
# ANNUAL REPORT

## 2022

**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, 2022**

☐ **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 of incorporation)** | **(I.R.S. Employer 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 | Trading Symbol | Name of each exchange on which registered |
|---|---|---|
| **Common Stock, $0.001 Par Value Per Share** | **GALT** | **The NASDAQ Stock 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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. Yes ☐ No ☒

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, 2022 was $59 million.

The number of shares outstanding of the registrant's common stock as of February 28, 2023 was 59,443,682.

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**FOR THE YEAR ENDED DECEMBER 31, 2022**

**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, cancer and selected other diseases. 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 galectin proteins have a demonstrated role in the pathogenesis of a given disease. We focus on diseases with serious, life-threatening consequences and those where current treatment options are limited specifically in NASH (non-alcoholic steatohepatitis) with cirrhosis and certain cancer indications. 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 one of our programs becomes advanced and requires significant additional resources.

Our lead galectin-3 inhibitor is belapectin (GR-MD-02), which has been demonstrated in preclinical models to reverse liver fibrosis and cirrhosis and in clinical studies to decrease portal hypertension and prevent its complication: the development of esophageal varices. Belapectin 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 galectin-3 gene "knocked-out" can no longer develop fibrosis in response to experimental stimuli compared to animals with an intact galectin-3 gene. We are using our galectin-3 inhibitor to treat advanced liver fibrosis and liver cirrhosis in NASH 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 compensated cirrhosis and portal hypertension (NASH-CX).

In February 2023, we completed randomizations totaling 357 patients in a large, global Phase 2b/3 clinical trial. Our study protocol was filed with the FDA on April 30, 2020, for a seamless adaptively-designed Phase 2b/3 clinical study, the NAVIGATE trial, evaluating the safety and efficacy of our galectin-3 inhibitor, belapectin, for the prevention of esophageal varices in patients with non-alcoholic steatohepatitis (NASH) cirrhosis (Further details are available at www.clinicaltrials.gov under study NCT04365868); this study began enrolling patients in Q2-2020. In September 2020, the Company received a letter from the FDA providing comments, asking questions and providing guidance on various aspects of the ongoing NAVIGATE trial. These comments were addressed, and the study proceeded accordingly.

Additionally, a study protocol entitled "A Single-dose, Open-label, Pharmacokinetic Study of Belapectin (GR-MD-02) in Subjects With Normal Hepatic Function and Subjects With Varying Degrees of Hepatic Impairment" has been filed with the FDA to examine the effects of the drug in subjects with normal hepatic function and subjects with varying degrees of hepatic impairment (study details are listed under study NCT04332432 on www.clinicaltrials.gov); this study became fully enrolled in February 2022.

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, including physical and chemical drug characterization, and commercial development. We also have established through our majority-owned joint venture subsidiary, Galectin Sciences LLC, a discovery program developing small molecules that inhibit galectin-3 and may afford alternative drug delivery (e.g., oral) and as a result expand the potential uses of galectin-3 inhibitor beyond belapectin. Three chemical series of composition of matter patents have been filed.

We are also pursuing a development pathway to clinical enhancement and commercialization for our lead compounds in immuno-oncology following our previous successful collaboration with Providence Portland Cancer Center. In 2022, we filed a new IND with FDA for advanced or metastatic head and neck cancer using belapectin in combination with a checkpoint (PD-1) inhibitor and received a Study May Proceed letter. The proposed phase 2 trial commencement is dependent on timing of financing.

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 attached to other proteins, called glycoproteins that are responsible for various functions within the body, most notably inflammation and fibrosis. Galectins, in particular galectin-3,act as a molecular glue, bringing together molecules that have sugars on them. Galectin-3, is known to be markedly increased in a number of significant diseases including inflammatory diseases leading to organs scarring (e.g. liver, lung, kidney, and heart) and cancers. The increase in galectin-3, by creating the so-called galectin-3 fibrosome, promotes the progression of multiple diseases. Published data substantiating the importance of galectin-3 in the fibrotic process arises from gene knockout experiments in animal studies. For instance, mice genetically altered to eliminate the galectin-3 gene, and thus unable to produce galectin-3, do not develop liver fibrosis in response to toxic insult to the liver.

We have one new proprietary chemical entity (NCE) in development, belapectin, which has shown promise in preclinical and clinical studies for the treatment of liver fibrosis, severe skin disease, and cancer (melanoma and head and neck squamous cell carcinoma). Currently, we are focusing on development of belapectin for the treatment of NASH cirrhosis and head and neck cancer. Belapectin is a proprietary, patented compound derived from natural, plant-based, starting materials, which following chemical processing, exhibits the properties of binding to and inhibiting galectin-3.

Our product pipeline is shown below:

| **Indication** | **Drug** | **Status** |
|---|---|---|
| **Prevention of esophageal varices in NASH cirrhosis** | | |
| Phase 1 interaction trial:<br>NASH-CX trial and<br>NASH-FX trial | belapectin | IND submitted January 2013. Results from the Phase 1 interaction trial were reported in 2014, with final results reported in January 2015.<br>The Phase 2 NASH FX trial was conducted in patients with advanced fibrosis but not cirrhosis. Its principal purpose was to evaluate various imaging modalities. The NASH FX trial top line data was reported in September 2016 and published in Alimentary Pharmacology and Therapeutics in 2016.<br><br>The Phase 2 NASH CX trial was conducted in patients with compensated cirrhosis and portal hypertension. The NASH CX trial top line data was reported in December 2017 and was published in *Gastroenterology* in 2020. |
| NASH NAVIGATE | | Following FDA feedback, the NAVIGATE trial is an adaptive Phase 2b/3 trial for the prevention of esophageal varices in NASH patients with compensated cirrhosis and clinical signs of portal hypertension. A Phase 2b interim efficacy analysis will be incorporated to confirm previous Phase 2 data, select an optimal dose and reaffirm the risk/benefit of belapectin. The Phase 3 end of study analysis will evaluate the development of esophageal varices as the same primary outcome of efficacy and a composite clinical endpoint including progression to varices requiring treatment as a key secondary outcome of efficacy ( www.clinicaltrials.gov NCT04365868). The final patient was randomized in February 2023. |
| Phase 1 study: hepatic insufficiency | | A hepatic impairment study is being conducted in subjects with normal hepatic function and subjects with varying degrees of hepatic impairment (www.clinicaltrials.gov NCT04332432) and began enrolling patients in the second quarter of 2020. The study completed enrollment in February 2022. |
| **Cancer Immunotherapy** | | |
| Melanoma, Head, Neck Squamous Cell Carcinoma (HNSCC) | belapectin | Investigator IND study was completed. A Phase 1B study began in Q-1 2016. Early data was reported in February 2017 and additional data were reported in September 2018. Data from an extension trial was reported in July 2021 for additional melanoma and HNSCC patients which provided a rational basis for additional trials which the Company is exploring. In the third quarter of 2022, the Company announced its IND application for belapectin in combination with a checkpoint inhibitor for the treatment of HNSCC was filed and a Study May Proceed letter was received from FDA. The Company is reviewing options for financing this trial which will determine when such trial could commence. |

*Liver cirrhosis.* Belapectin is our lead product candidate for treatment of compensated NASH cirrhosis in patients with portal hypertension. Our preclinical data show that belapectin has a significant therapeutic effect on liver fibrosis as shown in several relevant animal models. In addition, in NASH animal models, belapectin has been shown to reduce liver fat, inflammation, portal pressure, and ballooning degeneration (death of liver cells). Therefore, we chose belapectin as the lead candidate in a development program targeted initially at fibrotic liver disease associated with non-alcoholic steatohepatitis (NASH). 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 safety of belapectin and pharmacodynamics biomarkers of disease. On March 1, 2013, the FDA indicated we could proceed with a US Phase 1 clinical trial for belapectin with a development program aimed at obtaining support for a proposed indication of belapectin for treatment of NASH with advanced fibrosis. The Phase 1 trial was completed and demonstrated that belapectin up to 8 mg/kg Lean Body Mass (LBM), i.v. was safe and well tolerated.

Additionally, an open label drug-drug phase 1 interaction study was completed in healthy volunteers during the second quarter of 2015 with belapectin and it showed that with 8 mg/kg LBM dose of belapectin and 2 mg/kg LBM dose of midazolam there was no drug-drug interaction, and no serious adverse events or drug-related adverse events were observed. The secondary objective was to assess the safety and tolerability of belapectin when administered concomitantly with midazolam.

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

**NASH-FX Trial:** The NASH-FX trial was a Phase 2a pilot trial for patients with NASH and advanced fibrosis that explored use of three non-invasive imaging technologies. It was a short, single site, four-month trial in 30 NASH patients with advanced fibrosis (F3) randomized 1:1 to either 9 bi-weekly doses of 8 mg/kg LBM of belapectin or placebo. The trial did not meet its primary 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. With a four-month treatment period and a small number of patients per arm the study was not powered to demonstrate efficacy results in established advanced liver fibrosis. In the trial however, belapectin was found to be safe and well tolerated with no serious adverse events and showing evidence of a pharmacodynamic effect. These results provided support for further development in NASH.

**NASH-CX Trial:** The NASH-CX trial was a larger multi-center clinical trial that explored the use of belapectin for the treatment of patients with well-compensated NASH cirrhosis and portal hypertension. Enrollment 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 LBM of belapectin, 8 mg/kg LBM of belapectin or placebo. Approximately 50% of patients at baseline had esophageal varices (a complication of portal hypertension). The primary endpoint was a reduction in hepatic venous pressure gradient (HVPG), a hemodynamic measure that estimates portal hypertension. Patients received an infusion of belapectin or placebo every other week for one year and were evaluated to determine the change in HVPG as compared with placebo. Secondary or exploratory endpoints included evaluation of fibrosis on liver biopsy, measurement of liver stiffness (FibroScan) and assessment of liver metabolism ($^{13}$C-methacetin breath test). Top line data readout was reported in December 2017. The study demonstrated a favorable safety profile and clinically meaningful efficacy results in patients without esophageal varices at baseline as demonstrated by a decrease in portal pressure associated with the prevention of development of varices when compared to placebo.

In the total patient population, the primary endpoint HVPG showed a trend toward benefit with belapectin 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 LBM dose and 8 mg/kg LBM dose of belapectin, respectively.

In those NASH cirrhosis patients with portal hypertension who have not yet developed esophageal varices at baseline (about 50% of the total population), there was a statistically significant effect of the 2 mg/kg LBM dose of belapectin on the absolute change in HVPG (-1.08 mm Hg, $p<0.01$). The effect of the 8 mg/Kg LBM dose of belapectin on absolute or percent change in HVPG from baseline to week 54 was not significant.

Also because of the clinical relevance of this population, a responder analysis was performed on those patients without esophageal 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 belapectin 2 mg/kg LBM group was statistically significant ($p<0.01$) while that of the 8 mg/kg LBM group was not.

Over the 54-week treatment period, in patients without varices at baseline there were also a statistically significantly fewer new varices that developed in the belapectin treatment groups (0% and 4% in the 2 mg/kg LBM and the 8 mg/kg LBM, respectively) vs placebo (18%). This meant that the decrease seen in portal pressure was associated with a decreased incidence of esophageal varices. The results were noticeable in the belapectin 2 mg/Kg LBM group as statistical significance against placebo was achieved for both parameters. As esophageal varices can lead to hemorrhagic complication, which can be fatal, and are a severe complication of liver cirrhosis, we believe the prevention of esophageal varices may represent a clinically relevant measure of clinical efficacy in patients with NASH cirrhosis.

The major conclusions from the NASH-CX trial results were that: (i) belapectin 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, (ii) Belapectin in the total patient population was associated 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 the prevention of esophageal varices is a clinically relevant endpoint related to patient outcomes, (iv) While there was a drug effect in both the 2 mg/kg LBM and 8 mg/kg LBM groups on the development of varices and liver biopsy there was a consistently greater and statistically significant effect of the 2 mg/kg LBM dose of belapectin, (v) belapectin appears to be safe and well tolerated in this one year clinical trial, a feature that is of prime importance for a cirrhotic population and (vi) This is the first large, randomized clinical trial to demonstrate a clinically meaningful improvement in portal hypertension in patients with compensated NASH cirrhosis who have not yet developed esophageal varices.

Further information and details on the NASH-CX results is available in public presentations posted to our website and filed with the SEC and in a peer reviewed publication in *Gastroenterology* 2020;158:1334–1345.

**NASH NAVIGATE Trial:** Building on the experience of the NASH-CX trial, the NAVIGATE Trial is a seamless adaptively-designed Phase 2b/3 clinical study evaluating the safety and efficacy of our galectin-3 inhibitor, belapectin, for the prevention of esophageal varices in patient with non-alcoholic steatohepatitis (NASH) cirrhosis. The major features of this innovative Phase 2b/3 study design are: i) In patients with NASH cirrhosis and clinical signs of portal hypertension but without esophageal varices at baseline, this trial will assess the effect of belapectin on the incidence of new varices (the primary endpoint) – as well as assessing the effect of belapectin on the incidence of additional clinically significant cirrhosis-related outcomes (a key secondary efficacy endpoint), (ii) The study targets NASH patients with a clearly identified unmet medical need: patients with compensated cirrhosis who have clinical signs of portal hypertension and, thus, are at risk of developing esophageal varices, a potentially life-threatening complication of cirrhosis (bleeding varices are a cause of death in about one-third of cirrhotic patients). There is currently no approved treatment for preventing varices in these patients. In addition, the development of esophageal varices reflects the progression of hepatic cirrhosis and thus portends the development of other cirrhosis complications such as ascites, hepatic encephalopathy, and liver failure, and (iii) During the first 18 months, two belapectin dose levels (2 mg/kg LBM and 4 mg/kg LBM) will be compared to placebo (phase 2b). Then, at the interim analysis (IA), the best belapectin dose will be selected, based on efficacy and safety, for continued evaluation (Phase 3). The belapectin dose selected for the phase 2b/3 were based on the analysis of the NASH-CX trial. Prior belapectin clinical studies have also indicated the good tolerance and safety profile of belapectin with doses of up to 8 mg/kg LBM for up to 52 weeks, an important feature to inform the future risk benefit analysis in patients with NASH cirrhosis.

The study design provides for a pre-specified interim analysis (IA). The IA of efficacy and safety data will be conducted after all planned subjects in Phase 2b component have completed at least 78 weeks (18 months) of treatment and a second esophago-gastro-duodeno endoscopic assessment. The purpose of the IA is to allow potential seamless adaptive modifications of the study, including: (1) the selection of the optimal dose of belapectin for Phase 3, (2) the re-estimation of the study sample size for Phase 3 portion of the trial, (3) the re-evaluation of the randomization ratio for the Phase 3 portion of the trial, (4) the refinement of the inclusion and exclusion criteria for the Phase 3 portion of the trial, including the cirrhosis status, (5) and/or termination of the study for overwhelming efficacy or for futility.

The trial design also includes a blinded sample size re-estimation ("SSR") during the Phase 2b, prior to the IA, to allow for potential sample size readjustment. The SSR will be conducted when 50% of the patients have completed 18 months of therapy. This will allow us to confirm the underlying assumption regarding the rate of varices development, currently estimated from our prior Phase 2b trial (NASH-CX). The study design also minimizes invasive testing requirements, such as the measurement of HVPG or repeated liver biopsies, which we believe are particularly risky in patients with portal hypertension and will facilitate enrollment and retention of patients. It also provides for a seamless transition of patients from the Phase 2b component into the phase 3 stage, including the potential addition of new patients. The trial design preserves the surrogate end-point concepts (development of new varices versus variceal hemorrhage) previously discussed with FDA.

We believe that these adaptations taken together are innovative and optimize conduct of the NAVIGATE trial with a clinically relevant primary outcome giving belapectin the best opportunity to show a positive therapeutic effect to address an unmet medical need. As a testimony of this innovation, the NAVIGATE trial design was presented to the hepatology community and featured during the last meeting of the American Association for the Study of Liver Diseases, in November 2021. If the IA results of the NAVIGATE trial are compelling, there could be the potential for accelerated FDA approval and/or partnership opportunity with a pharmaceutical company.

In the Phase 3 component of this trial, as proposed in the protocol, the primary endpoint remain the development of varices. Secondary endpoints include a composite clinical outcomes endpoint, including varices requiring treatment (development of large varices or varices with a red wale), decompensating events, all-cause mortality, MELD score increase, liver transplant. Also, NASH non-invasive biomarkers will be evaluated. To target a population at risk of developing esophageal varices, patient selection will be based on clinical signs of portal hypertension, including, but not limited to, a low platelet count, an increased spleen size and/or evidence of abdominal collaterals circulation.

The focus and goal of the therapeutic program is to stop the progression of and/or reverse portal hypertension and thereby prevent the development of varices, potentially one of the most immediately life-threatening complication of cirrhosis. Based on the results of the NASH-CX trial and 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 clinical signs of portal hypertension for whom, currently no specific, liver targeted, treatment are available.

The COVID-19 pandemic has delayed and may continue to delay our regulatory and ethics approvals, recruitment of sites, and enrollment of patients for our Phase 2b/3 NAVIGATE trial despite a recent uptick in screening activities. Many investigational centers in the United States and Europe have experienced shut-downs, and while some have loosened or removed restrictions, there may be a risk of experiencing new shut-downs and restrictions. In some countries, shutdown orders have also affected the regulatory process to authorize study starts. Governments and medical facilities focused their resources for battling the COVID-19 pandemic. For several reasons, the pandemic made enrolling patients for the NAVIGATE trial more challenging, including because patients eligible for the NAVIGATE trial have liver cirrhosis and, as such, are at a greater health risk of complications from COVID-19. It is also important to consider the safety of our candidate participants first, as cirrhotic patients with portal hypertension are immune compromised. As we emerged from the COVID-19 pandemic, site recruitment and patient enrollment accelerated and we experienced increases in enrollment, particularly in the United States. However, we did not see the enrollment in Europe that we anticipated, and conditions there remain uncertain. Consequently, we activated multiple sites in Latin America. The final patient was randomized in February 2023, and we expect topline results from the IA in Fall of 2024.

We have activated more than 150 clinical trial sites in 14 countries for the NAVIGATE trial.

Further details on the NAVIGATE trial can be found on www.clinicaltrials.gov under study NCT04365868 and on our NAVIGATE website (navigatenash.com).

The Company also has commenced a Hepatic Impairment Study, which will run in parallel with the phase 2b/3 trial as part of the development program. The Hepatic Impairment Study is being conducted at three sites and involves approximately 40 patients (divided amongst normal healthy volunteers, and patients with hepatic impairment categorized as Child-Turcotte-Pugh (CTP) classes A (mild), B (moderate), and C (severe). Each subject will receive a single infusion of belapectin (4 mg/kg LBM) and their serum belapectin levels will be monitored for up to approximately two weeks to define the effects of various stages of cirrhosis on serum belapectin levels. The tolerance and safety of belapectin will be evaluated. Enrollment in this study was completed in February 2022, and the results will be announced when available. Based on the results from this hepatic impairment study, the Company may consider including patients with more advanced cirrhosis in the Phase 3 portion of its NAVIGATE trial. Until dosing and safety profile is further informed in CTP Class B and/or Class C patients, the NAVIGATE trial will enroll only CTP Class A patients. Further details on this hepatic impairment study can be found on www.clinicaltrials.gov study NCT04332432.

*Cancer Immunotherapy.* We believe there is potential for galectin inhibition to play a key role in the innovative 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 ourgalectin-3 inhibitor to further enhance the immune system function to help the body 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 and their micro-environment, where it fosters the malignant nature of the tumors, and protects the tumors from immune attack by the patient's own defense mechanism. 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 belapectin 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 Phase 1B studies of belapectin in combination with Yervoy® (ipilimumab) in metastatic melanoma and another phase 1B study in combination with KEYTRUDA (pembrolizumab) in patients with metastatic melanoma and head and neck squamous cell carcinoma. These studies were conducted under the sponsorship of Providence Portland Medical Center's Earle A. Chiles Research Institute (EACRI).

The phase IB study in combination with Yervoy was rapidly discontinued after the first patients were recruited because of the availability of new treatment in the selected population.

Promising results were reported in the Phase 1b trial combining belapectin with pembrolizumab (KEYTRUDA®). When aggregated cohorts are combined, in advanced melanoma, a 50% objective response rate with belapectin in combination with KEYTRUDA, was documented. In addition, a 33% response rate was documented in patients with head and neck cancer The results have been published in 2021 in a highly rated peer reviewed journal (Curti et al. Journal of Immunotherapy of cancer 2021;9:e002371). There was also a suggestion that the combination of belapectin with pembrolizumab could decrease the auto-immune side-effect induced by pembrolizumab. These side-effects, which are directly linked to the mechanism of action of pembrolizumab, can be poorly tolerated and even severe enough to lead to treatment interruption, even if the effect on the cancer was encouraging. This is, a very frustrating situation for patients who have to discontinue an active treatment but have no other options available to them. We believe these data, taken together with the observed favorable safety and tolerability of the combination, provide a rationale to move the belapectin program in oncology forward.

Late in 2021, we engaged three noted physicians – Dr. Chetan Bettegowda, from Johns Hopkins, and Dr. Nishant Agrawal and Dr. Ari Rosenberg, both from University of Chicago Medical Center – as consultants to help define the path forward in oncology. In consultation with our oncology experts, we have now selected the treatment of recurrent or metastatic head and neck cancer as the lead indication to pursue for belapectin in combination with an immune checkpoint inhibitor. The decision is notably based on the lack of available treatments for these patients, the limited number of therapies in development, and the resulting very high medical need. We filed an IND with FDA and are planning a phase 2 trial to be filed with the FDA oncology division.

