharetta, GA. From April 2010 through August 2012, Mr. Callicutt was the Chief Financial Officer of Vystar Corporation, a publicly-traded company that holds proprietary technology to remove antigenic proteins from natural rubber latex. Prior to that Mr. Callicutt was Chief Financial Officer of IVOX, Inc., Tikvah Therapeutics and Corautus Genetics, a publicly-traded biotechnology company which was developing gene therapy for treatment of cardiovascular disease. Mr. Callicutt previously spent more than fourteen years in public accounting, most recently as a senior manager at Deloitte, where he specialized in technology companies from 1989 to 2003. Mr. Callicutt is a Certified Public Accountant and graduated with honors from Delta State University with a B.B.A. in accounting and computer information systems.

J. Rex Horton, age 48, became the Company s Executive Director of Regulatory Affairs and Quality Assurance in January 2013. Mr. Horton most recently was Director of Regulatory Affairs at Chelsea Therapeutics, where he successfully led the organization through its first NDA filing and favorable FDA Advisory Committee Meeting. In past leadership roles at Solvay Pharmaceuticals and Abbott Laboratories, he led approval efforts for key products including Androgel® Stickpack, Creon® Capsules and Luvox® CR Capsules. He has also provided chemistry, manufacturing and controls (CMC) regulatory leadership and support of INDs and NDAs, including Estrogel® and Androgel® Pump. Mr. Horton was a member of the executive leadership team that successfully implemented solutions to significant regulatory issues encountered by Solvay in its interactions with the FDA. Mr. Horton earned his Bachelor s degree in industrial/manufacturing & systems engineering from The Georgia Institute of Technology. He is a member of the Regulatory Affairs Professional Society (RAPS), Drug Information Association (DIA) and American Association of Pharmaceutical Scientists (AAPS).

Eliezer Zomer, Ph.D., age 71, has been our Executive Vice President of Manufacturing and Product Development since the Company s inception in 2000. Prior to joining our Company, Dr. Zomer had been the founder of Alicon Biological Control, where he served from November 2000 to July 2002. From December 1998 to July 2000, Dr. Zomer served as Vice President of Product Development at SafeScience, Inc. and Vice President of Research and Development at Charm Sciences, Inc. from June 1987 to November 1998. Dr. Zomer received a B. Sc. degree in industrial microbiology from the University of Tel Aviv in 1972, a Ph.D. in biochemistry from the University of Massachusetts in 1978, and undertook a post-doctoral study at the National Institute of Health.

Adam E. Allgood, Pharm.D., R.Ph, age 54, became our Executive Director of Clinical Development on June 29, 2015. Dr. Allgood was most recently associate director of global pharmaceutical regulatory affairs at UCB Inc., a multinational biopharmaceutical company, from October 2011 to May 2015. His prior positions include leadership roles at Abbott Laboratories from February 2009 to September 2011 in regulatory affairs and Solvay Pharmaceuticals from January 1988 to January 2009 in clinical development and medical affairs, spanning a variety of therapeutic areas including gastroenterology, immunology, rheumatology, neurology, and women s health. Dr. Allgood earned his Doctor of Pharmacy (Pharm.D.) degree summa cum laude from Mercer University College of Pharmacy and Health Sciences in Atlanta and is a Registered Pharmacist (R.Ph.). He is a member of the American Pharmacists Association (APHA), and the Association of the United States Army (AUSA).

None of the directors, executive officers and key employees share any familial relationship.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our officers and directors, and persons who beneficially own more than ten percent of our common stock, to file reports of ownership and changes of ownership of such securities with the SEC. Except as set forth below, all reports were timely filed during the fiscal year ended December 31, 2018.

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On May 29, 2018, Kary Eldred filed a Form 3 relating to his appointment as a director of the Company on May 22, 2018. Upon the reporting person s appointment as a director, he also received a grant of stock options on May 22, 2018. The reporting person filed a Form 4 relating to such grant on May 29, 2018. Both of these referenced filings should have been made within two business days of the date of grant of the stock options.

On June 18, 2018, Harold H. Shlevin filed a Form 4 reporting the acquisition of a stock option, which was granted on June 8, 2018. The Form 4 should have been filed within two business days after the date of grant.