**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 protect 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 belapectin 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 Diabetic Nephropathy and Associated Disorders." The patent covers both composition claim for and uses of the Company's carbohydrate-based galectin inhibitor compound belapectin 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 belapectin 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 belapectin for use in patients with liver fibrosis in combination with other potential therapeutic agents. The patent covers use of belapectin 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. belapectin is covered by this patent and it provides opportunities for development of additional compounds in the class.

As of December 31, 2022, Galectin Therapeutics Inc. held 20 granted U.S. patents, 100 foreign granted, 5 foreign patent applications pending, and 1 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 many of our United States patents span out to 2034 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 3 granted U.S. patents, 11 granted international patents, 2 US patent application pending, and 21 foreign applications pending.

**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. We do not anticipate building additional in-house research or development facilities or hiring significantly additional staff other than for purposes of designing and managing our out-sourced research and development activities.

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.

During the years ended December 31, 2022 and 2021, our expenditures for research and development were $31.7 million and $23.8 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, belapectin 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.

**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 meet FDA requirements. Additionally, belapectin is manufactured as a sterile liquid formulation. We have experienced, and may experience in the future, certain delays related to COVID-19 related supply issues with certain components necessary to manufacture belapectin.

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 our 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,
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 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.

**Human Capital Resources**

As of February 28, 2023, we currently have twelve full-time employees, nine 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 several 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 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 or any other websites 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.***

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, 2022 was $310 million. We had $18.6 million of unrestricted cash as of December 31, 2022 and $50 million available under a line of credit provided by our chairman, Richard E. Uihlein.. The Company believes there is sufficient cash to fund currently planned operations at least through December 31, 2024. We will require more cash to fund our operations after December 31, 2024 and believe we will be able to obtain additional financing. However, there can be no assurance that we will be successful in obtaining such new financing or, if available, that such financing will be on terms favorable to us.

We 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. Though his investments in the Company, Mr. Uihlein has been a critical source of funding via equity and debt financings. There is no assurance as to the level of future investments to be made in the Company by Mr. Uihlein. If adequate funds are not otherwise available, we may need to significantly curtail operations. To obtain additional funding, we may need to enter into arrangements that require us to relinquish rights to certain technologies, products and/or potential markets. To the extent that additional capital is raised through the sale of equity, or securities convertible into equity, our equity holders may experience dilution of their proportionate ownership of the Company.

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

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

Our ability to generate revenue from product sales and achieve profitability will depend upon our ability to successfully commercialize products, including our lead product candidate, 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, belapectin, and we cannot be certain that our 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.

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

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 belapectin, 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.

***Difficulty and delays in enrolling patients and registering sites for conducting clinical trials may prevent or delay product development and strain our limited financial resources.***

There are other life sciences companies conducting clinical trials in patients with the disease indications that our product candidates target. As a result, we must compete with them for clinical sites, physicians and the limited number of patients who fulfill the stringent requirements for participation in clinical trials. Also, due to the confidential nature of clinical trials, we do not know how many of the eligible patients may be enrolled in competing studies and who are consequently not available to us for our clinical trials.

In addition, our clinical trials have been affected by and may continue to be affected by the COVID-19 pandemic. Clinical site initiation and patient enrollment as well as availability of certain required lab kits for our non-COVID-19 product candidates have been and may continue to be delayed due to prioritization of hospital resources toward the COVID-19 pandemic. Some patients have not been and others may not want or be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, any inability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19, may adversely impact our clinical trial operations.

Patient enrollment depends on many factors, including the size of the patient population, the nature of the trial protocol, the proximity of patients to clinical sites, the eligibility criteria for the study and potential reduced enrollment due to the COVID-19 pandemic. The delay or inability to meet planned patient enrollment may result in increased costs and delays or termination of the trial, which could have a harmful effect on our ability to develop products.

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

Even if belapectin 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, provide lab kits, collect data and analyze data and samples. In addition, certain clinical trials for our products may be conducted by government-sponsored agencies and will be dependent on governmental participation and funding. We have contracted with a third party, Covance, for assistance with the design and conduct of our NAVIGATE trial.

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 belapectin.***

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

***We are exposed to 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 pre-clinical, clinical liability and other liability risks that are inherent in the testing 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. 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 insurance coverage that may be obtained by us could have a material adverse effect on our business, financial condition and results of operations.

***We face intense competition in the biotechnology and pharmaceutical industries.***

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

***The market for our proposed products is rapidly changing and competitive, and new drugs and new treatments that 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. Our resources are limited and we may experience technical challenges inherent in such technologies. 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, and 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 a few employees and external 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. With little or no redundancy in our personnel, the loss of any personnel or failure to attract or retain other key personnel and consultants could result in a loss of experience and accumulated knowledge and prevent us from developing our products and core technologies and pursuing collaborative relationships.

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

As a publicly traded company, we are subject to the reporting requirements of the Exchange Act. The Exchange Act requires that we file annual, quarterly and current reports. Our failure to prepare and disclose this information in a timely manner could subject us to penalties under federal securities laws, expose us to lawsuits and restrict our ability to access financing. We may be required to implement additional and expensive finance and accounting systems, procedures and controls as we grow our business and organization to satisfy new reporting requirements, which will increase our costs and require additional management resources.

***Our long-term success is dependent not only upon the success of our 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 belapectin for such trials. Manufacturing of belapectin is performed by third parties on a contract basis and production is ongoing to generate what we believe are sufficient quantities of belapectin for our NAVIGATE or other clinical trials. Manufacturing could become delayed due to circumstances beyond our control which could delay any 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 previously been a defendant in a shareholder derivative action, and any possible future such lawsuits may adversely affect our business, financial condition, results of operations and cash flows.***

We and certain of our officers and directors have previously been defendants in a state court shareholder derivative action that concluded in our favor. In addition, there is the potential for other future 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 any 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 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, 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 is conducted;
- the length of time required and ability to enroll eligible patients;
- the number of patients that participate in the trials;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- per patient trial costs;
- third party contractors failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner;
- our drug product candidates having different chemical and pharmacological properties in humans than in lab testing;
- the need to suspend or terminate our clinical trials;
- insufficient or inadequate supply or quality of drug product candidates or other necessary materials to conduct our trials;
- potential additional safety monitoring, or other conditions required by FDA or comparable foreign regulatory authorities regarding the scope or design of our clinical trials, or other studies requested by regulatory agencies;
- problems engaging IRBs to oversee trials or in obtaining and maintaining IRB approval of studies;
- the duration of patient follow-up;
- the efficacy and safety profile of the product candidate;
- the costs and timing of obtaining regulatory approvals; and
- the costs involved in enforcing or defending patent claims or other intellectual property rights.

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

***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 they obtained promising results in earlier trials. Despite the results reported in some of our earlier clinical trials for belapectin, our clinical trials may not demonstrate sufficient levels of safety and efficacy necessary to obtain the requisite regulatory approvals for our drugs, and thus, our proposed drugs may not be approved for marketing. If later-stage clinical trials do not produce favorable results, our ability to achieve regulatory approval for any of our product candidates may be adversely impacted. The failure to adequately demonstrate the safety and effectiveness of a proposed formulation or product under development could delay or prevent regulatory clearance of the potential drug. The resulting delays in commercialization could materially harm our business.

***Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following any marketing approval.***

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

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

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

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

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

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

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

**Risks Related to Our Intellectual Property**

***Our competitive position is contingent upon the protection of our intellectual property.***

Development and protection of our intellectual property are critical to our business. All of our intellectual property, patented or otherwise, has been invented and/or developed by employees or former employees of the Company. Our success depends, in part, on our ability to obtain patent protection for our products or processes in the U.S. and other countries, protect trade secrets and prevent others from infringing on our proprietary rights. We will only be able to protect our product candidates from unauthorized making, using, selling, offering to sell or importation by third parties to the extent that we have rights under valid and enforceable patents or trade secrets that cover these activities. If we do not adequately protect our intellectual property, competitors may be able to practice our technologies.

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

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

- others may be able to make compounds that are competitive with our product candidates but are not covered by the claims of our patents;
- we might not have been the first to make the inventions covered by our pending patent applications;
- we might not have been the first to file patent applications for these inventions;
- it is possible that our pending patent applications will not result in issued patents;
- we may not develop additional proprietary technologies that are patentable; or
- the patents of others may have an adverse effect on our business.

We also may rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. Although we require our scientific and technical employees and consultants to enter into broad assignment of inventions agreements, and all of our employees, consultants and corporate partners with access to proprietary information to enter into confidentiality agreements, these agreements may not be honored. Enforcing a claim that a third party illegally obtained, and is using, our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

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

Some or all of our patent applications may not issue as patents, or the claims of any issued patents may not afford meaningful protection for our technologies or products. In addition, patents issued to us or our licensors, if any, may be challenged and subsequently narrowed, invalidated or circumvented. Patent litigation is widespread in the biotechnology industry and could harm our business. Litigation might be necessary to protect our patent position or to determine the scope and validity of third-party proprietary rights.

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

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

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

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

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

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

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

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

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

Because we operate in the highly technical field of biotechnology and pharmaceutical development, we rely in part on trade secret protection in order to protect our proprietary trade secrets and unpatented know-how. However, trade secrets are difficult to protect, and we cannot be certain that others will not develop the same or similar technologies on their own. We have taken steps, including entering into confidentiality agreements with all of our employees, consultants and corporate partners to protect our trade secrets and unpatented know-how. These agreements generally require that the other party keep confidential and not disclose to third parties all confidential information developed by the party or made known to the party by us during the course of the party's relationship with us. We also typically obtain agreements from these parties that 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 Information Technology and Cybersecurity**

***We are dependent on information technology and our systems and infrastructure face certain risks, including from cybersecurity breaches and data leakage.***

We rely extensively on information technology systems, networks and services that are managed and hosted provided by third-parties or their vendors, to assist in conducting our business. A significant breakdown, invasion, corruption, destruction or interruption of critical information technology systems or infrastructure, by our personnel or others with authorized access to our systems or unauthorized persons could negatively impact our operations. The ever-increasing use and evolution of technology, including cloud-based computing, creates opportunities for the unintentional dissemination or intentional destruction or modification of confidential information stored in our, or our third-party providers' systems, portable media or storage devices. We could also experience a business interruption, theft of confidential information or reputational damage from malicious cyber-attacks, which may compromise our system infrastructure or lead to data leakage, either internally or at our third-party providers. As the COVID-19 pandemic continues to progress, we have observed an increase in cybersecurity incidents across the industry, predominantly ransomware and social engineering attacks. As the cyber-threat landscape evolves, these attacks are growing in frequency, sophistication and intensity, and due to the nature of some of these attacks, there is also a risk that they may remain undetected for a period of time. There can be no assurance that we will be able to prevent breakdowns or breaches to our or our third-party providers' databases or systems that could adversely affect our business.

**Risks Related to Our Common Stock**

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

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

- the results of our pre-clinical studies and clinical trials, including interim results, as well as those of our competitors;
- regulatory actions with respect to our products or our competitors' products;
- our ability to integrate operations, technology, products and services;
- our ability to execute our business plan;
- operating results below expectations;
- our issuance of additional securities, including debt or equity or a combination thereof, which may be necessary to fund our operating expenses 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;
- engagement and retention of senior management needed for our clinical trials; and
- novel and unforeseen market forces and trading strategies, such as the massive short squeeze rally caused by retail investors on companies such as Gamestop.

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, 2022), and empowers our board of directors to prescribe, by resolution and without stockholder approval, a class or series of undesignated shares, including the number of shares in the class or series and the voting powers, designations, rights, preferences, restrictions and the relative rights in each such class or series. Accordingly, in the event that additional undesignated shares are authorized under our charter documents, our board of directors 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 if and when we have 200 or more 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 may engage in 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, which includes the offer and sell shares of our common stock having an aggregate offering price of up to $40,000,000 from time to time pursuant to our At The Market Issuance Sales Agreement with H.C. Wainwright & Co., LLC. 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.

***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.

***Our shares of common stock 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 is considered "thinly-traded." This situation may be attributable to several factors, including the fact that we are a small company that is relatively unknown to stock analysts, stockbrokers, institutional investors and others in the investment community that generate or influence sales volume. Furthermore, even if our stock came to the attention of such persons, they may be reluctant to follow us or purchase or recommend the purchase of our shares. Therefore, 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 13.5% of our outstanding common stock as of February 28, 2023 (which does not include any shares issuable upon exercise of options and warrants) and the 10X Fund, LP , which now owns 10.4% of the issued and outstanding shares of common stock of the Company as of February 28, 2023 (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.

***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.

**The outbreak of the novel strain of coronavirus, SARS-CoV-2, which causes COVID-19, could adversely impact our business, including our preclinical studies and clinical trials.**

As a result of the COVID-19 outbreak, or similar future pandemics, we have and may in the future experience disruptions that could severely impact our business and our anticipated rollout and/or continuation of our NAVIGATE trial, including:

- delays or difficulties in enrolling patients in our clinical trials;
- delays or disruptions in non-clinical experiments due to unforeseen circumstances at contract research organizations and vendors along their supply chain;
- increased rates of patients withdrawing from our clinical trials following enrollment as a result of contracting COVID-19, being forced to quarantine, or not accepting in office or home health visits;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as sites for our NAVIGATE trial and hospital staff supporting the conduct of such trials;

- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures (particularly any procedures that may be deemed non-essential), which may impact the integrity of subject data and clinical study endpoints;

- interruption or delays in the operations of the FDA and comparable foreign regulatory agencies, which may impact review and approval timelines;

- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems; and

- limitations on employee resources that would otherwise be focused on the conduct of our preclinical studies and clinical trials, including because of sickness of employees or their families, the desire of employees to avoid contact with large groups of people, an increased reliance on working from home or mass transit disruptions.

These and other factors arising from the COVID-19 pandemic could worsen in countries that are already afflicted with COVID-19, could continue to spread to additional countries, or could return to countries where the pandemic has been partially contained, each of which could further adversely impact our ability to conduct clinical trials and our business generally, and could have a material adverse impact on our operations and financial condition and results.

In addition, the trading prices for our common stock and other biopharmaceutical companies have been highly volatile as a result of the COVID-19 epidemic. As a result, we may face difficulties raising capital through sales of our common stock or such sales may be on unfavorable terms. The COVID-19 outbreak continues to rapidly evolve. The extent to which the outbreak may impact our business, preclinical studies and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions and actions to contain the outbreak or treat its impact, such as social distancing and quarantines or lock-downs in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

**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 employees 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.

## 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 28, 2023, there were 134 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.

***Dividends***

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.** ***[Reserved]***

**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," "could" or "may." All statements, other than statements of historical facts, included herein that address activities, events, or developments that the Company expects or anticipates will or may occur in the future, are forward-looking statements, including statements regarding: 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 December 31, 2024; 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,
- 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,
- 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
- the impact resulting from the outbreak of COVID-19, which has delayed and may continue to delay our clinical trial and development efforts, as well as the impact that COVID-19 has on the volatility of the capital market and our ability to access the capital market.

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.

**Overview**

We are a clinical stage biopharmaceutical company engaged in drug research and development to create new therapies for fibrotic disease, cancer and selected other diseases. 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 galectin proteins have a demonstrated role in the pathogenesis of a given disease. We focus on diseases with serious, life-threatening consequences and those where current treatment options are limited specifically in NASH (non-alcoholic steatohepatitis) with cirrhosis and certain cancer indications. 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 one of our programs becomes advanced and requires significant additional resources.

Our lead galectin-3 inhibitor is belapectin (GR-MD-02), which has been demonstrated in preclinical models to reverse liver fibrosis and cirrhosis and in clinical studies to decrease portal hypertension and prevent its complication: the development of esophageal varices. Belapectin 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 galectin-3 gene "knocked-out" can no longer develop fibrosis in response to experimental stimuli compared to animals with an intact galectin-3 gene. We are using our galectin-3 inhibitor to treat advanced liver fibrosis and liver cirrhosis in NASH 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 compensated cirrhosis and portal hypertension (NASH-CX).

**Results of Operations from the Years Ended December 31, 2022 and 2021**

***Research and Development Expense***

| | Year ended December 31, | | 2022 as Compared to 2021 | |
|---|---|---|---|---|
| | 2022 | 2021 | $Change | % Change |
| | (in thousands, except %) | | | |
| Research and development | $ 31,737 | $ 23,818 | $ 7,919 | 33% |

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 and for additional toxicology studies to support advanced development, 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, belapectin and GM-CT-01; however only belapectin is in active development.

Our research and development expenses were as follows:

| | Year Ended December 31, | |
|---|---|---|
| | 2022 | 2021 |
| | (in thousands) | |
| Direct external expenses: | | |
| Clinical programs | $ 26,748 | $ 20,830 |
| Pre-clinical activities | 1,262 | 562 |
| Other research and development expenses: | | |
| Payroll and other including stock-based compensation | 3,727 | 2,426 |
| | $ 31,737 | $ 23,818 |

Clinical programs expenses increased in the year ended December 31, 2022 over the year ended December 31, 2021 primarily due to costs related to our the NAVIGATE clinical trial activities and preparations and some preclinical activities incurred in support of the planned clinical program such as development and reproductive toxicity studies, clinical supplies and other supportive activities. Payroll and other costs increased primarily due to additional employees being hired in research and development.

***General and Administrative Expense***

| | Year ended December 31, | | 2022 as Compared to 2021 | |
|---|---|---|---|---|
| | 2022 | 2021 | $ Change | % Change |
| | (in thousands, except %) | | | |
| General and administrative | $ 6,615 | $ 6,361 | $ 254 | 4% |

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, 2022, as compared to the same period for 2021 are due to an increase in non-cash stock-based compensation of $399,000 partially offset by decreases in legal fees and insurance expense of $146,000 and $131,000, respectively.

***Other Income and Expense***

During the year ended December 31, 2022, other income and expense consisted of $52,000 of interest income offset by interest expense and amortization of debt discounts on convertible notes payable and convertible line of credit of $1,033,000.

During the year ended December 31, 2021, other income and expense consisted of $4,000 of interest income offset by amortization of the debt discount associated with warrants issued with a line of credit entered into in December 2017 of $174,000 which is classified as interest expense, and interest expense and amortization of debt discounts on convertible notes payable of $315,000.

**Results of Operations from the Years Ended December 31, 2021 and 2020**

***Research and Development Expense***

| | Year ended December 31, | | 2021 as Compared to 2020 | |
|---|---|---|---|---|
| | 2021 | 2020 | $Change | % Change |
| | (in thousands, except %) | | | |
| Research and development | $ 23,818 | $ 17,976 | $ 5,842 | 32% |

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 and for additional toxicology studies to support advanced development, 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, belapectin and GM-CT-01; however only belapectin is in active development.

Our research and development expenses were as follows:

| | Year Ended December 31, | |
|---|---|---|
| | 2021 | 2020 |
| | (in thousands) | |
| Direct external expenses: | | |
| Clinical programs | $ 20,830 | $ 14,229 |
| Pre-clinical activities | 562 | 532 |
| Other research and development expenses: | | |
| Payroll and other including stock-based compensation | 2,426 | 3,215 |
| | $ 23,818 | $ 17,976 |

Clinical programs expenses increased in the year ended December 31, 2021 over the year ended December 31, 2020 primarily due to costs related to our the NAVIGATE clinical trial activities and preparations and some preclinical activities incurred in support of the planned clinical program such as development and reproductive toxicity studies, clinical supplies and other supportive activities.

***General and Administrative Expense***

| | Year ended December 31, | | 2021 as Compared to 2020 | |
|---|---|---|---|---|
| | 2021 | 2020 | $ Change | % Change |
| | (in thousands, except %) | | | |
| General and administrative | $ 6,361 | $ 5,468 | $ 893 | 16% |

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, 2021, as compared to the same period for 2020, are due to an increase in non-cash stock-based compensation of $373,000 and increase in insurance expense of $395,000.

***Other Income and Expense***

During the year ended December 31, 2021, other income and expense consisted of $4,000 of interest income offset by amortization of the debt discount associated with warrants issued with a line of credit entered into in December 2017 of $174,000 which is classified as interest expense, and interest expense and amortization of debt discounts on convertible notes payable of $315,000.

**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, 2022, we raised a net total of $244.5 million from these offerings. At December 31, 2022, the Company had $18.6 million of unrestricted cash and cash equivalents in addition to $50 million available under a line of credit provided by our chairman available to fund future operations. The Company believes there is sufficient cash to fund currently planned operations at least through December 31, 2024. We will require more cash to fund our operations after December 31, 2024 and believe we will be able to obtain additional financing. The currently planned operations include costs related to our adaptively designed NAVIGATE Phase 2b/3 clinical trial. 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.

*2022 compared to 2021*

Net cash used in operations increased by $6,748,000 to $31,056,000 for 2022, as compared to $24,308,000 for 2021. Cash operating expenses increased principally due to increased research and development activities primarily related to our NAVIGATE clinical trial and associated activities.

There were no equipment purchases or other investing activities in 2022 or 2021.

Net cash provided by financing activities was $10,000,000 during 2022 as compared to $36,814,000 during 2021, due primarily to the transactions described below.

In 2022, we received $10,000,000 in proceeds under a convertible line of credit provided by our chairman. In 2021, we received proceeds of $30,000,000 from three related-party convertible notes payable, $2,950,000 from the exercise of common stock warrants and $3,864,000 in net proceeds from issuance of common shares under our ATM.

*2021 compared to 2020*

Net cash used in operations increased by $3,707,000 to $24,308,000 for 2021, as compared to $20,601,000 for 2020. Cash operating expenses increased principally due to increased research and development activities primarily related to our NAVIGATE clinical trial and associated activities.

There were no equipment purchases or other investing activities in 2021 or 2020.

Net cash provided by financing activities was $36,814,000 during 2021 as compared to $263,000 during 2020, due primarily to the transactions described below.

In 2021, we received proceeds of $30,000,000 from three related-party convertible notes payable, $2,950,000 from the exercise of common stock warrants and $3,864,000 in net proceeds from issuance of common shares under our ATM. In 2020, we received proceeds of $44,000 from issuances of common stock through the At the Market issuances and received $219,000 from exercise of common stock options.

***Operating leases***

Effective February 28, 2022, 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 March 1, 2022 and ending April 30, 2025 at an average rate of approximately $4,250 per month. The amended lease provided for free rent for the first six 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 and lab space for research and development activities in Natick, MA. 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.

**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 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 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.* Research and development expenses, including personnel costs, allocated facility costs, lab supplies, outside services, contract laboratory costs related to manufacturing drug product, clinical trials and preclinical studies are charged to research and development expense as incurred. The Company accounts for nonrefundable advance payments for goods and services that will be used in future research and development activities as expense when the service has been performed or when the goods have been received. Our current NAVIGATE clinical trial is being supported by third-party contract research organizations, or CROs, and other vendors. We accrue expenses for clinical trial activities performed by CROs based upon the estimated amount of work completed on each trial. For clinical trial expenses and related expenses associated with the conduct of clinical trials, the significant factors used in estimating accruals include the number of patients enrolled, the number of active clinical sites, and the duration for which the patients have been enrolled in the trial. We monitor patient enrollment levels and related activities to the extent possible through internal reviews, review of contractual terms and correspondence with CROs. We base our estimates on the best information available at the time. We monitor patient enrollment levels and related activities to the extent possible through discussions with CRO personnel and based our estimates of clinical trial costs on the best information available at the time. However, additional information may become available to us which will allow us to make a more accurate estimate in future periods. In that event, we may be required to record adjustments to research and development expenses in future periods when the actual level of activity becomes more certain.

*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. The expense recognized over the service period is required to include an estimate of the awards that will be forfeited.

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

Due to the nature of our operations, assets and debt, we are not exposed to any significant market risks at December 31, 2022 and 2021.

**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, 2022. Our management has concluded, based on their evaluation, that our disclosure controls and procedures were effective as of December 31, 2022 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.

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, 2022.

*(c) Changes in Internal Control Over Financial Reporting*

Except as follows, there was no change in our internal control over financial reporting that occurred during the fourth quarter of 2022 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. During the course of preparing and reviewing the Company's interim financial statements for the period ended September 30, 2022, we identified a computational error in an accrual relating to research and development costs. This error was corrected in the financial statements as of and for the period ended September 30, 2022. We determined that this deficiency constitutes a "material weakness" in our internal control over financial reporting. We have advised our audit committee of this deficiency in our internal control over financial reporting, and the fact that this deficiency constitutes a "material weakness." A material weakness in internal control over financial reporting is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis by our internal controls. We performed additional procedures during the fourth quarter of 2022 to remediate this material weakness. Specifically, we have implemented additional reviews of research and development accruals and have enhanced documentation of processes. Management believes that these efforts have effectively remediated the material weakness.

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

None.

**Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections**

Not applicable.

**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 eleven members, all of whom were elected at our 2022 Annual Meeting of Stockholders.

The following table sets for the certain biographical information about our directors as of February 28, 2023, and the qualifications, experiences and skills considered in determining that each such person should serve as a director.

| Name | Age | Director Since |
|---|---|---|
| Gilbert F. Amelio, Ph.D. (2)(3) | 79 | 2009 |
| James C. Czirr | 69 | 2009 |
| Kary Eldred (1) | 48 | 2018 |
| Kevin D. Freeman (1)(2)(3) | 61 | 2011 |
| Joel Lewis | 53 | 2017 |
| Gilbert S. Omenn, M.D., Ph.D. (2) | 81 | 2014 |
| Marc Rubin, M.D. (3) | 68 | 2011 |
| Elissa J. Schwartz, Ph.D. (3) | 52 | 2020 |
| Harold H. Shlevin, Ph.D. | 73 | 2019 |
| Richard E. Uihlein, Chairman | 77 | 2017 |
| Richard A. Zordani (1) | 50 | 2020 |

(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*, has served as a director pursuant to contractual rights set forth in certain warrants to purchase Common Stock that 10X Fund L.P. holds since February 2009, 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. Mr. Czirr is an early stage investor and on the board of directors of Gold Express a private gold mining company with multiple exploration properties in the U.S. 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 since 2018 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 a television program (Economic War Room with Kevin Freeman) that airs on BlazeTV. 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, became our President and Chief Executive Officer on September 2, 2020. Previously, he was the Managing Director of Shareholder Services at Uline, Inc. (a distributor of shipping, packaging and industrial supplies), a position he held from 2007 through 2019. Mr. Lewis is a financial executive with over 26 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 Oncofusion Therapeutics and MedsynBio LLC of Ann Arbor, MI. Dr. Omenn is the Harold T. Shapiro Distinguished University 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. 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, he was dean of the School of Public Health and Community Medicine and professor of medicine and a Howard Hughes Medical Institute investigator at the University of Washington and Member of the Fred Hutchinson Cancer Research Center. Earlier he was Associate Director of the White House Office of Science and Technology Policy and of the Office of Management and Budget. He is the author of 600 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 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 from January 2016 through May 2018, 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.

*Elissa J. Schwartz, Ph.D.,* a director appointed by the board in September 2020, is a disease modeler who is currently a professor of biological sciences and mathematics at Washington State University (WSU). She received a PhD in Biomedical Sciences from Mount Sinai–NYU, a BA in Mathematics from UC Berkeley, and interdisciplinary postdoctoral training in Biomathematics and Biostatistics from UCLA. She is also affiliated with the WSU College of Veterinary Medicine in microbiology and pathology, and she is currently on the WSU COVID-19 modeling task force. Dr. Schwartz is the author of over 30 scientific publications on infectious disease, the immune response, and biological modeling. She serves on the Board of Directors for the Society for Mathematical Biology, and she previously served as a consultant for Pharmerit International, LP, a pharmaceutical economics company. Dr. Schwartz has held fellowships with the Mathematical Biosciences Institute (Ohio State University) and the African Institute for Mathematical Sciences (Cape Town, South Africa), and she served on the teaching faculty for courses in British Columbia, India, and Nepal. We believe Dr. Schwartz' qualifications to sit on our Board of Directors include her extensive expertise in biomathematics and biostatistics in the pharmaceutical industry.

*Harold Shlevin, Ph.D.*, retired from being our President and Chief Executive Officer on September 2, 2020, a position he had held since June 14, 2018; however, Dr. Shlevin has entered into a consulting agreement with the Company which ran through December 31, 2021. Dr. Shlevin previously served as our Chief Operating Officer and Secretary from October 1, 2012. Dr. Shlevin previously had been employed at the Georgia Institute of Technology's Advanced Technology Development Center as Principle 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 January 2006, 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. Previously, Dr. Shlevin served on the Board of Directors of Cardiome Pharma Corporation (NASDAQ: CRME), now known as Correvio Pharma Corp. (NASDAQ: CORV) from 2004 to June 2016. He was Chair of the Compensation Committee and member of the Corporate Governance Committee and Audit Committees. We believe Dr. Shlevin's qualifications to sit on our Board of Directors include his extensive executive leadership and management experience in the pharmaceutical industry.

*Richard E. Uihlein*, a director since 2017 and Chairman since May 2018, 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.

*Richard A. Zordani,* a director appointed by the board in September 2020, has been the Director of Shareholder Services at Uline, Inc. (a distributor of shipping, packaging and industrial supplies) since 2013. Prior to joining Uline, Mr. Zordani served as a Director and Vice President for Diversified Financial Management Corp. (Pritzker family office) where he advised on complex legal and tax structures for domestic and foreign entities and trusts from 2003 through 2013 and an Audit Manager for Altschuler, Melvoin & Glasser LLP (now RSM McGladrey) from 1996 through 2003. Mr. Zordani received his undergraduate degree from the University of Illinois at Urbana/Champaign and is a Registered CPA in the state of Illinois. We believe that Mr. Zordani's qualifications to sit on our Board include his business and financial expertise.

**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.

**Hedging Policy**

At this time, the Company has not adopted a policy regarding the ability of officers, directors and employees to purchase financial instruments (including prepaid variable forward contracts, equity swaps, collars, and exchange funds) or otherwise engage in transactions, that hedge or offset, or are designed to hedge or offset, any decrease in the market value of the Company's equity securities.

**Clawback Policy**

At this time, the Company has not adopted a policy regarding the recovery by the Company of certain incentive-based compensation awarded to current and former executives in the event of a accounting errors. In February 2023, the Nasdaq Stock Market released a proposed version of a clawback rule that would require listed companies to have a clawback policy. Upon the SEC's approval of such rule, the Company intends to adopt a clawback policy in compliance with Nasdaq listing requirements.

**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 Richard A. Zordani (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 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. Zordani 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**

*Joel Lewis*, see above under directors.

*Pol F. Boudes, M.D.,* age 65, became the Company's Chief Medical Officer on March 2, 2020. Prior to joining the Company, Dr. Boudes served as the Chief Medical Officer of CymaBay Therapeutics from March 2014 through October 2019, where he worked on CymaBay's proprietary NASH compound and was instrumental in inventing and launching programs in rare liver diseases. Prior to his time at CymaBay, Dr. Boudes served as the Chief Medical Officer of Amicus Therapeutics, a company focusing on rare lysosomal storage disorders. Following this experience, Dr. Boudes became a Board member of Protalix BioTherapeutics, a company developing plant cell expressed recombinant proteins with improved therapeutic profiles, notably for lysosomal disorders. Before his time working as a Chief Medical Officer, Dr. Boudes held positions of increased responsibilities in clinical development at Bayer HealthCare Pharmaceuticals, Wyeth Research, Hoffman-La Roche and Pasteur Merieux.

*Jack W. Callicutt*, age 55, became our Chief Financial Officer on July 1, 2013. From August 2011 through June 2012, Mr. Callicutt was the Chief Financial Officer of REACH 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.

None of the directors, executive officers and significant 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. All reports were timely filed during the fiscal year ended December 31, 2022, except as set forth below.

*Delinquent Section 16(a) Reports*

One of our directors, James C. Czirr, and one of our 10% shareholders, 10X Fund, L.P. did not timely file two change on ownership reports on Form 4, resulting in the untimely disclosure of two transactions.

**Item 11.** ***Executive Compensation***

**COMPENSATION PHILOSOPHY DISCUSSION**

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 Philosophy Discussion ("Compensation Discussion") describes our 2022 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 Compensation Discussion is intended to be read in conjunction with the tables that follow, which provide detailed historical compensation information for our following NEOs:

| Name | Title |
|---|---|
| Joel Lewis | Chief Executive Officer and President |
| Pol F. Boudes, M.D. | Chief Medical Officer |
| 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.

**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 last "Say-on-Pay vote" held at our 2022 annual meeting of stockholders approximately 90% of votes cast were in favor of the compensation of our NEOs, as disclosed in the proxy materials for the 2022 annual meeting. At our 2019 annual meeting, the holders of approximately 78% of our outstanding common stock voting on the matter voted in favor of holding the tockholder 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 2025 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 50$^{th}$ 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 2022.

The Compensation Committee may use a compensation consultant in 2023 and will take into account publicly-available data relating to the compensation practices and policies of other companies within and outside our industry. The Compensation Committee intends to benchmark its executive compensation program to target at least the 50$^{th}$ 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 during the NAVIGATE trial.

**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.

| Name | 2022 Base Salary | 2021 Base Salary |
|---|---|---|
| Joel Lewis | $ 525,000(1) | $ 500,000(1) |
| Pol F. Boudes, M.D.. | $ 475,000 | $ 455,000 |
| Jack W. Callicutt | $ 320,000 | $ 302,100 |

(1) Pursuant to Mr. Lewis's Employment Agreement and Deferred Stock Unit Agreement, 20% of Mr. Lewis' base salary will be paid in cash and 80% will be paid in the form of deferred-stock units in accordance with the terms and subject to the provisions of the DSU Agreement.

***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. The 2022 performance bonuses were paid in February 2023.

| Name | | Performance Bonus Amount | Awarded Amount As % of Base Salary |
|---|---|---|---|
| Joel Lewis | $ | 262,500(1) | 50% |
| Pol F. Boudes, M.D. | $ | 142,500 | 30% |
| Jack W. Callicutt | $ | 96,000 | 30% |

(1) Pursuant to Mr. Lewis's Employment Agreement and Deferred Stock Unit Agreement, 20% of Mr. Lewis' bonus will be paid in cash and 80% will be paid in the form of deferred-stock units in accordance with the terms and subject to the provisions of the DSU Agreement

***Long-Term Incentive Compensation***

The Company believes that by providing its NEOs the opportunity to increase their ownership of Company stock, the interests of its NEOs will be more closely-aligned with the best interests of the Company's stockholders and it will encourage long-term performance. The stock awards enable the NEOs to participate in the appreciation in the value of the Company's stock, while personally participating in the risks of business setbacks.

Under the long-term incentive portion of the Program, the NEOs are granted options based upon achievement of the Company performance and individual performance objectives and rank in the Company. All option grants under the Program through December 2019 were made under the 2009 Incentive Compensation Plan. Grants made after January 1, 2020, were made pursuant to the 2019 Omnibus Equity Incentive Plan.

On January 24, 2022, the NEOs were awarded the options noted below based on 2021 performance. For the performance options, 25% vest on each of June 30, 2022, December 31, 2022, June 30, 2023, and December 31, 2023. The exercise price of the options is set at the closing price of our stock as of the grant date.

| Name | Grant Date | Number of Securities Underlying Options | | Exercise Price |
|---|---|---|---|---|
| Joel Lewis | 1/24/2022 | 70,000 | $ | 1.98 |
| Pol Boudes, M.D. | 1/24/2022 | 50,000 | $ | 1.98 |
| Jack W. Callicutt | 1/24/2022 | 50,000 | $ | 1.98 |

***Material Terms of Employment Contracts of Named Executive Officers***

Set forth below are descriptions of the principal terms of the employment agreements for each of our NEOs. Each employment agreement provides for post-termination restrictive covenants and payments due upon termination of employment or change in control of the Company, which is provided in further detail under the section entitled "Potential Payments Upon Termination or Change in Control."

*Joel Lewis, Chief Executive Officer*

In connection with the appointment of Mr. Lewis, the Company and Mr. Lewis entered into an employment agreement, dated August 31, 2020 (the "Employment Agreement"), and a Deferred Stock Unit Agreement, dated August 31, 2020 (the "DSU Agreement"). The Employment Agreement has an initial term of two years and automatically renews for additional one-year terms thereafter, unless either Mr. Lewis or the Company elects not to renew. Mr. Lewis will serve as Chief Executive Officer of the Company effective as of September 2, 2020 (the "Start Date"), and will be paid an annual base salary of $500,000. Under the terms of the Employment Agreement, 20% of his base salary will be paid in cash, and 80% will be paid in the form of deferred-stock-units ("DSUs") in accordance with the terms and subject to the provisions set forth in the DSU Agreement. In addition, Mr. Lewis is entitled to participate in the Company's performance bonus plan with a potential of up to 50% of his annual base salary, which will also be paid 20% in cash and 80% in DSU's. Further, Mr. Lewis received on the date of the agreement an initial grant of options to purchase 250,000 shares of the Company's common stock, par value $0.001 per share, which options shall vest one-twelfth on a quarterly basis for twelve consecutive quarters, such that the options shall be fully vested twelve quarters following the date of grant (the "Award"). The options under the Award shall be issued pursuant to the Company's 2019 Omnibus Equity Incentive Plan (the "Plan"). Pursuant to the Employment Agreement, Mr. Lewis is also eligible to receive healthcare benefits as may be provided from time to time by the Company to its employees generally, to participate in the Company's 401(k) plan and to receive paid time off annually in accordance with the Company's policies in effect from time to time. Finally, pursuant to the Employment Agreement, the Company will be required to furnish a lump sum cash payment to Mr. Lewis upon a termination of Mr. Lewis without "Cause" or upon Mr. Lewis' resignation for "Good Reason" as such terms are defined in the Employment Agreement or in the event the Company gives notice of non-renewal on or before September 30, 2023. The Employment Agreement includes customary intellectual property, assignment, and other representations by Mr. Lewis.

On July 25, 2022, we entered into amendments to the Employment Agreement and DSU Agreement with Mr. Lewis. Pursuant to the amendments, Mr. Lewis' base salary earned in 2023 will be paid 20% in cash and 80% in DSUs. Additionally, the term of the Employment Agreement was extended until December 31, 2024. Unless either party gives written notice of non-renewal at least 60 days prior to December 31, 2024, the amended employment agreement will automatically renew for an additional twelve months. Also, if either Mr. Lewis terminates his employment for Good Reason (ii) the Company terminates Mr. Lewis's employment without Cause, or if this Employment Agreement expires as a result of the Company giving written notice of non-renewal, then the Company shall pay to Mr. Lewis (1) any accrued benefits, (2) a lump sum amount equal to twelve (12) months of Mr. Lewis's base salary payable within thirty (30) days after the date of such termination, and (3) the performance bonus, if any, for the year in which termination occurs, based on actual individual and Company performance results and multiplied by a fraction, (A) the numerator of which shall be the number of days elapsed from the beginning of the fiscal year in which such termination occurs and (B) the denominator of which shall be 365; provided, however, that the portion of the performance bonus payable in the form of DSUs, will be paid in accordance with the terms of the DSU Award Agreements. Notwithstanding the foregoing, the payments described in clauses above are expressly conditioned upon Mr. Lewis executing returning a full release of the Company and its affiliates and from all obligations and any usual and customary indemnification obligations of the Company to Mr. Lewis as an officer thereof.

Pursuant to the DSU Agreement, 80% of Mr. Lewis' base salary under the Employment Agreement shall be payable in DSUs, which DSUs credited to Mr. Lewis as of any date shall be fully vested and nonforfeitable at all times. Pursuant to an amendment to the DSU Agreement in July 2022, the Company shall issue the shares underlying the outstanding whole number of DSUs credited to Mr. Lewis as follows: twenty five percent shall be issued on March 1, 2023, twenty five percent shall be issued on September 1, 2028 and fifty percent shall be issued on March 1, 2024.

*Pol F. Boudes, M.D., Chief Medical Officer*

On February 19, 2020, the Company entered into an Employment Agreement with Dr. Boudes (the "Agreement"), which governs the terms of Dr. Boudes' employment in his position as the Company's Chief Medical Officer. Dr. Boudes will serve as the Chief Medical Officer of the Company during an initial term that commences on March 2, 2020 (the "Commencement Date") and expires on February 28, 2021 (the "Initial Term"). Following the Initial Term, the term of the Agreement automatically renews for successive twelve (12) month terms unless either party provides the other party with notice of non-renewal at least sixty (60) days prior to the expiration of the then-current term. Under the Agreement, the Company has agreed to pay Dr. Boudes a base salary of $444,500 per year (the "Base Salary"). Provided that certain performance objectives are met, Dr. Boudes will also be entitled to receive an annual performance bonus equal to thirty percent (30%) of the Base Salary (the "Performance Bonus"). Subject to certain restrictions described in the Agreement, Dr. Boudes will receive a $100,000 signing bonus pursuant to the Agreement. Dr. Boudes will also be granted options to purchase 300,000 shares (the "Options") of the Company's common stock pursuant to the Company's 2019 Omnibus Equity Incentive Plan. The Options vest as follows: twenty percent (20%) of the Options shall vest upon one (1) year of employment, twenty percent (20%) of the Options shall vest upon two (2) years of employment, twenty percent (20%) of the Options shall vest upon three (3) years of employment, and the remaining forty percent (40%) of the Options shall vest upon four (4) years of employment.

*Jack W. Callicutt, Chief Financial Officer*

We entered into an employment agreement with Mr. Callicutt dated July 1, 2013 (the "Callicutt Employment Agreement"), in conjunction with Mr. Callicutt's appointment as our Chief Financial Officer. Pursuant to the terms of the Callicutt Employment Agreement, Mr. Callicutt received an initial base salary of $175,000 and was eligible to receive a performance bonus equal to 20% of his base salary. Effective March 31, 2015, Mr. Callicutt's annual base salary was increased to $240,000, and his annual base salary was increased again to $260,000 in February 2016. In June 2018, Mr. Callicutt's annual base salary increased to $285,000. He also received a signing bonus of $10,000. In addition to his cash compensation, the Company awarded Mr. Callicutt a grant of options to purchase 200,000 shares of the Company's Common Stock at an exercise price equal to the closing price of the Company's Common Stock on July 1, 2013, with 25,000 shares vesting on December 31, 2013, 50,000 shares vesting on December 31, 2014, 50,000 shares vesting on December 31, 2015 and 75,000 shares vesting on December 31, 2016. The options were granted pursuant to the 2009 Incentive Compensation Plan and expire ten years after the date of grant.

On August 11, 2017, we entered into an amendment to the Callicutt Employment Agreement with Mr. Callicutt (the "Amendment"). Pursuant to the Amendment, (i) Mr. Callicutt's target bonus opportunity was increased to 30% of his base salary and (ii) an error in the severance provision of the Callicutt Employment Agreement was corrected. Prior to the Amendment, the Callicutt Employment Agreement did not provide for any severance if Mr. Callicutt's employment was terminated by the Company "without cause," or by Mr. Callicutt for "good reason" after the date that was 24 months after the Commencement Date.