On June 20, 2018, each of 10X Fund, L.P. and 10X Capital Management, LLC, the general partner of 10X Fund, L.P., filing jointly, and James C. Czirr, the managing member of 10X Capital Management, LLC, filing separately, reported on Forms 4 (i) the disposition by 10X Fund, L.P. of 31,860 shares of common stock on June 14, 2018, (ii) a separate disposition by 10X Fund, L.P. of 44,525 shares of common stock also on June 14, 2018, (iii) a disposition of 15,475 shares of common stock by 10X Fund, L.P. on June 15, 2018, and (iv) a disposition of 60,000 shares of common stock by 10X Fund, L.P. on June 18, 2018. The above transactions on June 14, 2018 and June 15, 2018, should have been reported on Forms 4 within two business days of the respective transactions.

Item 11. *Executive Compensation*

COMPENSATION DISCUSSION AND ANALYSIS

The Compensation Committee is responsible for creating and reviewing the compensation of the Company s executive officers, as well as overseeing the Company s compensation and benefit plans and policies and administering the Company s equity incentive plans. The following Compensation Discussion and Analysis (CD&A) describes our 2018 executive compensation program and explains the Company s compensation philosophy, policies, and practices, focusing primarily on the compensation of our named executive officers, or NEOs. This CD&A is intended to be read in conjunction with the tables that follow, which provide detailed historical compensation information for our following NEOs:

Name	Title
Peter G. Traber, M.D.	Chief Executive Officer, President and Chief Medical Officer until July 6, 2018
Harold H. Shlevin, Ph.D.	Chief Operating Officer until July 6, 2018, then Chief Executive Officer and President
Jack W. Callicutt	Chief Financial Officer

Compensation Philosophy

The Company believes in providing a competitive total compensation package to its executives through a combination of base salary, annual performance bonuses, and long-term equity awards. The executive compensation program is designed to achieve the following objectives:

provide competitive compensation that will help attract, retain and reward qualified executives;

align executives interests with our success by making a portion of the executive s compensation dependent upon corporate performance; and

align executives interests with the interests of stockholders by including long-term equity incentives.

The Compensation Committee believes that the Company s executive compensation program should include annual and long-term components, including cash and equity-based compensation, and should reward consistent performance that meets or exceeds expectations. The Compensation Committee evaluates both performance and compensation to make sure that the compensation provided to executives remains competitive relative to compensation paid by companies of similar size and stage of development operating in the life sciences industry and taking into account the Company s relative performance and its own strategic objectives.

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Executive Compensation Review and Design

The Company has historically conducted a review of the aggregate level of its executive compensation, as well as the mix of elements used to compensate its NEOs. The Company has based this review primarily on the experience of the members of the Compensation Committee and our Board, many of whom sit on the boards of directors of, or have previously advised, numerous companies, including companies in the life sciences industry.

At our 2016 annual meeting of stockholders approximately 91% of our outstanding common stock voting on the matter voted in favor of the compensation of our NEOs, as disclosed in the proxy materials for the 2016 annual meeting. At our 2013 annual meeting, the holders of approximately 62% of our outstanding common stock voting on the matter voted in favor of holding the stockholder advisory vote every three years. As a result of such vote, our Board decided to hold the Say-on-Pay advisory vote every three years. Accordingly, the Company s next Say-on-Pay advisory vote on the compensation of our NEOs will be held at our 2019 annual meeting of stockholders.

In 2014 and 2015, the Compensation Committee undertook a review of our compensation policies and practices and retained the compensation consulting firm of Barney & Barney LLC to provide compensation information and analysis with respect to the life science and healthcare industry and with respect to our peer companies within the industry. Barney & Barney LLC reviewed information from industry and other sources, surveys and databases, including publicly-available compensation information of other companies with which we compete, to gauge the competitiveness of our compensation programs. Barney & Barney LLC then reported its findings to the Compensation Committee, with recommendations to bring the Company s executive compensation closer to the 50th percentile of the total compensation of our competitor companies. These findings continued to inform the Compensation Committee s decisions on compensation in subsequent years, including 2018.

The Compensation Committee plans to use a compensation consultant in the future and to take into account publicly-available data relating to the compensation practices and policies of other companies within and outside our industry. For 2019 and future years, the Compensation Committee intends to benchmark its executive compensation program to target the 50th percentile of the total compensation programs of our competitor companies; however, adjusted as deemed to be in the best interest of the Company to assure retention of key employees as the Phase 3 clinical trial is designed and commenced.

Elements of Executive Compensation

The compensation program for the Company s NEOs consists principally of three components:

- base salary;
- performance and retention bonuses;
- long-term compensation in the form of equity-based awards.