***Employee Benefits & Perquisites***

From time to time, the Company has provided the NEOs with employee benefits and perquisites that our Board believes are reasonable. Our NEOs are eligible to participate in the same broad-based employee benefit plans that are offered to our other employees, such as health insurance, disability insurance, life insurance and a 401(k) plan. These benefits are provided as part of the basic conditions of employment for all of our employees, and therefore providing them to our NEOs does not represent a significant incremental cost to us. The Company does not view employee benefits and perquisites as a significant element of its comprehensive compensation structure, but does believe they can be useful in attracting, motivating, and retaining the executive talent for which the Company competes. The Company believes that these additional benefits may assist the NEOs in performing their duties and provide time efficiencies for the NEOs in appropriate circumstances, and the Company may consider providing additional employee benefits and perquisites in the future. All future practices regarding employee benefits and perquisites will be approved and subject to periodic review by the Compensation Committee.

**SUMMARY COMPENSATION TABLE**

The following table summarizes the compensation paid to our NEOs for the fiscal years ended December 31, 2022 and 2021.

| Name and Principal Position | Year | Salary ($) | Bonus ($) | Option Awards ($) (1) | All Other Compensation ($) | Total ($) |
|---|---|---|---|---|---|---|
| Joel Lewis, Chief Executive Officer & President | 2022(2) | 522,917 | 262,500 | 103,517 | 85,247(3) | 974,181 |
| | 2021(2) | 500,000 | 250,000 | 329,177 | 88,444(4) | 1,167,621 |
| Pol F. Boudes, M.D., Chief Medical Officer | 2022(5) | 473,333 | 142,500 | 73,940 | 104,804(6) | 794,577 |
| | 2021(5) | 452,583 | 136,500 | 235,126 | 99,474(7) | 923,683 |
| Jack W. Callicutt, | 2022(8) | 318,508 | 96,000 | 73,940 | 78,116(9) | 566,564 |
| Chief Financial Officer | 2021(8) | 302,100 | 90,630 | 235,126 | 78,062(10) | 705,918 |

(1) Represents the aggregate grant date fair value of option awards made during 2022 and 2021 computed in accordance with the Stock Compensation Topic of the FASB ASC, as modified of supplemented. Fair value was calculated using the Black-Scholes options pricing model. For a description of the assumptions used to determine these amounts, see Note 9 of the Notes to the Consolidated Financial Statements in our Annual Reports on Form 10-K (or Form 10-K/A, as applicable) for the fiscal years ended December 31, 2022 and 2021.

(2) Mr. Lewis's performance bonuses for 2022 and 2021 were approved in January 2022 and January 2023, respectively. Pursuant to his employment agreement 20% of his salary and bonus are paid in cash and 80% are awarded in deferred stock units.

(3) Includes $73,047 for health and other insurance and $12,200 for 401(k) plan contributions.

(4) Includes $76,844 for health and other insurance and $11,600 for 401(k) plan contributions.

(5) Dr. Boudes' performance bonuses for 2022 and 2021 were approved in January 2022 and January 2023, respectively.

(6) Includes $92,604 for health and other insurance and $11,200 for 401(k) plan contributions.

(7) Includes $87,874 for health and other insurance and $11,600 for 401(k) plan contributions.

(8) Mr. Callicutt's performance bonuses for 2022 and 2021 were approved in January 2022 and January 2023, respectively.

(9) Includes $65,916 for health and other insurance and $12,200 for 401(k) plan contributions.

(10) Includes $66,462 for health and other insurance and $11,600 for 401(k) plan contributions.

## OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END 2022

The following table sets forth information regarding all outstanding equity awards held by the NEOs at December 31, 2022. The exercise price of the options is set at the closing price of our stock at the date prior to or as of the date of grant. Outstanding options have been approved by our Compensation Committee and our Board.

| | Option Awards | | | | | Stock Awards | | | |
|---|---|---|---|---|---|---|---|---|---|
| Name | Number of Securities Underlying Unexercised Options (#) Exercisable | Number of Securities Underlying Unexercised Options (#) Unexercisable | Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#) | Option Exercise Price ($) | Option Expiration Date | Number of Shares or Units of Stock That Have Not Vested (#) | Market Value of Shares or Units of Stock That Have Not Vested ($) | Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested (#) | Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested ($) |
| Joel Lewis | 54,250(1) | — | | 2.39 | 12/14/2027 | — | — | — | — |
| | 35,000(2) | — | | 4.72 | 01/16/2029 | | | | |
| | 40,000(3) | — | | 2.86 | 01/09/2030 | | | | |
| | 187,500(4) | 62,500(4) | | 2.65 | 08/31/2030 | | | | |
| | 52,500(5) | 17,500(5) | | 2.11 | 03/25/2031 | | | | |
| | — | 140,000(6) | | 2.11 | 03/25/2031 | | | | |
| | 35,000(7) | 35,000(7) | | 1.98 | 01/24/2032 | | | | |
| Pol F. Boudes, M.D. | 120,000(8) | 180,000(8) | | 1.75 | 03/12/2030 | — | — | — | — |
| | 37,500(5) | 12,500(5) | | 2.11 | 03/25/2031 | | | | |
| | — | 100,000(6) | | 2.11 | 03/25/2031 | | | | |
| | 25,000(7) | 25,000(7) | | 1.98 | 01/24/2032 | | | | |
| Jack W. Callicutt | 26,000(9) | — | | 13.38 | 01/21/2024 | — | — | — | — |
| | 8,706(10) | — | | 1.37 | 01/20/2026 | | | | |
| | 90,000(11) | — | | 5.87 | 01/15/2028 | | | | |
| | 90,000(12) | — | | 4.16 | 05/22/2028 | | | | |
| | 50,000(13) | — | | 4.72 | 01/16/2029 | | | | |
| | 50,000(14) | — | | 2.86 | 01/09/2030 | | | | |
| | 37,500(5) | 12,500(5) | | 2.11 | 03/25/2031 | | | | |
| | — | 100,000(6) | | 2.11 | 03/25/2031 | | | | |
| | 25,000(7) | 25,000(7) | | 1.98 | 01/24/2032 | | | | |

(1) 100% of the options vested in full on December 14, 2018.
(2) 100% of the options vested in full on January 16, 2020.
(3) 100% of the options vested in full on December 31, 2020.
(4) One-twelfth of the total options vest quarterly from August 31, 2020, which was the grant date.
(5) 25% of the options vested on September 30, 2021, 25% vested on March 31, 2022, 25% vested on September 30, 2022, 25% vest on March 31, 2023.
(6) 100% of the options vest when the Company has received the interim results of the NAVIGATE clinical trial and makes a public announcement that it has received the interim results.
(7) 25% of the options vested on June 30, 2022, 25% vested on December 31, 2022, 25% vest on June 30, 2023, 25% vest on December 31, 2023.
(8) 20% of the options vest on each of March 2, 2021, March 2, 2022, and March 2023 and 40% of the options vest on March 2, 2024.
(9) 25% of the options vested on January 21, 2014, the grant date with the remainder vested ratably on a monthly basis over a three-year period.
(10) 25% of the options vested on January 29, 2015, the grant date with the remainder vested ratably on a monthly basis over a three-year period.
(11) 25% of the options vested on January 15, 2018 (grant date), 25% vested on June 30, 2018, and 50% vested on December 31, 2018.
(12) 25% of the options vested on June 30, 2018, 25% vested on September 30, 2018, and 50% vested on December 31, 2018.
(13) 25% of the options vested on June 30, 2019, 25% vested on December 31, 2019, 25% vested on June 30, 2020, and 25% vested on December 31, 2020.
(14) 25% of the options vested on June 30, 2020, 25% vested on December 31, 2020, 25% vested on June 30, 2021, and 25% vested on December 31, 2021.

***2009 Incentive Compensation Plan***

The options granted under our 2009 Incentive Compensation Plan, the options will become immediately vested and exercisable upon a change of control. Upon termination of employment for cause, all outstanding options immediately terminate. Options remain exercisable for one year following termination due to the executive's death or disability or retirement, or for twelve months after termination for any other reason other than for cause.

Under the 2009 Incentive Compensation Plan, change of control is defined as:

(1) the acquisition of beneficial ownership of 50% or more of either the value of then outstanding equity securities of the Company or the combined voting power of our securities, except for any acquisition directly from us, any acquisition by us or any person that owns a controlling interest in the Company, or any acquisition by any of our employee benefit plans;

(2) during any period of three (3) consecutive years, a majority of the Board is no longer comprised of individuals who, as of the beginning of that period, constituted our Board and individuals whose nomination for election was approved by the Board;

(3) a reorganization, merger, statutory share exchange or consolidation or similar transaction, a sale or other disposition of all or substantially all of the assets of the Company, or the acquisition of assets or equity of another entity by the Company, in each case unless (i) substantially all of the owners, respectively, of our outstanding shares of common stock or the combined voting power of our securities immediately before the transaction beneficially own more than 50% of, respectively, the common stock and the combined voting power of the securities of the resulting corporation, in substantially the same proportions as their ownership immediately prior to the transaction, (ii) no person owns 50% of, respectively, the common stock and the combined voting power of the securities of the resulting corporation, unless such ownership existed prior to the transaction and (iii) at least a majority of the members of the board of directors of the resulting entity were members of the Board of Directors of the Company at the time of the execution of the initial agreement or of the action of the Board providing for such transaction ; or

(4) approval by the stockholders of a complete liquidation or dissolution of the Company.

"Disability" is defined as a permanent and total disability (within the meaning of Code Section 22(e)), as determined by a medical doctor satisfactory to the Compensation Committee.

"Cause" means the failure by the executive to perform, in a reasonable manner, his or her duties as assigned by the Company, (ii) any violation or breach by the executive of his or her employment, consulting or other similar agreement with the Company, if any, (iii) any violation or breach by the executive of any non-competition, non-solicitation, non-disclosure and/or other similar agreement with the Company, (iv) any act by the executive of dishonesty or bad faith with respect to the Company, (v) use of alcohol, drugs or other similar substances in a manner that adversely affects the executive's work performance, or (vi) the commission by the executive of any act, misdemeanor, or crime reflecting unfavorably upon the executive or the Company.

***2019 Omnibus Equity Incentive Plan***

Under the 2019 Omnibus Equity Incentive Plan, if there is a merger or consolidation of the Company with or into another corporation or a sale of substantially all of the Company's stock (a "Corporate Transaction"), and the outstanding awards are not assumed by surviving company (or its parent company) or replaced with economically equivalent awards granted by the surviving company (or its parent company), the Company will cancel any outstanding awards that are not vested and nonforfeitable as of the consummation of such Corporate Transaction (unless the Company accelerates the vesting of any such awards) and with respect to any vested and nonforfeitable awards, the Company may either (i) allow all grantees to exercise options and SARs within a reasonable period prior to the consummation of the Corporate Transaction and cancel any outstanding options or SARs that remain unexercised upon consummation of the Corporate Transaction, or (ii) cancel any or all of such outstanding awards (including options and SARs) in exchange for a payment (in cash, or in securities or other property) in an amount equal to the amount that the grantee would have received (net of the exercise price with respect to any options or SARs) if the vested awards were settled or distributed or such vested options and SARs were exercised immediately prior to the consummation of the Corporate Transaction. If an exercise price of the option or SAR exceeds the fair market value of our Common Stock and the option or SAR is not assumed or replaced by the surviving company (or its parent company), such options and SARs will be cancelled without any payment to the grantee.

***Potential Payments Upon Termination or Change-in-Control***

*Joel Lewis:*

If either Mr. Lewis terminates his employment for Good Reason (ii) the Company terminates Mr. Lewis's employment without Cause, or if this Employment Agreement expires as a result of the Company giving written notice of non-renewal, then the Company shall pay to Mr. Lewis (1) any accrued benefits, (2) a lump sum amount equal to twelve (12) months of Mr. Lewis's base salary payable within thirty (30) days after the date of such termination, and (3) the performance bonus, if any, for the year in which termination occurs, based on actual individual and Company performance results and multiplied by a fraction, (A) the numerator of which shall be the number of days elapsed from the beginning of the fiscal year in which such termination occurs and (B) the denominator of which shall be 365; provided, however, that the portion of the performance bonus payable in the form of DSUs, will be paid in accordance with the terms of the DSU Award Agreements. Notwithstanding the foregoing, the payments described in clauses above are expressly conditioned upon Mr. Lewis executing returning a full release of the Company and its affiliates and from all obligations and any usual and customary indemnification obligations of the Company to Mr. Lewis as an officer thereof.

Under the Deferred Stock Unit Agreement, if a Change in Control of the Company occurs prior to the date on which Mr. Lewis is scheduled to receive shares and cash in an installment payment or in a lump sum (a "Settlement Date"), Mr. Lewis' account will be credited with the consideration payable in such Change in Control with respect to the shares subject to the DSUs then credited to Mr. Lewis' Account immediately prior to such Change in Control. If Mr. Lewis' employment with the Company continues after a Change in Control, Mr. Lewis' account will be credited with the cash value of the portion of his base salary and annual performance bonus that would have been credited in the form of DSUs but for the Change in Control. The portion of Mr. Lewis' Account denominated in cash pursuant to the preceding sentence (i.e., the amount attributable to base salary and annual performance bonuses credited to Mr. Lewis' Account after the Change in Control) shall be credited with interest at three (3%) percent compounded annually. For avoidance of doubt, a Change in Control shall not result in acceleration of the settlement of Mr. Lewis' Account and the payment of all amounts or other property credited to Mr. Lewis' Account in connection with the Change in Control shall be paid or delivered to Mr. Lewis on as soon as reasonably practicable after the Settlement Date.

*Pol Boudes:*

Under the Employment Agreement with Dr. Boudes, if (i) Dr. Boudes terminates the Agreement for Good Reason (as defined in the Agreement) or (ii) the Company terminates the Agreement without Cause (as defined in the Agreement), then the Company shall pay to Dr. Boudes: (1) the Base Salary accrued through the date of termination, (2)(A) if termination occurs within twelve (12) months of the Commencement Date, an amount equal to three (3) months of the Base Salary, or (B) if such termination occurs after the twelve-month anniversary of the Commencement Date, but prior to the eighteen-month anniversary of the Commencement Date, an amount equal to six (6) months of the Base Salary or (C) if termination occurs after the eighteen-month anniversary of the Commencement Date, but prior to the twenty four-month anniversary of the Commencement Date, an amount equal to nine (9) months of Base Salary or (D) if termination occurs after the twenty four-month anniversary of the Commencement Date, an amount equal to twelve (12) months of the Base Salary, (3) reimbursement of unreimbursed expenses and (4) payment of a portion of the Performance Bonus.

If, within the period ending twelve (12) months after the date of a Change of Control, Dr. Boudes' employment with the Company is (i) terminated without Cause or (ii) terminated for Good Reason by Dr. Boudes, the Company shall pay to Dr. Boudes (A) the Base Salary accrued through the date of termination, to the extent not theretofore paid, (B) reimbursement of any unreimbursed expenses, (C) a pro-rated amount of the Performance Bonus assuming payout at maximum performance and (D) an amount equal to twelve (12) months of Base Salary, payable in a lump sum no later than thirty (30) days following such termination. Upon any such Change of Control, Dr. Boudes' unvested Options shall be one hundred percent (100%) vested, but shall otherwise continue to be governed by the terms and conditions of the Plan and the applicable stock option agreement.

*Jack Callicutt:*

Mr. Callicutt's Employment Agreement provides that if, within the period ending twelve (12) months after the date of a Change of Control, Mr. Callicutt's employment with the Company is (i) without Cause by the Company (or by the acquiring or successor business entity following a Change of Control), or (ii) terminated for Good Reason by Mr. Callicutt, the Company shall pay to Mr. Callicutt (A) the Base Salary accrued through the date of termination, to the extent not theretofore paid, (B) reimbursement of any unreimbursed expenses, (C) a portion of the amount of the Performance Bonus (as defined in the Employment Agreement) equal to the maximum amount of the Performance Bonus multiplied by a fraction, (X) the numerator of which shall be the number of days elapsed from the beginning of the calendar year in which such termination occurs and (Y) the denominator of which shall be the total number of days in the calendar year in which such termination occurs (being 365 in a full year and 184 in 2013) and (D) an amount equal to twelve (12) months of Mr. Callicutt's Base Salary, payable in a lump sum no later than thirty (30) days following such termination. Upon any such Change of Control, Mr. Callicutt's unvested options to purchase shares of the Company's common stock shall be one hundred percent (100%) vested, but shall otherwise continue to be governed by the terms and conditions of the Stock Option Agreement. However, if, in connection with a transaction that technically meets, or may meet, the definition of Change of Control (as defined in the Employment Agreement), Mr. Callicutt's employment by the Company or a successor to the Company is terminated, but Mr. Callicutt is immediately re-hired as an employee of a successor to the Company or surviving company in such a transaction in a comparable position, with the same or greater total annual cash compensation, including bonus potential, and with an employment agreement containing substantially equivalent provisions as this Agreement with respect to termination of the Mr. Callicutt and severance, no benefits shall be payable under the Change of Control provision of the Employment Agreement.

**DIRECTOR COMPENSATION**

The following table details the total compensation earned by our non-employee directors during the year ended December 31, 2022.

| Name | Fees Earned or Paid in Cash ($) | Restricted Stock Awards ($) (1) | Option Awards ($) (2) | Non-Equity Incentive Plan Compensation ($) | All Other Compensation ($) (3) | Total ($) |
|---|---|---|---|---|---|---|
| Gilbert F. Amelio, Ph.D. | 50,500 | — | 58,934 | — | — | 109,434 |
| James C. Czirr | 35,000 | — | 58,934 | — | — | 93,934 |
| Kary Eldred | 42,500 | — | 58,934 | — | — | 101,434 |
| Kevin D. Freeman | 51,000 | — | 58,934 | — | — | 109,934 |
| Gilbert S. Omenn, M.D., Ph.D. | 45,000 | — | 58,934 | — | — | 109,934 |
| Marc Rubin, M.D. | 38,500 | — | 58,934 | — | — | 97,434 |
| Elissa J. Schwartz, Ph.D. | 38,500 | — | 58,934 | — | — | 97,434 |
| Harold H. Shlevin, Ph.D. | 35,000 | — | 58,934 | — | — | 114,200 |
| Richard Uihlein | — | 35,000 | 58,934 | — | — | 93,394 |
| Richard A. Zordani | 50,000 | — | 58,934 | — | — | 108,934 |

(1) Mr. Uihlein elected to receive restricted stock in lieu of cash retainer for their service. The restricted shares vested in full on December 31, 2022.

(2) Represents the grant date fair value of option awards based upon the Black Scholes valuation model made in 2022. The option grants were made on January 24, 2022. Each non-employee director received one grant of 40,000 options which will vest in full on December 31, 2022. For a description of the assumptions used to determine these amounts, see Note 9 to the Notes to the Consolidated Financial Statements herein our Annual Report on Form 10-K for the fiscal year ended December 31, 2022.

(3) Excludes travel expense reimbursements.

| Name | Number of Shares Subject to Option Awards Held as of December 31, 2022 |
|---|---|
| Gilbert F. Amelio, Ph.D. | 225,000 |
| James C. Czirr | 405,125 |
| Kary Eldred | 251,875 |
| Kevin D. Freeman | 329,839 |
| Gilbert S. Omenn, M.D., Ph.D. | 328,750 |
| Marc Rubin, M.D. | 254,565 |
| Elissa J. Schwartz, Ph.D. | 150,000 |
| Harold H. Shlevin, Ph.D. | 543,000 |
| Richard Uihlein | 216,362 |
| Richard A. Zordani | 150,000 |
| TOTAL | 2,854,516 |

For a more detailed description of the assumptions used for purposes of determining grant date fair value, see Note 9 to the Consolidated Financial Statements and "Management's Discussion and Analysis of Financial Condition and Results of Operations — Critical Accounting Policies and Estimates — Stock-Based Compensation" included herein the Form 10-K for the 2022 fiscal year.

We also reimburse our directors for reasonable travel and other related expenses.

Pursuant to the Company's cash compensation program for directors, non-employee directors of the Company will receive an annual cash retainer of $35,000. Each Nominating and Corporate Governance Committee member will receive an additional cash retainer of $3,500; each Compensation Committee member will receive an additional cash retainer of $5,000; and each Audit Committee member will receive an additional cash retainer of $7,500. In addition to the annual fee and committee membership retainers, the Nominating and Corporate Governance Committee Chairman will receive an annual cash retainer of $3,500; the Compensation Committee Chairman will receive an annual cash retainer of $5,000; and the Audit Committee Chairman will receive an annual cash retainer of $7,500.

**Item 12.** ***Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters***

The following table sets forth, as of February 28, 2023, certain information concerning the beneficial ownership of our common stock and Series A Preferred Stock by (i) each person known by us to own beneficially five percent (5%) or more of the outstanding shares of each class, (ii) each of our directors and named executive officers, and (iii) all of our executive officers and directors as a group. The table also sets forth, in its final column, the combined voting power of the voting securities on all matters presented to the stockholders for their approval at the Annual Meeting, except for such separate class votes as are required by law.

The number of shares beneficially owned by each 5% stockholder, director or executive officer is determined under the rules of the Securities and Exchange Commission, or SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under those rules, beneficial ownership includes any shares as to which the individual or entity has sole or shared voting power or investment power and also any shares that the individual or entity has the right to acquire within 60 days after February 28, 2023 through the exercise of any stock option, warrant or other right, or the conversion of any security. Unless otherwise indicated, each person or entity has sole voting and investment power (or shares such power with his or her spouse) with respect to the shares set forth in the following table. The inclusion in the table below of any shares deemed beneficially owned does not constitute an admission of beneficial ownership of those shares.

| Name and Address (1) | Shares of Common Stock Beneficially Owned (2) | Percent of Common Stock (3) | Shares of Series A Preferred Stock Beneficially Owned | Percent of Series A Preferred Stock (4) |
|---|---|---|---|---|
| **5% Stockholders** | | | | |
| James C. Czirr | 13,026,601(5) | 19.9% | 100,000 | 7.9% |
| 10X Fund, L.P. (8) | 11,901,193(6) | 18.3% | — | — |
| David Smith (9) | — | — | 175,000 | 13.9% |
| Early Equities LLC (9) | — | — | 100,000(7) | 7.9% |
| Richard E. Uihlein (11) | 20,684,300(12) | 28.7% | — | — |
| **Directors and Named Executive Officers** | | | | |
| James C. Czirr | 13,026,601(5) | 19.9% | 100,000 | 7.9% |
| Gilbert F. Amelio, Ph.D. | 215,614 | * | — | — |
| Kevin Freeman | 996,625(10) | 1.6% | — | — |
| Joel Lewis | 1,342,623 | 2.2% | — | — |
| Gilbert S. Omenn, M.D., Ph.D. | 340,990 | * | 50,000 | 3.8% |
| Marc Rubin, M.D. | 198,146 | * | — | — |
| Richard E. Uihlein | 20,684,300(12) | 24.4% | — | — |
| Richard A. Zordani | 110,353 | * | — | — |
| Elissa J. Schwartz, Ph.D. | 81,000 | * | — | — |
| Kary Eldred | 993,875(13) | 1.7% | — | — |
| Harold H. Shlevin, Ph.D. | 481,706 | * | — | — |
| Pol F. Boudes | 255,000 | * | — | — |
| Jack W. Callicutt | 397,905 | * | — | — |
| **All executive officers and directors as a group (13 persons)** | 39,124,738(14) | 48.1% | 150,000 | 11.7% |

* Less than 1%.

(1) Except as otherwise indicated, the address for each named person is c/o Galectin Therapeutics Inc., 4960 Peachtree Industrial Blvd., Suite 240, Norcross, GA 30071.

(2) Includes the following number of shares of our common stock issuable upon exercise of outstanding stock options granted to our named executive officers and directors that are exercisable within 60 days after February 28, 2023.

| Directors, Nominees and Named Executive Officers | Options Exercisable Within 60 Days |
|---|---|
| James C. Czirr | 335,125 |
| Gilbert F. Amelio, Ph.D. | 155,000 |
| Marc Rubin, M.D. | 184,565 |
| Gilbert S. Omenn, M.D., Ph.D | 258,750 |
| Kevin Freeman | 259,839 |
| Kary Eldred | 181,875 |
| Joel Lewis | 442,583 |
| Richard E. Uihlein. | 146,362 |
| Harold Shlevin, Ph.D. | 473,000 |
| Richard A. Zordani | 80,000 |
| Elissa J. Schwartz, Ph.D. | 80,000 |
| Pol F. Boudes, M.D. | 255,000 |
| Jack Callicutt | 389,706 |
| All executive officers and directors as a group | 3,241,805 |

(3) For each named person and group included in this table, percentage ownership of our common stock is calculated by dividing the number of shares of our common stock beneficially owned by such person or group by the sum of (i) 59,443,682 shares of our common stock outstanding as of February 28, 2023 and (ii) the number of shares of our common stock that such person has the right to acquire within 60 days after February 28, 2023.

(4) Based on 1,260,000 shares of Series A preferred stock outstanding as of February 28, 2023.

(5) Includes (i) 6,178,940 shares of common shares, and (ii) 5,732,253 common shares issuable upon exercise of warrants as to which Mr. Czirr, in his capacity as a managing member of 10X Capital Management Fund, LLC, a Florida limited liability company and general partner of 10X Fund (referred to herein as 10X Management) has shared voting and investment power, and disclaims beneficial ownership, also includes 773,616 shares of common stock owned directly by Mr. Czirr, 335,125 shares issuable upon the exercise of vested stock options owned by Mr. Czirr, and 16,667 shares of our common stock issuable upon conversion of Series A preferred stock owned by Mr. Czirr.

(6) Includes (i) 6,178,940 shares of common shares, and (ii) 5,732,253 common shares issuable upon exercise of warrants.

(7) Mr. Smith is the manager of Early Equities LLC, a Connecticut limited liability company, and may be deemed to have voting and investment control over, but disclaims beneficial ownership of, the shares of Series A preferred stock.

(8) Contact: c/o 10X Capital Management, LLC at Investment Law Group attn: Bob Mottern 545 Dutch Valley Road NE, Suite A, Atlanta, GA 30324.

(9) Contact: c/o David Smith 34 Shorehaven Road E., Norwalk, CT 06855.

(10) Includes 546,885 shares of the Company's common stock managed by Cross Consulting and Services, LLC, a Texas limited liability company, d/b/a Freeman Global Investment Counsel. Mr. Freeman, in his capacity as CEO of Freeman Global Investment Counsel, has voting and investment control over, but disclaims beneficial ownership of, these shares.

(11) Contact: c/o Uline Corporation, 12575 Uline Drive, Pleasant Prairie, WI 53158

(12) Includes (i) 8,027,001 shares of common stock, (ii) 3,136,384 common shares issuable upon the exercise of common stock purchase warrants, (iii) 146,362 common shares issuable upon the exercise of common stock options, (iv) 83,334 common shares issuable upon conversion of Series C preferred non-voting stock, (iv) 5,915,409 common shares issuable upon conversion of convertible notes payable and (v) 3,375,810 common shares issuable upon conversion of convertible line of credit..

(13) Includes 47,215 shares of common stock, 16,869 common stock purchase warrants, and 181,875 common stock options personally owned by Mr. Eldred and 431,527 shares of common stock and 311,964 common stock purchase warrants owned by two private foundations over which Mr. Eldred shares management control, and 4,425 shares of Common Stock held in a trust for a minor child; however, Mr. Eldred disclaims beneficial ownership of the shares and warrants owned by such private foundations and trust.

(14) Includes 5,732,253 common shares issuable upon exercise of warrants and common shares acquired upon exercise of warrants or issued as stock dividends on the Series B preferred stock net of shares sold or distributed to 10X Fund limited partners, as to which Mr. Czirr has voting and investment control but are counted one time for purposes of this total. For additional information about the beneficial ownership of our capital stock by Mr. Czirr, see note 5.

**EQUITY COMPENSATION PLAN INFORMATION**

The following table provides information as of December 31, 2022, about the securities issued, or authorized for future issuance, under our equity compensation plans, consisting of our 2001 Stock Incentive Plan, our 2003 Non-Employee Director Stock Incentive Plan, our 2009 Incentive Compensation Plan and our 2019 Omnibus Equity Incentive Plan at December 31, 2022.

| Plan Category | Number of Securities to be issued upon exercise of outstanding options | Weighted-average exercise price of outstanding options | Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) |
|---|---|---|---|
| Equity compensation plans approved by security holders | 5,745,561 | $ 2.90 | 1,966,279 |

**Item 13.** ***Certain Relationships, Related Transactions and Director Independence***

**Certain Relationships and Related Transactions**

Except as set forth below, since the beginning of fiscal year 2022, we did not participate in any transactions in which any of the Company's executive officers, any beneficial owner of more than 5% of our common stock, nor any of their immediate family members, had a direct or indirect material interest.

Our Audit Committee Charter requires that members of the Audit Committee, all of whom are independent directors, conduct an appropriate review of, and be responsible for the oversight of, all related party transactions on an ongoing basis. Except as set forth below, there were no related party transactions during the fiscal year ended December 31, 2022.

The Company entered into an unsecured convertible line of credit totaling $60 million convertible notes payable with Richard E. Uihlein, a director and shareholder, pursuant to an agreement in July 2022. Additional details of the convertible line of credit are included in Footnote 10 to the financial statements in this Form 10-K.

**Compensation Committee Interlocks and Insider Participation**

None of our executive officers or directors serves as a member of the board of directors or compensation committee of any entity that has one or more of its executive officers serving as a member of our Board of Directors or Compensation Committee.

**Board Determination of Director Independence**

Our board of directors has reviewed the materiality of any relationship that each of our directors has with the Company, either directly or indirectly. Based upon this review, our board has determined that all of our directors other than Mr. Lewis and Dr. Shlevin are "independent directors" as defined by The NASDAQ Stock Market. Our board of directors also determined that Drs. Amelio, Rubin, and Mr. Freeman, who comprise our nominating and governance committee, all satisfy the independence standards for such committees established by the SEC and the NASDAQ Marketplace Rules, as applicable. With respect to our audit committee, our board of directors has determined that Messrs. Zordani, Freeman and Eldred satisfy the independence standards for such committee established by Rule 10A-3 under the Exchange Act, the SEC and the NASDAQ Marketplace Rules, as applicable. Furthermore, the Nominating and Corporate Governance Committee, with concurrence by the Board, has determined that Mr. Zordani is an "audit committee financial expert" within the meaning of SEC rules. With respect to our compensation committee, our board of directors has determined that Drs. Omenn, Amelio and Mr. Freeman satisfy the independence standards for such committee established by Rule 10C-1 under the Exchange Act, the SEC and the NASDAQ Marketplace Rules, as applicable.

In making such determinations, the board of directors considered the relationships that each such non-employee director or director nominee has with our company and all other facts and circumstances the board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director. In considering the independence of our directors, our board of directors considered the association of each such non-employee director has with us and all other facts and circumstances our board of directors deemed relevant in determining independence.

**Item 14.** ***Principal Accountant Fees and Services***

The Board of Directors has appointed Cherry Bekaert LLP as our independent auditors for the fiscal year ending December 31, 2022.

**FEES PAID TO CHERRY BEKAERT LLP**

| | Fiscal Year 2022 | Fiscal Year 2021 |
|---|---|---|
| Audit Fees (1) | $ 155,000 | $ 143,000 |
| Audit-Related Fees (2) | 15,000 | 8,500 |
| Tax Fees | 27,875 | 33,275 |
| All Other Fees | — | — |
| Total Fees | $ 197,875 | $ 184,775 |

(1) *Audit Fees.* These are fees for professional services for the audit of our annual financial statements dated December 31, 2022 and 2021 included in our Annual Reports on Form 10-K for fiscal years then ended, and review of financial statements included in our Quarterly Reports on Form 10-Q for each fiscal quarter during the 2022 and 2021 fiscal years.

(2) *Audit-Related Fees*. These are fees for assurance and related services that are reasonably related to the performance of the audit or review of our financial statements, including financial disclosures made in our equity finance documentation and registration statements filed with the SEC that incorporate financial statements and the auditors' report thereon and reviewed with our Audit Committee on financial accounting/reporting standards.

The Audit Committee has considered whether the provision of non-core audit services to Galectin Therapeutics by Cherry Bekaert LLP is compatible with maintaining independence.

*Pre-Approval Policy and Procedures*

The Audit Committee of our Board of Directors has adopted policies and procedures which set forth the manner in which the Committee will review and approve all services to be provided by the independent auditor before the auditor is retained to provide such services. The policy requires Audit Committee pre-approval of the terms and fees of the annual audit services engagement, as well as any changes in terms and fees resulting from changes in audit scope or other items. The Audit Committee also pre-approves, on an annual basis, other audit services, and audit-related and tax services set forth in the policy, subject to estimated fee levels, on a project basis and aggregate annual basis, which have been pre-approved by the Committee.

All other services performed by the auditor that are not prohibited non-audit services under SEC or other regulatory authority rules must be separately pre-approved by the Audit Committee. Amounts in excess of pre-approved limits for audit services, audit-related services and tax services require separate pre-approval of the Audit Committee.

Our Chief Financial Officer reports quarterly to the Audit Committee on the status of pre-approved services, including projected fees. All of the services reflected in the above table were approved by the Audit Committee.

**PART IV**

**Item 15.** ***Exhibits and Financial Statement Schedules***

(a) 1. Consolidated Financial Statement Schedules

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

2. Consolidated Financial Statement Schedules

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

3. Exhibits

| Exhibit Number | Description of Document |
|---|---|
| 3.1 | Amended and Restated Articles of Incorporation of Galectin Therapeutics Inc., as amended (Incorporated by reference to the Company's Current Report on Form 8-K filed with the Commission on May 30, 2012.) |
| 3.2 | Amended and Restated Bylaws of Galectin Therapeutics Inc., as amended (Incorporated by reference to the Company's Current Report on Form 8-K filed with the Commission on September 27, 2016.) |
| 3.3 | Certificate of Designation of Preferences, Rights and Limitations of Series A 12% Convertible Preferred Stock of Pro Pharmaceuticals, Inc., as filed with the Secretary of State of the State of Nevada on October 5, 2007. (Incorporated by reference to the Company's Current Report on Form 8-K filed with the Commission on October 9, 2007.) |
| 3.4 | First Amendment to Certificate of Designation of Preferences, Rights and Limitations of Series A 12% Convertible Preferred Stock of Galectin Therapeutics, Inc., as filed with the Secretary of State of the State of Nevada on May 15, 2017. (Incorporated by reference to the Company's Current Report on Form 8-K filed with the Commission on May 19, 2017.) |
| 3.5 | Certificate of Designation of Preferences, Rights and Limitation of Series C Super Dividend Convertible Preferred Stock of Pro-Pharmaceuticals, Inc., as filed with the Secretary of State of Nevada on December 30, 2010. (Incorporated by reference to the Company's Current Report on Form 8-K as filed with the Commission on January 6, 2011.) |
| 3.6 | Certificate of Change as filed with the Nevada Secretary of State on March 1, 2012. (Incorporated by reference to the Company's Current Report on Form 8-K as filed with the Commission on March 23, 2012.) |
| 3.7* | Amendment to the Articles of Incorporation of Galectin Therapeutics Inc. |
| 4.1 | Form of Common Stock Purchase Warrant (Incorporated by reference to the Company's Current Report on Form 8-K as filed with the Commission on December 29, 2016.) |
| 4.2 | Form of Common Stock Purchase Warrant issued to Richard E. Uihlein (Incorporated by reference to the Company's Current Report on Form 8-K as filed with the Commission on December 19, 2017.) |
| 4.3 | First Amendment to Common Stock Purchase Warrant, dated December 20, 2018, by and between Richard E. Uihlein and the Company (Incorporated by reference to the Company's Current Report on Form 8-K as filed with the Commission on January 3, 2019.) |
| 4.4 | Second Amendment to Common Stock Purchase Warrant, dated January 11, 2019, by and between Richard E. Uihlein and the Company (Incorporated by reference to the Company's Current Report on Form 8-K as filed with the Commission on January 15, 2019.) |
| 4.5 | Form of Amended and Restated Class B Common Stock Purchase Warrant (Incorporated by reference to the Company's Current Report on Form 8-K as filed with the Commission on January 15, 2019.) |

| Exhibit Number | Description of Document |
|---|---|
| 4.6 | Form of Amended and Restated 10X Fund Class B Common Stock Purchase Warrant (Incorporated by reference to the Company's Current Report on Form 8-K as filed with the Commission on January 15, 2019.) |
| 4.7 | Form of Common Stock Purchase Warrant (Incorporated by reference to the Company's Registration Statement on Form S-3 as filed with the Commission on March 6, 2019.) |
| 4.8 | Form of Warrant Agency Agreement (Incorporated by reference to the Company's Registration Statement on Form S-3 as filed with the Commission on March 6, 2019.) |
| 4.9 | Form of Common Stock Purchase Warrant (Incorporated by reference to the Company's Registration Statement on Form S-3 as filed with the Commission on March 6, 2019.) |
| 4.10 | Form of Common Stock Purchase Warrant (Incorporated by reference to exhibit 4.1 the Company's Current Report on Form 8-K as filed with the Commission on July 26, 2022.) |
| 4.11 | Description of Registrant's securities (Incorporated by reference to exhibit 4.20 the Company's Annual Report on Form 10-K for the year ended December 31, 2020, as filed on March 31, 2021.) |
| 10.1† | Galectin Therapeutics 2009 Incentive Compensation Plan (as amended) (Incorporated by reference to the Company's Annual Report on Form 10-K as filed with the Commission on March 6, 2019.) |
| 10.2† | Form of Restricted Stock Grant Agreement (under the 2009 Incentive Compensation Plan). (Incorporated by reference to the Company's Annual Report on Form 10-K as filed with the Commission on March 30, 2009.) |
| 10.3† | Form of Non-Qualified Stock Option Grant Agreement (under the 2009 Incentive Compensation Plan). (Incorporated by reference to the Company's Annual Report on Form 10-K as filed with the Commission on March 30, 2009.) |
| 10.4† | Form of Incentive Stock Option Grant Agreement (under the 2009 Incentive Compensation Plan). (Incorporated by reference to the Company's Annual Report on Form 10-K as filed with the Commission on March 30, 2009.) |
| 10.5† | Galectin Therapeutics 2019 Omnibus Equity Incentive Plan (Incorporated by reference to Appendix A to the Company's definitive proxy statement filed with the Commission on October 17, 2019.) |

| Exhibit Number | Description of Document |
|---|---|
| 10.6† | Employment Agreement dated June 20, 2013 between Jack W. Callicutt and Galectin Therapeutics Inc. (Incorporated by reference to the Company's Quarterly Report on Form 10-Q as filed with the Commission on August 14, 2013.) |
| 10.7† | Amendment to Employment Agreement dated August 11, 2017 between Jack W. Callicutt and Galectin Therapeutics Inc. (Incorporated by reference to the Company's Quarterly Report on Form 10-Q as filed with the Commission on August 14, 2017.) |
| 10.8 | Project Addendum (with Master Services Agreement), dated March 6, 2015, by and between Galectin Therapeutics Inc. and PPD Development, L.P. (Incorporated by reference to the Company's Current Report on Form 8-K as filed with the Commission on March 12, 2015.)*** |
| 10.9 | Project Addendum Modification, dated March 11, 2016, by and between Galectin Therapeutics, Inc. and PPD Development, L.P. (Incorporated by reference to the Company's Annual Report on Form 10-K as filed with the Commission on March 15, 2016.)*** |
| 10.10† | Employment Agreement, dated February 19, 2020, by and between Galectin Therapeutics Inc. and Pol F. Boudes, M.D. (Incorporated by reference to the Company's Current Report on Form 8-K as filed with the Commission on February 20, 2020.) |
| 10.11*** | Master Services Agreement, effective as of March 12, 2020, by and between Galectin Therapeutics, Inc. and Covance Inc. (Incorporated by reference to the Company's Current Report on Form 8-K as filed with the Commission on March 17, 2020.) |
| 10.12*** | Work Order, dated as of March 12, 2020, by and between Galectin Therapeutics, Inc. and Covance Clinical Research Unit Inc. (Incorporated by reference to the Company's Current Report on Form 8-K as filed with the Commission on March 17, 2020.) |
| 10.13*** | Work Order, dated as of June 22, 2020, by and between Galectin Therapeutics Inc. and Covance Inc. (Incorporated by reference to the Company's Current Report on Form 8-K as filed with the Commission on June 26, 2020.) |
| 10.14 | Convertible Promissory Note, dated April 16, 2021 (Incorporated by reference to the Company's Current Report on Form 8-K as filed with the Commission on April 19, 2021.) |
| 10.15 | Loan Agreement, dated September 17, 2021 (Incorporated by reference to the Company's Current Report on Form 8-K as filed with the Commission on September 21, 2021.) |
| 10.16 | Unsecured Convertible Promissory Note, dated September 17, 2021 (Incorporated by reference to the Company's Current Report on Form 8-K as filed with the Commission on September 21, 2021.) |
| 10.17 | Unsecured Convertible Promissory Note, dated December 20, 2021 (Incorporated by reference to the Company's Current Report on Form 8-K as filed with the Commission on December 21, 2021.) |
| 10.18 | Line of Credit Letter Agreement, dated as of July 25, 2022, by and between Richard E. Uihlein and the Company. (Incorporated by reference to exhibit 10.1 the Company's Current Report on Form 8-K as filed with the Commission on July 26, 2022.) |
| 10.19 | Form of Convertible Promissory Note issued to Richard E. Uihlein. (Incorporated by reference to exhibit 10.2 the Company's Current Report on Form 8-K as filed with the Commission on July 26, 2022.) |
| 10.20 | Employment Agreement Amendment of Joel Lewis. (Incorporated by reference to exhibit 10.3 the Company's Current Report on Form 8-K as filed with the Commission on July 26, 2022.) |
| 10.21 | 2023 Deferred Stock Unit Agreement. (Incorporated by reference to exhibit 10.4 the Company's Current Report on Form 8-K as filed with the Commission on July 26, 2022.) |
| 10.22 | 2020 Deferred Stock Unit Amendment. (Incorporated by reference to exhibit 10.5 the Company's Current Report on Form 8-K as filed with the Commission on July 26, 2022.) |

| Exhibit Number | Description of Document |
|---|---|
| 21.1* | Subsidiaries of Galectin Therapeutics Inc. |
| 23.1* | Consent of Cherry Bekaert LLP, an independent registered public accounting firm. |
| 31.1* | Certification Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934. |
| 31.2* | Certification Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934. |
| 32.1# | Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 32.2# | Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 101.INS | Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document. |
| 101.SCH | Inline XBRL Taxonomy Extension Schema Document |
| 101.CAL | Inline XBRL Taxonomy Extension Calculation Linkbase Document |
| 101.DEF | Inline XBRL Taxonomy Extension Definition Linkbase Document |
| 101.LAB | Inline XBRL Taxonomy Extension Label Linkbase Document |
| 101.PRE | Inline XBRL Taxonomy Extension Presentation Linkbase Document |
| 104 | The cover page for the Company's Annual Report on Form 10-K for the year ended December 31, 2021, has been formatted in Inline XBRL and contained in Exhibit 101 |

* Filed herewith.
\# Furnished herewith and not "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.
*** Galectin Therapeutics, Inc. has requested confidential treatment with respect to portions of this exhibit. Those portions have been omitted from the exhibit and filed separately with the U.S. Securities and Exchange Commission.
† Executive Compensation Arrangement pursuant to 601(b)(10)(iii)(A) of Regulation S-K

**Item 16. Form 10–K Summary**

None

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on March 30, 2023.