Base Salary

Base salary is the only fixed-pay component in our executive compensation program. Base salaries for the NEOs are initially established through arm s-length negotiation at the time the NEO is hired, taking into account such NEO s

qualifications, experience, prior salary, the scope of his or her responsibilities, and known competitive market compensation paid by other companies for similar positions within the industry. Base salaries are reviewed annually and adjusted from time to time to realign salaries with market levels after taking into account individual responsibilities, performance, and experience. In making decisions regarding salary increases, the Company may also draw upon the experience of members of the Compensation Committee and the Board of Directors, many of whom sit on the boards of directors of, or have previously advised, numerous companies, including companies in the life sciences industry. The Compensation Committee has not previously applied specific formulas to determine increases. This strategy is consistent with the Company s intent of offering base salaries that are cost-effective while remaining competitive.

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In June 2018 after the resignation of Dr. Traber from his position as Chief Executive Officer, President and Chief Medical Officer, the Compensation Committee reviewed the base salaries of our NEOs, taking into account the considerations described above. As a result, as a result of his election as Chief Executive Officer and President, Dr. Shlevin s base salary was adjusted to $500,000 effective June 6, 2018. As a result of his election to Secretary, Mr. Calllicutt s base salary was adjusted to $285,000.

Name	2018 Base Salary	2017 Base Salary
Peter G. Traber, M.D.	$ 512,500	$ 512,500
Harold H. Shlevin, Ph.D.	$ 500,000	$ 260,000
Jack W. Callicutt	$ 285,000	$ 260,000

For 2019, the Compensation Committee made no adjustments to the base salaries of our NEO s.

Performance Bonuses

In addition to the payment of base salaries, the Company believes that annual performance bonuses can play an important role in providing appropriate incentives to its NEOs to achieve the Company s strategic objectives. In prior years, performance bonuses were awarded based on the Company s Employee Short-Term and Long-Term Incentive Program (the Program), which was adopted for executives and employees of the Company. The Program is a performance-based program and was adopted in recognition of the importance of aligning executive and employee interests with that of our stockholders. Our Program is designed to reward the efforts of our executives and employees and to be competitive in attracting and retaining them. There are two elements of the Program: (1) a short-term incentive in the form of cash bonuses and (2) a long-term incentive in the form of stock option grants. The cash bonus incentive is targeted to be up to 30% to 50% of the NEO s base salary as of the end of the applicable year. Half of each NEO s annual performance bonus is based upon achievement of the Company s documented performance objectives for the year and the other half is based upon achievement of individual performance objectives set for the year. In 2018, however, in lieu of the standard individual performance objectives, the Board approved potential cash incentive bonuses (the Transaction Bonuses) applicable only to employees who were employed by the Company on January 1, 2018, including Peter G. Traber, Harold H. Shlevin and Jack W. Callicutt.

The potential Transaction Bonuses are payable in connection with a Transaction (as defined below). A Transaction is (i) any licensing, development, partnership, or similar arrangements relating to any of the Company s drug candidates (a Partnership Transaction) or (ii) the acquisition of the Company or any of its material assets (an Acquisition Transaction). The amounts payable pursuant to the Transaction Bonuses will be equal to 10% of the recipient s 2018 base salary for each $50 million payable to the Company or the Company s shareholders, as applicable, pursuant to the Transaction to the extent paid in cash or marketable securities, up to a maximum payment of 300% of base salary. If Transaction is a Partnership Transaction and payments to the Company are deferred or otherwise made over time, the amount of the Transaction Bonuses will be based on the Board s reasonable estimate of the value of the Transaction. To be entitled to receive a Transaction Bonus, if the Transaction is an Acquisition Transaction, an individual must be employed by the Company on the date the Transaction is consummated, or, if the Transaction is a Partnership Transaction, an individual must be employed by the Company on the date that the definitive transaction agreement(s) are executed. No Transaction Bonuses were earned in 2018.

Additionally, the Board also approved retention bonuses payable to certain employees of the Company, including Dr. Traber, Dr. Shlevin and Mr. Callicutt, equal to 75% of such employee s 2018 salary (the Retention Bonuses) if such employees remained employed by the Company through December 31, 2018 and based upon the annualized salary level in effect on such date. If no Transaction was consummated on or prior to December 31, 2018, then the

Retention Bonuses was payable no later than January 15, 2019. If a Transaction was consummated on or prior to December 31, 2018, each eligible employee was to receive that portion of the Retention Bonus equal to any cash bonuses paid to such employee for 2017 on or before January 15, 2019. The

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balance of the Retention Bonus was to be payable in equal monthly install