GALECTIN THERAPEUTICS INC.

By: /S/ JOEL LEWIS
Name: JOEL LEWIS.
Title: Chief Executive Officer and President

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

| Signature | Title | Date |
|---|---|---|
| /S/ JOEL LEWIS<br>Joel Lewis | Chief Executive Officer, President and Director<br>(principal executive officer) | March 30, 2023 |
| /S/ JACK W. CALLICUTT<br>Jack W. Callicutt | Chief Financial Officer<br>(principal financial and accounting officer) | March 30, 2023 |
| /S/ RICHARD E. UIHLEIN<br>Richard E. Uihlein | Director and Chairman of the Board | March 30, 2023 |
| /S/ GILBERT F. AMELIO, Ph.D.<br>Gilbert F. Amelio, Ph.D. | Director | March 30, 2023 |
| /S/ JAMES C. CZIRR<br>James C. Czirr | Director | March 30, 2023 |
| /S/ KARY ELDRED<br>Kary Eldred | Director | March 30, 2023 |
| /S/ KEVIN D. FREEMAN<br>Kevin D. Freeman | Director | March 30, 2023 |
| /S/ GILBERT S. OMENN, M.D., Ph.D.<br>Gilbert S. Omenn, M.D., Ph.D. | Director | March 30, 2023 |
| /S/ MARC RUBIN, M.D.<br>Marc Rubin, M.D. | Director | March 30, 2023 |
| /S/ ELISSA J. SCHWARTZ, Ph.D.<br>Elissa J. Schwartz, Ph.D. | Director | March 30, 2023 |
| /S/ HAROLD H. SHLEVIN, Ph.D.<br>Harold H. Shlevin, Ph.D. | Director | March 30, 2023 |
| /S/ RICHARD A. ZORDANI<br>Richard A. Zordani | Director | March 30, 2023 |

**Galectin Therapeutics Inc. and subsidiaries**
**Table of Contents**

**Report of Independent Registered Public Accounting Firm**

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

**Opinion on the Consolidated Financial Statements**

We have audited the accompanying consolidated balance sheets of Galectin Therapeutics Inc. and Subsidiaries (the "Company") as of December 31, 2022 and 2021, and the related consolidated statements of operations, changes in redeemable convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the years then ended, and the related notes (collectively referred to as the "consolidated financial statements").

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the years then ended, in conformity with accounting principles generally accepted in the United States of America.

**Basis for Opinion**

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinions.

**Critical Audit Matters**

The critical audit matters communicated below are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

***Going Concern***

*Description of Matter*

As described further in Note 1 to the consolidated financial statements, the Company has incurred losses each year from inception through December 31, 2022, and expects to incur additional losses in the foreseeable future. Currently, management's forecasts and related assumptions illustrate the Company's ability to sufficiently fund operations and satisfy the Company's obligations as they come due for at least one year from the financial statement issuance date.

Management made judgments to conclude that it is probable that the Company's plans will be effectively implemented and will provide the necessary cash flows to fund the Company's obligations as they become due. The judgments with the highest degree of impact and subjectivity in reaching this conclusion included management's estimates of research and development clinical trial costs and other general and administrative costs. As a result, a high degree of auditor judgment and increased audit effort was required in performing audit procedures to evaluate the reasonableness of management's estimates.

*How We Addressed the Matter in Our Audit*

Our audit procedures included the following:

- Obtained an understanding of the internal controls and processes in place over the Company's preparation of forecasted information and considerations of the Company's obligations.
- We tested the reasonableness of the forecasted research and development expenses, operating expenses, and uses and sources of cash used in management's assessment of whether the Company has sufficient liquidity to fund operations for at least one year from the financial statement issuance date. This testing included inquiries with management, comparison of prior period forecasts to actual results, consideration of positive and negative evidence impacting management's forecasts, the Company's financing arrangements in place as of the report date, consideration of the Company's relationships with its financing partners, performance of a sensitivity analysis of accelerated uses of cash, and creation of an independent estimate of expected future cash flows.

***Valuation of Derivative Liabilities***

*Description of Matter*

As discussed in Note 5 to the consolidated financial statements, during the year ended December 31, 2021, the Company and a related party entered into three debt financing arrangements for a total of $30 million loaned to the Company. These arrangements include various conversion and other features, including a contingent interest component that has been bifurcated and recognized as a derivative liability. At December 31, 2022, the Company's derivative liabilities related to the related party convertible notes payable totaled $573 thousand. As more fully described in Note 6 to the consolidated financial statements, the Company utilizes a Monte Carlo Geometric Brownian Stock Path Model in measuring the fair value of the derivative liabilities, which requires the use of estimates and assumptions. Auditing management's valuations of the derivative liabilities was challenging due to the complexity of the valuation model and the inputs that are highly sensitive to changes such as the common stock market price, volatility, risk free rates, and yields.

*How We Addressed the Matter in Our Audit*

Our audit procedures included, among others, the following:

- Obtained an understanding of the internal controls and processes in place over the Company's process used in determining the valuation of the derivative liabilities.
- Evaluated the Company's use of the models used and tested the significant assumptions used in the models, as described above.
- We evaluated the completeness and accuracy of underlying data used in supporting the assumptions and estimates.
- In addition, we involved valuation specialists to assist in assessing the significant assumptions and methodologies used by the Company.

***Accrued and Prepaid Clinical Trial Expenses***

*Description of Matter*

The Company's accrued expenses total approximately $9.1 million at December 31, 2022, which included the estimated obligation for clinical trial expenses incurred as of December 31, 2022, but not paid as of that date in the amount of approximately $7.3 million. In addition, the Company's total prepaid expenses and other current assets totaled $2.0 million, which included amounts that were paid in advance of services incurred pursuant to clinical trials in the amount of approximately $1.1 million.

As discussed in Note 2 to the consolidated financial statements, when the third-party contract research organization and other vendor billing terms do not coincide with the Company's period-end, the Company is required to make estimates of its obligations to those vendors, including personnel costs, allocated facility costs, lab supplies, outside services, contract laboratory costs related to manufacturing drug product, clinical trials and preclinical studies costs incurred in a given accounting period and record accruals at the end of the period. The Company bases its estimates on its knowledge of the research and development programs, services performed for the period, past history for related activities, and the expected duration of the vendor service contract, where applicable. Payments for these activities are based on the terms of the individual arrangements and may result in payment terms that differ from the pattern of costs incurred. There may be instances in which payments made to vendors will exceed the level of services provided and result in a prepayment of the clinical expense.

Auditing the Company's accrued and prepaid clinical trial expenses is especially challenging due to the large volume of information received from multiple vendors that perform services on the Company's behalf. While the Company's estimates of accrued and prepaid clinical trial expenses are primarily based on information received related to each study from its vendors, the Company may need to make an estimate for additional costs incurred. Additionally, due to the long duration of clinical trials and the timing of invoicing received from vendors, the actual amounts incurred are not typically known at the time the financial statements are issued.

*How We Addressed the Matter in Our Audit*

Our audit procedures included, among others, the following:

- Obtained an understanding of the internal controls and processes in place over the Company's process used in determining the completeness and existence of accrued and prepaid clinical trial expenses.
- Tested the accuracy and completeness of the underlying data used in determining the accrued and prepaid clinical trial expenses and evaluating the assumptions and estimates used by management to adjust the actual information received. We corroborated the schedules of the underlying data used in the accrual calculation with the Company's third-party contract research organization who oversees the clinical trials. To evaluate the completeness of the accrual, we also tested subsequent invoices received to assess the impact to the accrual.

/s/ CHERRY BEKAERT LLP

We have served as the Company's auditor since 2015.

Atlanta, Georgia
March 30, 2023

**GALECTIN THERAPEUTICS INC. AND SUBSIDIARIES**
**CONSOLIDATED BALANCE SHEETS**

| | December 31, | |
|---|---|---|
| | 2022 | 2021 |
| | (in thousands, except per share amounts) | |
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 18,592 | $ 39,648 |
| Prepaid expenses and other current assets | 1,960 | 2,172 |
| Total current assets | 20,552 | 41,820 |
| Property and equipment, net | — | — |
| Other | 733 | 7 |
| Total assets | $ 21,285 | $ 41,827 |
| **LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)** | | |
| Current liabilities: | | |
| Accounts payable | $ 3,890 | $ 1,805 |
| Accrued expenses | 9,058 | 7,163 |
| Accrued dividends payable | 64 | 65 |
| Total current liabilities | 13,012 | 9,033 |
| Convertible notes payable and accrued interest, net of debt discounts – related party (Note 5) | 29,964 | 29,048 |
| Derivative liabilities (Note 6) | 573 | 1,130 |
| Borrowing and accrued interest under convertible line of credit, net of debt discount – related party (Note 10) | 9,864 | — |
| Other liabilities | 66 | — |
| Total liabilities | 53,479 | 39,211 |
| Commitments and contingencies (Note 12) | | |
| Series C 6% super dividend redeemable convertible preferred stock; 1,000 shares authorized, 176 issued and outstanding at December 31, 2022 and 2021, redemption value: $8,335,000, liquidation value: $1,786,000 at December 31, 2022 | 1,723 | 1,723 |
| Stockholders' equity (deficit): | | |
| Undesignated stock, $0.01 par value; 20,000,000 shares authorized at December 31, 2022 and 2021, 20,000,000 shares designated at December 31, 2022 and 2021, respectively | — | — |
| Series A 12% convertible preferred stock; 1,742,500 shares authorized, 1,260,000 and 1,302,500 issued and outstanding at December 31, 2022 and 2021, respectively, liquidation value $1,260,000 at December 31, 2022 | 510 | 527 |
| Common stock, $0.001 par value; 150,000,000 shares authorized at December 31, 2022 and 2021, 59,426,005 and 59,341,305 issued and outstanding at December 31, 2022 and 2021, respectively | 59 | 59 |
| Additional paid-in capital | 275,081 | 271,001 |
| Accumulated deficit | (309,567) | (270,694) |
| Total stockholders' equity (deficit) | (33,917) | 893 |
| Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit) | $ 21,285 | $ 41,827 |

See notes to consolidated financial statements.

**GALECTIN THERAPEUTICS INC. AND SUBSIDIARIES**
**CONSOLIDATED STATEMENTS OF OPERATIONS**

| | Year Ended December 31, | |
|---|---|---|
| | **2022** | **2021** |
| | **(in thousands, except per share amounts)** | |
| Operating expenses: | | |
| Research and development | $ 31,737 | $ 23,818 |
| General and administrative | 6,615 | 6,361 |
| Total operating expenses | 38,352 | 30,179 |
| Total operating loss | (38,352) | (30,179) |
| Other income (expense): | | |
| Interest income | 52 | 3 |
| Interest expense | (1,033) | (489) |
| Change in fair value of derivatives | 557 | 138 |
| Total other income (expense) | (424) | (348) |
| Net loss | $ (38,776) | $ (30,527) |
| Preferred stock dividends | (97) | (171) |
| Net loss applicable to common stockholders | $ (38,873) | $ (30,698) |
| Basic and diluted net loss per share | $ (0.65) | $ (0.52) |
| Weighted average common and potential common shares outstanding basic and diluted | 59,391 | 58,527 |

See notes to consolidated financial statements.

**GALECTIN THERAPEUTICS INC. AND SUBSIDIARIES**
**CONSOLIDATED STATEMENTS OF CHANGES IN REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)**
**For the Years Ended December 31, 2022 and 2021**
**(amounts in thousands except share data)**

| | Series C Super Dividend Redeemable Convertible Preferred Stock | |
|---|---|---|
| | Number of Shares | Amount |
| **Balance at January 1, 2021** | **176** | **$ 1,723** |
| **Balance at December 31, 2021** | **176** | **$ 1,723** |
| **Balance at December 31, 2022** | **176** | **$ 1,723** |

See notes to consolidated financial statements.

**GALECTIN THERAPEUTICS INC. AND SUBSIDIARIES**
**CONSOLIDATED STATEMENTS OF CHANGES IN REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT) — (Continued)**
**For the Years Ended December 31, 2022 and 2021**
**(amounts in thousands except share data)**

| | Series A 12% Convertible Preferred Stock | | Common Stock | | | | |
|---|---|---|---|---|---|---|---|
| | Number of Shares | Amount | Number of Shares | Amount | Additional Paid-In Capital | Retained Deficit | Total Stockholders' Equity (Deficit) |
| **Balance at January 1, 2021** | **1,302,500** | **$ 527** | **57,077,055** | **$ 56** | **$ 261,883** | **$ (239,996)** | **$ 22,470** |
| Series A 12% convertible preferred stock dividend | | | 26,050 | | 79 | (79) | |
| Series C super dividend redeemable convertible preferred stock dividend | | | 31,112 | | 92 | (92) | |
| Issuance of common stock | | | 845,214 | 1 | 3,863 | | 3,864 |
| Issuance of common stock for warrant exercises | | | 1,180,240 | 2 | 2,948 | | 2,950 |
| Issuance of common stock for stock option exercises | | | 148,941 | | | | |
| Stock-based compensation expense | | | 32,693 | | 2,136 | | 2,136 |
| Net loss | | | | | | (30,527) | (30,527) |
| **Balance at December 31, 2021** | **1,302,500** | **$ 527** | **59,341,305** | **$ 59** | **$ 271,001** | **$ (270,694)** | **$ 893** |
| Series A 12% convertible preferred stock dividend | | | 25,625 | | 40 | (40) | |
| Series C super dividend redeemable convertible preferred stock dividend | | | 35,200 | | 57 | (57) | |
| Conversion of Series A Convertible Preferred to common | (42,500) | (17) | 7,287 | | 17 | | |
| Issuance of common stock purchase warrants in connection with related party line of credit | | | | | 899 | | 899 |
| Stock-based compensation expense | | | 16,588 | | 3,067 | | 3,067 |
| Net loss | | | | | | (38,776) | (38,776) |
| **Balance at December 31, 2022** | **1,260,000** | **$ 510** | **59,426,005** | **$ 59** | **$ 275,081** | **$ (309,567)** | **$ (33,917)** |

See notes to consolidated financial statements.

**GALECTIN THERAPEUTICS INC. AND SUBSIDIARIES**
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

| | Year Ended December 31, | |
|---|---|---|
| | 2022 | 2021 |
| | (in thousands) | |
| CASH FLOWS FROM OPERATING ACTIVITIES: | | |
| Net loss | $ (38,776) | $ (30,527) |
| Adjustments to reconcile net loss to net cash from operating activities: | | |
| Amortization of right to use asset | 32 | 41 |
| Stock-based compensation expense | 2,867 | 2,076 |
| Non-cash interest expense | 410 | 283 |
| Change in fair value of derivatives | (557) | (138) |
| Changes in operating assets and liabilities: | | |
| Prepaid expenses and other assets | 101 | 65 |
| Accrued interest on convertible notes payable and convertible line of credit – related party | 623 | 206 |
| Accounts payable, accrued expenses and other liabilities | 4,244 | 3,686 |
| Net cash from operating activities | (31,056) | (24,308) |
| CASH FLOWS FROM INVESTING ACTIVITIES: | | |
| Net cash from investing activities | — | — |
| CASH FLOWS FROM FINANCING ACTIVITIES: | | |
| Net proceeds from convertible line of credit – related party | 10,000 | — |
| Net proceeds from convertible notes payable – related party | — | 30,000 |
| Net proceeds from issuance of common stock and warrants | — | 6,814 |
| Net cash from financing activities | 10,000 | 36,814 |
| NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS | (21,056) | 12,506 |
| CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD | 39,648 | 27,142 |
| CASH AND CASH EQUIVALENTS, END OF PERIOD | $ 18,592 | $ 39,648 |
| NONCASH FINANCING ACTIVITIES: | | |
| Payment of preferred stock dividends in common stock | $ 97 | $ 171 |
| Fair value of derivatives regarding related party convertible notes payable | — | 1,268 |
| Reclassification of accrued bonus to additional paid in capital | 200 | 60 |
| Noncash right to use lease asset | 111 | — |
| Common stock purchase warrants issued in connection with related party line of credit | 899 | — |

See notes to consolidated financial statements.

## 1. Nature of Business, Basis of Presentation and Liquidity

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

The Company was founded in July 2000, was incorporated in the State of Nevada in January 2001 under the name "Pro-Pharmaceuticals, Inc.," and changed its name to "Galectin Therapeutics Inc." on May 26, 2011.

The Company has operated at a loss since its inception and has had no revenues. The Company anticipates that losses will continue for the foreseeable future. At December 31, 2022, the company had $18,592,000 of unrestricted cash and cash equivalents available to fund future operations. In July 2022, the Company entered into a $60 million unsecured line of credit financing with its chairman, Richard E. Uihlein (See Note 10). The Company believes there is sufficient cash, including availability of the line of credit, to fund currently planned operations at least through December 31, 2024. To meet its future capital needs, the Company intends to raise additional capital through debt or equity financings, collaborations, partnerships or other strategic transactions. However, there can be no assurance that the Company will be able to complete any such transactions on acceptable terms or otherwise. The inability of the Company to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on the Company's business, results of operations and financial condition. The Company has the ability to delay certain research activities and related clinical expenses if necessary due to liquidity concerns until a date when those concerns are relieved.

The Company is subject to a number of risks similar to those of clinical stage companies, including dependence on key individuals, uncertainty of product development and generation of revenues, dependence on outside sources of capital, risks associated with clinical trials of products, dependence on third-party collaborators for research operations, need for regulatory approval of products, risks associated with protection of intellectual property, and competition with larger, better-capitalized companies. Successful completion of the Company's development program and, ultimately, the attainment of profitable operations is dependent upon future events, including obtaining adequate financing to fulfill its development activities and achieving a level of revenues adequate to support the Company's cost structure. There are no assurances that the Company will be able to obtain additional financing on favorable terms, or at all, or successfully market its products.

## 2. Summary of Significant Accounting Policies

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States ("GAAP").

*Basis of Consolidation.* The consolidated financial statements include the accounts of the Company and Galectin Therapeutics Security Corp., its wholly-owned subsidiary, which was incorporated in Delaware on December 23, 2003 and Galectin Sciences LLC (see Note 13). All intercompany transactions have been eliminated.

*Use of Estimates.* The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and judgments that may affect the reported amounts of assets, liabilities, equity, revenue, expenses and related disclosure of contingent assets and liabilities. Management's estimates and judgments include assumptions used in stock option valuations, useful lives of property and equipment and intangible assets, accrued liabilities, derivative valuations, deferred income taxes and various other assumptions that are believed to be reasonable under the circumstances. Actual results may differ from those estimates under different assumptions or conditions.

*Fair Value Measurements*. The Company has certain financial assets and liabilities recorded at fair value. Fair values determined by Level 1 inputs utilize observable data such as quoted prices in active markets. Fair values determined by Level 2 inputs utilize data points other than quoted prices in active markets that are observable either directly or indirectly. Fair values determined by Level 3 inputs utilize unobservable data points in which there is little or no market data, which require the reporting entity to develop its own assumptions. The estimated value of accounts payable and accrued expenses approximates their carrying value due to their short-term nature. See Footnote 6 for Fair Value of Derivatives related to Convertible Notes Payable at December 31, 2022 and 2021, which are level 3 liabilities.

*Cash and Cash Equivalents.* The Company considers all highly-liquid investments with original maturities of 90 days or less at the time of acquisition to be cash equivalents. The Company had no cash equivalents at December 31, 2022 or 2021.

*Prepaid Expenses and Other Current Assets.* Prepaid expenses and other assets consist principally of prepaid insurance, deposits related to the NAVIGATE trial and deferred financing costs (see Note 10).

*Property and Equipment.* Property and equipment, including leasehold improvements, are stated at cost, net of accumulated depreciation and amortization, and are depreciated or amortized using the straight-line method over the estimated useful lives of the related assets of generally three years for computers and office equipment, five years for furniture and fixtures and the shorter of the useful life or life of the lease for leasehold improvements.

*Security Deposit.* At December 31, 2022 and 2021, the Company had a security deposit of $6,000 for leased office space included in Prepaid Expenses and Other Current Assets.

*Long-Lived Assets.* The Company reviews all long-lived assets for impairment whenever events or circumstances indicate the carrying amount of such assets may not be recoverable. Recoverability of assets to be held or used is measured by comparison of the carrying value of the asset to the future undiscounted net cash flows expected to be generated by the asset. If such asset is considered to be impaired, the impairment recognized is measured by the amount by which the carrying value of the asset exceeds the discounted future cash flows expected to be generated by the asset. There were no impairments of long-lived assets at December 31, 2022 or 2021.

*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 professional service fees, such as those arising from the services of attorneys and accountants and accrued payroll expenses. In connection with these service fees, our estimates are most affected by our understanding of the status and timing of services provided relative to the actual services incurred by the service providers. In the event that we do not identify certain costs that have been incurred or we under- or over-estimate the level of services or costs of such services, our reported expenses for a reporting period could be understated or overstated. The date on which certain services commence, the level of services performed on or before a given date, and the cost of services are often subject to our judgment. We make these judgments based upon the facts and circumstances known to us in accordance with accounting principles generally accepted in the U.S.

*Warrants.* The Company has issued common stock warrants in connection with the execution of certain equity and debt financings. The fair value of warrants is determined using the Black-Scholes option-pricing model using assumptions regarding volatility of our common share price, remaining life of the warrant, and risk-free interest rates at each period end. There were no warrant liabilities as of December 31, 2022 or 2021.

*Research and Development Expenses.* Research and development expenses, including personnel costs, allocated facility costs, lab supplies, outside services, contract laboratory costs related to manufacturing drug product, clinical trials and preclinical studies are charged to research and development expense as incurred. The Company accounts for nonrefundable advance payments for goods and services that will be used in future research and development activities as expense when the service has been performed or when the goods have been received. Our current NAVIGATE clinical trial is being supported by third-party contract research organizations, or CROs, and other vendors. We accrue expenses for clinical trial activities performed by CROs based upon the estimated amount of work completed on each trial. For clinical trial expenses and related expenses associated with the conduct of clinical trials, the significant factors used in estimating accruals include the number of patients enrolled, the number of active clinical sites, and the duration for which the patients have been enrolled in the trial. We monitor patient enrollment levels and related activities to the extent possible through internal reviews, review of contractual terms and correspondence with CROs. We base our estimates on the best information available at the time. We monitor patient enrollment levels and related activities to the extent possible through discussions with CRO personnel and based our estimates of clinical trial costs on the best information available at the time. However, additional information may become available to us which will allow us to make a more accurate estimate in future periods. In that event, we may be required to record adjustments to research and development expenses in future periods when the actual level of activity becomes more certain.

*Income Taxes.* The Company accounts for income taxes in accordance with the accounting rules that requires an asset and liability approach to accounting for income taxes based upon the future expected values of the related assets and liabilities. Deferred income tax assets and liabilities are determined based on the differences between the financial reporting and tax bases of assets and liabilities and for tax loss and credit carry forwards and are measured using the expected tax rates estimated to be in effect when such basis differences reverse. Valuation allowances are established, if necessary, to reduce the deferred tax asset to the amount that will, more likely than not, be realized.

*Concentration of Credit Risk.* Financial instruments that subject the Company to credit risk consist of cash and cash equivalents. The Company maintains cash and cash equivalents and certificates of deposit with well-capitalized financial institutions. At times, those amounts may exceed federally insured limits. The Company has not experienced any losses in such accounts and believes it is not exposed to significant credit risk beyond the normal credit risk associated with commercial banking relationships. The Company has no other significant concentrations of credit risk.

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

*Recent Accounting Standards.* In August 2020, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2020-06, Debt — Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging — Contracts in Entity's Own Equity (Subtopic 815-40) ("ASU 2020-06") to simplify accounting for certain financial instruments. ASU 2020-06 eliminates the current models that require separation of beneficial conversion and cash conversion features from convertible instruments and simplifies the derivative scope exception guidance pertaining to equity classification of contracts in an entity's own equity. The new standard also introduces additional disclosures for convertible debt and freestanding instruments that are indexed to and settled in an entity's own equity. ASU 2020-06 amends the diluted earnings per share guidance, including the requirement to use the if-converted method for all convertible instruments. ASU 2020-06 is effective January 1, 2022 and should be applied on a full or modified retrospective basis, with early adoption permitted beginning on January 1, 2021. The Company adopted ASU 2020-06 effective January 1, 2022. The adoption of ASU 2020-06 did not have an impact on the Company's financial statements. See Notes 5 and 10 for disclosures related to convertible borrowings.

**3. Property and Equipment**

Property and equipment consist of the following at December 31:

| | 2022 | 2021 |
|---|---|---|
| | (in thousands) | |
| Leasehold improvements | $ 2 | $ 2 |
| Computer and office equipment | 13 | 13 |
| Furniture and fixtures | 59 | 59 |
| Total | 74 | 74 |
| Less accumulated depreciation and amortization | (74) | (74) |
| Property and equipment — net | $ — | $ — |

Depreciation and amortization expense for the years ended December 31, 2022 and 2021 was $0 and $0, respectively.

**4. Accrued Expenses**

Accrued expenses consist of the following at December 31:

| | 2022 | 2021 |
|---|---|---|
| | (in thousands) | |
| Legal and accounting fees | $ 65 | $ 68 |
| Accrued compensation | 973 | 728 |
| Lease liability | 40 | 8 |
| Accrued research and development costs and other | 7,980 | 6,359 |
| Total | $ 9,058 | $ 7,163 |

**5. Convertible Notes Payable – Related Party**

On April 16, 2021, the Company and Richard E. Uihlein entered into a debt financing arrangement whereby Mr. Uihlein loaned $10,000,000 to Company. In consideration for the loan, the Company issued a convertible promissory note (the "April 2021 Note") in the principal amount of ten million dollars.

The April 2021 Note has a maturity date of April 16, 2025, is prepayable at the option of the Company in whole or in part at any time and is convertible into the Company's common stock at a conversion price equal to $5.00 per share at the option of the noteholder. The April 2021 Note bears interest at the rate of two percent (2%) per annum, compounded annually with an effective interest rate of approximately 3%. For the years ended December 31, 2022 and 2021, approximately $200,000 and $142,000, respectively, of interest expense was accrued and included with the principal in the financial statements.

The April 2021 Note also includes a contingent interest component that requires the Company to pay additional interest at a rate of two and one-half percent (2.5%) per quarter (10% per annum) (the "Additional Interest") beginning on the date of issuance of this Note and ending on the maturity date, provided however, that such payment is only required if and only if the noteholder elects to convert the entire balance of the April 2021 Note into the Company's common stock on or prior to maturity. As the contingent event is not based on creditworthiness, such feature is not clearly and closely related to the host instrument and accordingly must be bifurcated and recognized as a derivative liability and a debt discount on the April 2021 Note at its inception. The fair value of the contingent interest derivative liability was $420,000 at note inception (April 16, 2021). The fair value of the contingent interest derivative liability was $249,000 and $495,000 and December 31, 2022 and 2021, respectively, and is recognized as a derivative liability in the consolidated balance sheet. The change in the fair value of the derivative liability from April 16, 2021 to December 31, 2021 and for the year ended December 31, 2022 of $75,000 and $(246,000), respectively, was charged to other expense/(income) for the years ended December 31, 2022 and 2021. The amortization of the original $420,000 debt discount of $105,000 and $74,000 was recorded as additional interest expense for the years ended December 31, 2022 and 2021, respectively.

On September 17, 2021, the Company and Mr. Uihlein entered into a loan agreement in the aggregate of $20,000,000 (the "Loan Agreement") to be funded in two closings and evidenced by two separate unsecured convertible promissory notes. The first of the two promissory notes was also executed and delivered on September 17, 2021, (the "September 2021 Note") to evidence the first loan in the principal amount of $10,000,000. The second closing under the Loan Agreement for the remaining $10,000,000 occurred on December 20, 2021.

The September 2021 Note has a maturity date of September 17, 2025, is prepayable at the option of the Company in whole or in part at any time and is convertible into the Company's common stock at a conversion price equal to $8.64 per share at the option of the noteholder. The September 2021 Note bears interest at the rate of two percent (2%) per annum, compounded annually with an effective interest rate of approximately 3%. For the years ended December 31, 2022 and 2021, approximately $200,000 and $58,000, respectively, of interest expense was accrued and included with the principal in the financial statements.

The September 2021 Note also includes a contingent interest component that requires the Company to pay additional interest at a rate of two and one-half percent (2.5%) per quarter (10% per annum) (the "Additional Interest") beginning on the date of issuance of this Note and ending on the maturity date, provided however, that such payment is only required if and only if the noteholder elects to convert the entire balance of the September 2021 Note into the Company's common stock on or prior to maturity. As the contingent event is not based on creditworthiness, such feature is not clearly and closely related to the host instrument and accordingly must be bifurcated and recognized as a derivative liability and a debt discount on the September Note at its inception. The fair value of the contingent interest derivative liability was $433,000 at note inception (September 17, 2021). The fair value of the contingent interest derivative liability was $109,000 and $250,000 and December 31, 2022 and 2021, respectively, and is recognized as a derivative liability in the consolidated balance sheet. The change in the fair value of the derivative liability from September 17, 2021 to December 31, 2021 and for the year ended December 31, 2022 of ($183,000) and ($141,000), respectively, was recorded to other expense/(income) for the years ended December 31, 2021 and 2022. The amortization of the original $433,000 debt discount of $108,000 and $32,000 was recorded as additional interest expense for the years ended December 31, 2022 and 2021, respectively.

On December 20, 2021, the second of the two promissory notes under the Loan Agreement was executed and delivered, (the "December 2021 Note") to evidence the second loan in the principal amount of $10,000,000. The December 2021 Note has a maturity date of December 20, 2025, is prepayable at the option of the Company in whole or in part at any time and is convertible into the Company's common stock at a conversion price equal to $5.43 per share at the option of the noteholder. The December Note bears interest at the rate of two percent (2%) per annum, compounded annually with an effective interest rate of approximately 3%. For the year ended December 31, 2022 and 2021, approximately $200,000 and $7,000, respectively, of interest expense was accrued and included with the principal in the financial statements.

The December 2021 Note also includes a contingent interest component that requires the Company to pay additional interest at a rate of two and one-half percent (2.5%) per quarter (10% per annum) (the "Additional Interest") beginning on the date of issuance of this Note and ending on the maturity date, provided however, that such payment is only required if and only if the noteholder elects to convert the entire balance of the December 2021 Note into the Company's common stock on or prior to maturity. As the contingent event is not based on creditworthiness, such feature is not clearly and closely related to the host instrument and accordingly must be bifurcated and recognized as a derivative liability and a debt discount on the December Note at its inception. The fair value of the contingent interest derivative liability was $415,000 at note inception (December 20, 2021). The fair value of the contingent interest derivative liability was $214,000 and $385,000 at December 31, 2022 and 2021, respectively, and is recognized as a derivative liability in the consolidated balance sheet. The change in the fair value of the derivative liability from December 20, 2021 to December 31, 2021 and for the year ended December 31, 2022 of ($30,000) and ($170,000), respectively was recorded to other expense/(income) for the years ended December 31, 2022 and 2021. The amortization of the original $415,000 debt discount of $104,000 and $3,000 was recorded as additional interest expense for the years ended December 31, 2022 and 2021, respectively.

The Company's contractual cash obligations related to the outstanding convertible notes payable is a repayment of the April 2021 Note of the $10,000,000 plus accrued interest on April 16, 2025 and a repayment of the September 2021 Note of the $10,000,000 plus accrued interest on September 17, 2025 and a repayment of the December 2021 Note of the $10,000,000 plus accrued interest on December 30, 2025, unless converted at the option of the noteholder.

**6. Fair Value of Financial Instruments**

There were no level 1 or 2 assets or liabilities at December 31, 2022 or 2021.

Level 3 assets and liabilities measured and recorded at fair value on a recurring basis at December 31, 2022 and 2021 were as follows:

| | December 31, 2022 | December 31, 2021 |
|---|---|---|
| Derivative Liability – Contingent Interest April Note | $ 249,000 | $ 495,000 |
| Derivative Liability – Contingent Interest September Note | $ 109,000 | $ 250,000 |
| Derivative Liability – Contingent Interest December Note | $ 215,000 | $ 385,000 |

The April 2021 Note derivative liability – contingent interest was valued using a Monte Carlo Geometric Brownian Stock Path Model. The key assumptions used in the model at December 31, 2022 and 2021 are as follows:

| | December 31, 2022 | December 31, 2021 |
|---|---|---|
| Stock Price | $ 1.13 | $ 2.07 |
| Conversion Price of conversion feature | $ 5.00 | $ 5.00 |
| Term | 2.29 years | 3.29 years |
| Risk Free Interest Rate | 4.41% | 0.97% |
| Credit Adjusted Discount Rate | 14.76% | 8.43% |
| Volatility | 81% | 80% |
| Dividend Rate | 0% | 0% |

The roll forward of the April 2021 Note derivative liability – contingent interest is as follows:

| | |
|---|---|
| Balance – December 31, 2020 | $ — |
| Issuance of April convertible note payable – related party | 420,000 |
| Fair Value Adjustment | 75,000 |
| Balance – December 31, 2021 | 495,000 |
| Fair Value Adjustment | (246,000) |
| Balance – December 31, 2022 | $ 249,000 |

The September 2021 Note derivative liability – contingent interest was valued using a Monte Carlo Geometric Brownian Stock Path Model. The key assumptions used in the model at inception, and at December 31, 2022 and 2021 are as follows:

| | December 31, 2022 | December 31, 2021 |
|---|---|---|
| Stock Price | $ 1.13 | $ 2.07 |
| Conversion Price of conversion feature | $ 8.64 | $ 8.64 |
| Term | 2.72 years | 3.72 years |
| Risk Free Interest Rate | 4.22% | 1.12% |
| Credit Adjusted Discount Rate | 14.76% | 8.42% |
| Volatility | 81% | 82% |
| Dividend Rate | 0% | 0% |

The roll forward of the September 2021 Note derivative liability – contingent interest is as follows:

| | |
|---|---|
| Balance – December 31, 2020 | $ — |
| Issuance of September convertible note payable – related party | 433,000 |
| Fair Value Adjustment | (183,000) |
| Balance – December 31, 2021 | 250,000 |
| Fair Value Adjustment | (141,000) |
| Balance – December 31, 2022 | $ 109,000 |

The December 2021 Note derivative liability – contingent interest was valued using a Monte Carlo Geometric Brownian Stock Path Model. The key assumptions used in the model at inception, and at December 31, 2022 and 2021 are as follows:

| | December 31, 2022 | December 31, 2021 |
|---|---|---|
| Stock Price | $ 1.13 | $ 2.07 |
| Conversion Price of conversion feature | $ 5.43 | $ 5.43 |
| Term | 2.97 years | 3.97 years |
| Risk Free Interest Rate | 4.22% | 1.12% |
| Credit Adjusted Discount Rate | 14.76% | 8.42% |
| Volatility | 83% | 84% |
| Dividend Rate | 0% | 0% |

The roll forward of the December 2021 Note derivative liability – contingent interest is as follows:

| | |
|---|---|
| Balance – December 31, 2020 | $ — |
| Issuance of September convertible note payable – related party | 415,000 |
| Fair Value Adjustment | (30,000) |
| Balance – December 31, 2021 | 385,000 |
| Fair Value Adjustment | (170,000) |
| Balance – December 31, 2022 | $ 215,000 |

**7. Stockholders' Equity**

At December 31, 2022, the Company had 150,000,000 shares of common stock and 20,000,000 undesignated shares authorized. As of December 31, 2022, 1,742,500 shares have been designated for Series A 12% Convertible Preferred Stock, 900,000 shares have been designated for Series B-1 Convertible Preferred Stock, 2,100,000 shares have been designated for Series B-2 Convertible Preferred Stock, 1,000 shares have been designated for Series C Super Dividend Convertible Preferred Stock, 2,508,000 shares have been designated for Series B-3 Convertible Preferred Stock, 12,748,500 have been designated as common stock and no shares remain undesignated. All issued and outstanding shares of Series B-1, Series B-2 and Series B-3 Preferred Stock were converted into Common Stock on January 19, 2019.

*2020 At Market Issuance of Common Stock*

On May 11, 2020, the Company entered into an At Market Issuance Sales Agreement (the "2020 At Market Agreement") with a sales agent under which the Company may issue and sell shares of its common stock having an aggregate offering price of up to $40.0 million from time to time through the sales agent. Sales of the Company's common stock through the sales agent, if any, will be made by any method that is deemed an "at the market" offering as defined by the U.S. Securities and Exchange Commission. The Company will pay to the sales agent a commission rate equal to 3.0% of the gross proceeds from the sale of any shares of common stock sold through the sales agent under the 2020 At Market Agreement. During the year ended December 31, 2021, the Company issued 845,214 shares of common stock under the 2020 At Market Agreement for net proceeds of $3,864,000. There were no issuances of common stock under the 2020 At Market Agreement during the year ended December 31, 2022.

***Series A 12% Convertible Preferred Stock — February 4, 2008 Private Placement***

On February 4, 2008, the Company closed a private placement begun in October 2007 of its Series A 12% Convertible Preferred Stock ("Series A") and related warrants. In this transaction, the Company sold units of securities at $6.00 per unit, each unit comprised of (i) one share of Series A Preferred, (ii) a warrant to purchase one share of common stock for $9.00, and (iii) a warrant to purchase one share of common stock for $12.00. Each share of the Series A is entitled to dividends at the rate of 12% per annum payable at the Company's option in cash or shares of common stock valued at the higher of $6.00 per share or 100% of the value weighted average price of the Company's share price for the 20 consecutive trading days prior to the applicable dividend payment date. Dividends are payable semi-annually on March 30 and September 30. The dividend paid on the initial dividend payment date is calculated from the date the Company deposited each subscription advance.

The shares of Series A are entitled to vote as a class with the Company's common stock and each share of Series A is convertible at any time to one-sixth of a share of common stock, subject to adjustment in the event of a stock dividend, stock split or combination, reclassification or similar event. The Company has the right to require conversion if the closing price of the common stock exceeds $18.00 for 15 consecutive trading days and a registration statement covering the resale of the shares of common stock issuable upon conversion of the Series A is then in effect. Each warrant is exercisable solely for cash beginning August 3, 2008 and expired on February 4, 2012. The exercise price of each warrant is adjustable in the event of a stock split or stock combination, capital reorganization, merger or similar event.

In 2022, 42,500 shares of Series A were converted into 7,287 shares of common stock. There were no shares of Series A converted into shares of common stock in 2021. Prior to 2021, a total of 465,000 shares of Series A had been converted into 73,865 shares of common stock.

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

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

On December 30, 2010, the Company sold and issued 212 shares of Series C at a price of $10,000 per share for gross proceeds of $2,120,000. The Company incurred $47,000 of cash transaction costs resulting in net cash proceeds of $2,073,000. In addition, the Company issued 500 warrants exercisable at $7.20 to a placement agent which had a de minimis value. Additionally, in January 2011, the Company sold and issued 13 shares of Series C at a price of $10,000 per share for gross proceeds of $130,000.

The terms of the Series C are as follows:

*Conversion Rights*. Each holder of Series C may convert all, but not less than all, of his Series C shares plus accrued and unpaid dividends into Common Stock at the price of $6.00 per share of Common Stock ("Conversion Price"), such that approximately 1,667 shares of Common Stock will be issued per each converted share of Series C (accrued and unpaid dividends will be issued as additional shares). At December 31, 2018 and 2017, the 176 outstanding shares of Series C were convertible into a total of approximately 293,340 shares of Common Stock.

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

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

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

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

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

In July 2011, 5 shares of Series C were converted into 8,334 shares of common stock and 5 Series C Post Conversion Dividend Rights (Dividend Rights) were issued. In 2013, 24 shares of Series C were converted into 40,193 shares of common stock and 24 Dividend Rights were issued. In 2014, 20 shares of Series C were converted into 33,756 shares of common stock and 20 Dividend Rights were issued. Per the terms of the Series C, these Dividend Rights shall continue to participate in dividends, however the Floor shall not apply. At December 31, 2016 and 2015, these Dividend Rights were determined to have a de minimis value, as the payment of a dividend is considered improbable at this time. The Company will continue to evaluate and assess the Series C Post Conversion Dividend Right for each reporting period.

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

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

ROI Percentage

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

Due to the redemption feature, the Company has presented the Series C outside of permanent equity, in the mezzanine of the consolidated balance sheets at December 31, 2022 and 2021. At December 31, 2022, the Series C redemption value was $8,335,000.

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

## 8. Warrants

Warrant activity is summarized as follows:

| | Warrants | Weighted average exercise price |
|---|---|---|
| Outstanding at December 31, 2020 | 12,538,204 | $ 4.22 |
| Issued | — | |
| Exercised | (1,180,240) | 2.50 |
| Canceled | (500,000) | 5.00 |
| Outstanding at December 31, 2021 | 10,857,964 | $ 4.37 |
| Issued | 700,000 | 4.43 |
| Exercised | — | |
| Canceled | — | |
| Outstanding at December 31, 2022 | 11,557,964 | $ 4.37 |

The following table summarizes information with regard to outstanding warrants issued in connection with equity and debt financings and consultants as of December 31, 2022.

| Issued in Connection With | Number Issued | Exercise Price | Exercisable Date | Expiration Date |
|---|---|---|---|---|
| February 12, 2009 Series B-1 Transaction $3.00 Investor Warrants — Class B | 1,200,000 | $ 3.00 | February 12, 2009 | February 12, 2024 |
| May 13, 2009 Series B-2 Transaction $3.00 Investor Warrants — Class B | 600,000 | $ 3.00 | May 13, 2009 | May 13, 2024 |
| June 30, 2009 Series B-2 Transaction $3.00 Investor Warrants — Class B | 333,333 | $ 3.00 | June 30, 2009 | June 30, 2024 |
| August 12, 2009 Series B-2 Transaction $3.00 Investor Warrants — Class B | 200,000 | $ 3.00 | August 12, 2009 | August 12, 2024 |
| September 30, 2009 Series B-2 Transaction $3.00 Investor Warrants — Class B | 216,666 | $ 3.00 | September 30, 2009 | September 30, 2024 |
| November 4, 2009 Series B-2 Transaction $3.00 Investor Warrants — Class B | 106,666 | $ 3.00 | November 4, 2009 | November 4, 2024 |
| December 8, 2009 Series B-2 Transaction $3.00 Investor Warrants — Class B | 133,143 | $ 3.00 | December 8, 2009 | December 8, 2024 |
| January 29, 2010 Series B-2 Transaction $3.00 Investor Warrants — Class B | 216,667 | $ 3.00 | January 29, 2010 | January 29, 2025 |
| March 8, 2010 Series B-2 Transaction $3.00 Investor Warrants — Class B | 223,334 | $ 3.00 | March 8, 2010 | March 8, 2025 |
| April 30, 2010 Series B-2 Transaction $3.00 Investor Warrants — Class B | 204,192 | $ 3.00 | April 30, 2010 | April 30, 2025 |
| May 10, 2010 Series B-2 Transaction $3.00 Investor Warrants — Class B | 143,166 | $ 3.00 | May 10, 2010 | May 10, 2025 |
| September 22, 2016 Series B-3 Transaction $3.00 Investor Warrants | 698,158 | $ 3.00 | September 22, 2016 | September 22, 2023 |
| September 29, 2016 Series B-3 Transaction $3.00 Investor Warrants | 846,100 | $ 3.00 | September 29, 2016 | September 29, 2023 |
| December 22, 2016 Private placement warrants | 1,466,204 | $ 5.00 | December 22, 2016 | December 23, 2023 |
| December 23, 2016 Series B-3 Transaction $3.00 Investor Warrants | 924,780 | $ 3.00 | December 23, 2016 | December 23, 2023 |
| December 28, 2016 Private placement warrants | 644,468 | $ 5.00 | December 28, 2016 | December 28, 2023 |
| February 27, 2017 Private placement warrants | 76,776 | $ 5.00 | February 27, 2017 | February 27, 2024 |
| 2018 and 2017 Warrants issued for services | 2,157 | $ 5.00 | Various dates in 2018 and 2017 | Various dates in 2025 and 2024 |
| May 23, 2019 Rights offering warrants | 2,622,154 | $ 7.00 | May 23, 2019 | May 23, 2026 |
| July 22, 2022 Warrants issued in connection of related party line of credit | 500,000 | $ 5.00 | July 22, 2022 | July 31, 2029 |
| December 19, 2022 Warrants issued for draw on related party line of credit | 200,000 | $ 3.00 | December 19, 2022 | July 31, 2029 |
| Total outstanding warrants | 11,557,964 | | | |

**9. Stock-Based Compensation**

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

At December 31, 2022, the Company has a stock-based compensation plan where the Company's common stock has been made available for equity-based incentive grants as part of the Company's compensation programs. In December 2019, the Company adopted the 2019 Omnibus Equity Incentive Plan (the "2019 Plan") which provided originally for the issuance of up to 4,000,000 shares of the Company's common stock, subsequently increased to 7,000,000 in December 2021, in the form of options, stock appreciation rights, restricted stock and other stock-based awards to employees, officers, directors, consultants and other eligible persons. At December 31, 2022, 1,966,279 shares were available for future grant under the 2019 Plan. Also, the Company previously had the 2009 Incentive Compensation Plan (the "2009 Plan") which, after amendments, provided for issuance of up to 6,733,334 shares of the Company's common stock in the form of options, stock appreciation rights, restricted stock and other stock-based awards to employees, officers, directors, consultants and other eligible persons. Provisions of the 2009 Plan stipulated that no grants could be made after February 2019; however, grants made prior to that date remain outstanding for their legal term.

***Stock-Based Compensation***

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

| | Year Ended December 31, | |
|---|---|---|
| | **2022** | **2021** |
| Research and development | $ 810 | $ 420 |
| General and administrative | 2,057 | 1,656 |
| Total stock-based compensation expense | $ 2,867 | $ 2,076 |

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

| | **2022** | **2021** |
|---|---|---|
| Risk-free interest rate | 1.85% | 0.66% |
| Expected life of the options | 5.7 years | 6.0 years |
| Expected volatility of the underlying stock | 93.7% | 91.7% |
| Expected dividend rate | 0% | 0% |

As noted above, the fair value of stock options is determined by using the Black-Scholes option pricing model. For all options granted since January 1, 2006 the Company has generally used option terms of between 5 to 10 years, generally with 5 to 6 years representing the estimated life of options granted to employees. The volatility of the common stock is estimated using historical volatility over a period equal to the expected life at the date of grant. The risk-free interest rate used in the Black-Scholes option pricing model is determined by reference to historical U.S. Treasury constant maturity rates with terms equal to the expected terms of the awards. An expected dividend yield of zero is used in the option valuation model, because the Company does not expect to pay any cash dividends on common stock in the foreseeable future. At December 31, 2022, the Company does not anticipate any option awards will be forfeited in the calculation of compensation expense due to the limited number of employees that receive stock option grants and the Company's historical employee turnover; however, any forfeitures will be accounted for as incurred.

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

| | Number of Shares | Weighted Average Exercise Price | Weighted Average Remaining Contractual Life (in years) | Aggregate Intrinsic Value (in thousands) |
|---|---|---|---|---|
| Outstanding, December 31, 2020 | 3,987,575 | $ 4.29 | | |
| Granted | 2,660,000 | 2.39 | | |
| Forfeited/Cancelled | (1,603,073) | 5.31 | | |
| Exercised | (148,941) | 2.35 | | |
| Outstanding, December 31, 2021 | 4,895,561 | $ 3.14 | | |
| Granted | 1,070,000 | 1.75 | | |
| Forfeited/Cancelled | (220,000) | 2.68 | | |
| Exercised | — | — | | |
| Outstanding, December 31, 2022 | 5,745,561 | $ 2.90 | 7.38 | $ 30 |
| Exercisable, December 31, 2022 | 3,551,395 | $ 3.35 | 6.71 | $ 29 |

The aggregate intrinsic value in the table above represents the total pre-tax amount, net of exercise price, which would have been received by option holders if all option holders had exercised all options with an exercise price lower than the market price on December 31, 2022, based on the closing price of the Company's common stock of $1.13 on that date.

The weighted-average grant-date fair values of options granted during 2022 and 2021 were $1.31 and $1.78, respectively. As of December 31, 2022 and 2021, there were unvested options to purchase 2,194,166 and 2,737,084 shares of common stock, respectively. Total expected unrecognized compensation cost related to such unvested options is $2,209,000 at December 31, 2022, which is expected to be recognized over a weighted-average period of 1.45 years.

The aggregate intrinsic value of stock options exercised for the year ended December 31, 2022 and 2021 was $0 and $532,447, respectively.

During the years ended December 31, 2022 and 2021, 1,452,918 and 284,583 options became vested, respectively. The total grant date fair value of options vested during the years ended December 31, 2022 and 2021 was $2,382,842 and $514,287, respectively.

The following table summarizes additional information regarding outstanding and exercisable options under our stock-based compensation plans at December 31, 2022:

| | Options Outstanding | | | Options Exercisable | |
|---|---|---|---|---|---|
| Exercise Price (Range) | Number of Shares | Weighted Average Remaining Contractual Life (in years) | Weighted Average Exercise Price | Number of Shares | Weighted Average Exercise Price |
| $0.87 – 1.00 | 120,500 | 3.96 | $ 0.89 | 120,500 | $ 0.89 |
| $1.01 – 3.00 | 4,364,521 | 8.11 | 2.19 | 2,300,356 | 2.31 |
| $3.01 – 5.00 | 903,040 | 5.85 | 4.14 | 773,039 | 4.31 |
| $5.01 – 8.00 | 220,000 | 5.11 | 5.92 | 220,000 | 5.92 |
| $8.01 – 13.38 | 137,500 | 1.06 | 13.38 | 137,500 | 13.38 |
| | 5,745,561 | 7.38 | $ 2.90 | 3,551,395 | $ 3.35 |

***Restricted Stock Issuances***

In March 2021, one director elected to take a restricted stock grant in lieu of cash retainers for 2021. A total of 16,588 shares of restricted stock valued at approximately $35,000 is being amortized to expense on a straight-line basis until December 31, 2021 when the stock vested in full.

In January 2022, one director elected to take a restricted stock grant in lieu of cash retainers for 2022. A total of 17,677 shares of restricted stock valued at approximately $35,000 is being amortized to expense on a straight-line basis until December 31, 2022 when the stock vested in full.

***Deferred Stock Units***

In September 2020, the Company entered into an employment agreement with its new Chief Executive Officer whereby 20% of his base salary and performance bonuses will be paid in cash, and 80% will be paid in the form of deferred stock units ("DSUs") in accordance with the terms and subject to the provisions set forth in the DSU Agreement. DSUs credited to Mr. Lewis as of any date shall be fully vested and nonforfeitable at all times. Pursuant to an amendment to the DSU Agreement in July 2022, the Company shall issue the shares underlying the outstanding whole number of DSUs credited to Mr. Lewis as follows: twenty five percent shall be issued on March 1, 2023, fifty percent shall be issued on March 1, 2024 and twenty five percent shall be issued on September 1, 2028.

For the year ended December 31, 2022, $418,000 of Mr. Lewis' compensation was recorded as stock compensation expense representing 268,596 shares of common stock to be issued under the DSU agreement with a weighted average grant date fair value of $1.56 per share. Also, Mr. Lewis' bonus for the year ended December 31, 2021 of $200,000 (which was included in accrued compensation at December 31, 2021) was approved in January 2022, and represents 103,627 shares of common stock to be issued under the DSU agreement with a grant date fair value of $1.93 per share. The $200,000 was reclassified from accrued compensation to additional paid in capital in January 2022.

For the year ended December 31, 2021, $400,000 of Mr. Lewis' compensation was recorded as stock compensation expense representing 142,206 shares of common stock to be issued under the DSU agreement with a weighted average grant date fair value of $2.81 per share. Also, Mr. Lewis' bonus for the year ended December 31, 2020 of $60,000 (which was included in accrued compensation at December 31, 2020) was approved in March 2021 and represents 27,027 shares of common stock to be issued under the DSU agreement with a grant date fair value of $2.22 per share. The $60,000 was reclassified from accrued compensation to additional paid in capital in March 2021. There is no unrecognized compensation expense related to the DSUs.

**10. Convertible Line of Credit – Related Party**

On July 25, 2022, the Company and Richard E. Uihlein (the "Lender") entered into a Line of Credit Letter Agreement (the "Credit Agreement"), pursuant to which the Lender shall provide the Company a line of credit of up to $60.0 million (the "Line of Credit") to finance the Company's working capital needs. The Company may draw upon the Line of Credit through July 31, 2024.

Each advance made pursuant to the Credit Agreement shall be evidenced by an unsecured, convertible promissory note (individually, a "Promissory Note," and collectively, the "Promissory Notes"), and bear interest at the Applicable Federal Rate for short term loans, plus two (2%) percent. Principal and interest on the Promissory Notes are due on or before January 31, 2026. Only with the consent of the Lender, may the Promissory Notes be prepaid, in whole or in part, at any time without premium or penalty, but with interest on the amount or amounts prepaid.

At the election of Lender, the principal and accrued interest on Promissory Note(s) may be converted into the number of shares of the Company's Common Stock equal to the amount of principal and accrued interest on such Promissory Note divided by the price equal to the closing price of the Common Stock on the date of such Promissory Note, but in no event less than $3.00 per share.

In connection with the Credit Agreement, the Company agreed to issue the Lender warrants to purchase up to an aggregate of 1,700,000 shares of the Company's common stock, par value $0.001 per share (collectively, the "Warrants"). Upon execution of the Credit Agreement, the Company issued the Lender a Warrant to purchase up to 500,000 shares of Company's Common Stock at an exercise price of $5.00 per share, which Warrant is exercisable upon issuance. Further, pursuant to the Credit Agreement, the Company shall issue to the Lender additional Warrants to purchase up to the remaining 1,200,000 shares of the Company's common stock, ratably, upon borrowings under the Credit Agreement, with exercise prices equal to 150% of the closing price of the Company's common Stock on the date of the Promissory Note evidencing such draw, but in no event more than $10.00 per share nor less than $3.00 per share. The Warrants expire on July 31, 2029.

The fair value of the 500,000 warrants vested at closing on July 25, 2022 was $738,000 at the date of issuance based on the following assumptions: an expected life of 7 years, volatility of 92%, risk free interest rate of 3.19% and zero dividends. The fair value of the vested warrants was recorded in other assets (non-current) as a deferred financing cost and will be amortized on a straight-line basis from July 25, 2022 through January 31, 2026. Amortization for the period ended December 31, 2022 of $92,000 was recorded as interest expense.

On December 19, 2022, the Company executed a $10 million Promissory Note under the Line of Credit. The interest rate on this draw is 6.4% (Applicable Federal Rate for short term loans on date of draw of 4.46% plus 2%). The effective interest rate is approximately 7.1%. Accrued interest on this draw was $23,000 at December 31, 2022. The principal and accrued interest is convertible at the option of the Lender at $3.00 per share. In accordance with the Credit Agreement, the Company issued the Lender a Warrant to purchase up to 200,000 shares of Company's Common Stock at an exercise price of $3.00 per share, which Warrant is exercisable upon issuance.

The fair value of the 200,000 warrants vested at closing on December 19, 2022 was $160,780 at the date of issuance based on the following assumptions: an expected life of 7 years, volatility of 91%, risk free interest rate of 4.06% and zero dividends. The proceeds were allocated between the Promissory Note and the warrants issued, and the amount allocated to the warrants was recorded as a debt discount netted against principal to be amortized on a straight-line basis, which is not materially different than the effective interest method, from December 19, 2022 through January 31, 2026. Amortization for the period ended December 31, 2022 of $2,000 was recorded as interest expense. The fair value of warrants that vest in the future based on borrowings will be computed when those borrowings occur and amortized over the remaining period through January 31, 2026.

## 11. Loss Per Share

Basic net loss per common share is computed by dividing the net loss available to common stockholders by the weighted average number of common shares outstanding during the period. For the years ended December 31, 2022 and 2021, as the Company was in a net loss position, the diluted loss per share computations for such periods did not assume the exercise of warrants and stock options or the conversion of Convertible Notes, or the conversion of convertible preferred stock as they would have had an anti-dilutive effect on loss per share.

The following potentially dilutive securities have been excluded from the computations of diluted weighted average shares outstanding as of December 31, 2022 and 2021 as the inclusion thereof would have been anti-dilutive:

| | Year Ended December 31, | |
|---|---|---|
| | 2022 (Shares) | 2021 (Shares) |
| Warrants to purchase shares of common stock | 11,557,964 | 10,857,964 |
| Options to purchase shares of common stock | 5,745,561 | 4,895,561 |
| Shares of common stock issuable upon conversion of convertible notes payable – related party | 5,815,514 | 5,214,806 |
| Shares of common stock issuable upon conversion of convertible line of credit – related party | 3,341,003 | - |
| Shares of common stock issuable upon conversion preferred stock | 503,340 | 510,424 |
| | **26,963,382** | **21,478,755** |

## 12. Commitments and Contingencies

***Lease Commitments***

The Company has one operating lease for its office space which was amended effective March 1, 2022 for a term of 38 months with no residual value guarantees or material restrictive covenants. The amended lease provided for free rent for the first six and one-half months of the lease and continues the security deposit of $6,000. In addition to base rental payments included in the contractual obligations table below, the Company is responsible for our pro-rata share of the operating expenses for the building. Our lease cost for the years ended December 31, 2022 and 2021 was $43,000 and $44,000, respectively, and is included in general and administrative expenses. As of December 31, 2022, the right to use lease asset consisted of $86,000 and is included in other assets. Also, at December 31, 2022, current lease liability of $40,000 is included in accrued expenses and the noncurrent lease liability of $66,000 is included in other long term liabilities. The Company renewed its existing office space lease effective in February 2022 for 38 months at substantially the same terms.

Maturity of operating lease as of December 31, 2022 in thousands:

| | |
|---|---|
| 2023 | $ 50 |
| 2024 | 51 |
| 2025 | 18 |
| Total | 119 |
| Less imputed interest | 13 |
| Present value of lease liability | $ 106 |

The discount rate used in calculating the present value of the lease payments was 11%.

***Legal Proceedings***

The Company records accruals for such contingencies to the extent that the Company concludes that their occurrence is probable and the related damages are estimable. There are no pending legal proceedings.

***Clinical Trial and Research Contingencies***

The Company has entered into agreements with contractors for research and development activities to further its product candidates. The contracts generally may be canceled at any time by providing thirty days' notice.

**13. Galectin Sciences LLC**

In January 2014, we created Galectin Sciences, LLC (the "LLC" or "Investee"), a collaborative joint venture co-owned by SBH Sciences, Inc. ("SBH"), to research and develop small organic molecule inhibitors of galectin-3 for oral administration. The LLC was initially capitalized with a $400,000 cash investment to fund future research and development activities, which was provided by the Company, and specific in-process research and development ("IPR&D") contributed by SBH. The estimated fair value of the IPR&D contributed by SBH, on the date of contribution, was $400,000. Initially, the Company and SBH have a 50% equity ownership interest in the LLC, with neither party having control over the LLC. Accordingly, from inception through the fourth quarter of 2014, the Company accounted for its investment in the LLC using the equity method of accounting. Under the equity method of accounting, the Company's investment was initially recorded at cost with subsequent adjustments to the carrying value to recognize additional investments in or distributions from the Investee, as well as the Company's share of the Investee's earnings, losses and/or changes in capital. The estimated fair value of the IPR&D contributed to the LLC was immediately expensed upon contribution as there was no alternative future use available at the point of contribution. The operating agreement provides that if either party does not desire to contribute its equal share of funding required after the initial capitalization, then the other party, providing all of the funding, will have its ownership share increased in proportion to the total amount contributed from inception. In the fourth quarter of 2014, after the LLC had expended the $400,000 in cash, SBH decided not to contribute its share of the funding required. As a result, the Company contributed the $73,000 needed for the fourth quarter of 2014 expenses of the LLC and an additional $2,306,000 in total from 2015 through 2020. The Company contributed $213,000 and $226,000 for the LLC expenses (recorded in research and development expenses) in 2022 and 2021, and SBH contributed $35,000 in 2019 and a total of $123,000 in 2017 and 2016, respectively. As of December 31, 2022, the Company's ownership percentage in the LLC was 85.3%. The Company accounts for the interest in the LLC as a consolidated, less than wholly owned subsidiary. Because the LLC's equity is immaterial, the value of the non-controlling interest is also deemed to be immaterial. The Company's portion of the LLC's net loss for 2014, prior to the change in accounting discussed previously, was $400,000, which includes the Company's proportionate share of the non-cash charge associated with the contributed IPR&D of $200,000.

**14. Income Taxes**

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

| | 2022 | 2021 |
|---|---|---|
| | (in thousands) | |
| Operating loss carryforwards | $ 53,119 | $ 54,949 |
| Tax credit carryforwards | 3,558 | 3,720 |
| Other temporary differences | 9,168 | 1,652 |
| | 65,845 | 60,321 |
| Less valuation allowance | (65,845) | (60,321) |
| Net deferred tax asset | $ — | $ — |

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

| | 2022 | 2021 |
|---|---|---|
| Tax benefit at U.S. statutory rates | (21%) | (21%) |
| State tax benefit | 4.2% | (4.7%) |
| Permanent differences | 0.5% | 0.5% |
| Other | (1.4%) | (0.1%) |
| Changes in valuation allowance | 17.7% | 25.3% |
| | **0%** | **0%** |

As of December 31, 2022, the Company has federal and state net operating loss carryforwards totaling $80,810,000 and $87,141,000, respectively, which will never expire as a result of the 2017 Tax Act. As of December 31, 2022, the Company has federal and state net operating loss carryforwards totaling $131,317,000 and $102,003,000 respectively, which expire through 2037. In addition, the Company has federal and state research and development credits of $2,276,000 and $1,282,000, respectively, which expire through 2042. Ownership changes, as defined by Section 382 of the Internal Revenue Code, may have limited the amount of net operating loss carryforwards that can be utilized annually to offset future taxable income. Past and subsequent ownership changes could further affect the limitation in future years. Because of the Company's limited operating history and its recorded losses, management has provided, in each of the last two years, a 100% valuation allowance against the Company's net deferred tax assets.

The Company is subject to taxation in the U.S. and various states. Based on the history of net operating losses all jurisdictions and tax years are open for examination until the operating losses are utilized or the statute of limitations expires. As of December 31, 2022 and 2021, the Company does not have any significant uncertain tax positions.

## *SHAREHOLDER INFORMATION*

### CORPORATE HEADQUARTERS

Galectin Therapeutics Inc.
4960 Peachtree Industrial Blvd., Suite 240
Norcross, GA 30071
Telephone: 678-620-3186
Fax: 770-864-1327
www.galectintherapeutics.com

### MANAGEMENT

**Joel Lewis**
Chief Executive Officer, President

**Jack W. Callicutt,**
Chief Financial Officer, Treasurer and Corporate Secretary

### TRANSFER AGENT

Continental Stock Transfer & Trust Company
17 Battery Place
New York, NY 10004
Telephone: 212-509-4000
www.continentalstock.com

### LEGAL COUNSEL

Dentons LLP
303 Peachtree St.
Suite 5300
Atlanta, GA 30308

### INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Cherry Bekaert LLP
1075 Peachtree St. NE
Suite 2200
Atlanta, GA 30309

### MARKET FOR SECURITIES

The Company's Common Stock is traded on NASDAQ under the symbol GALT.

### DIRECTORS (as of October 10, 2023)

**Gilbert F. Amelio, Ph.D.**, (1) (3) Executive Corporate Advisor, Senior Technologist and Retired CEO of Apple Computer and National Semiconductor.

**James C. Czirr,** Co-Founder and Managing Partner 10X Fund, L.P.

**Kary Eldred,** (2) Chief Investment Officer of Living Stones Foundation

**Kevin D. Freeman**, (1)(2) (3) CEO, Freeman Global Investment Counsel.

**Joel Lewis**, Chief Executive Officer and President Galectin Therapeutics, Inc.

**Gilbert S. Omenn, M.D., Ph.D.**, (1) 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

**Marc Rubin, M.D.**, (3) Executive Chairman of the Board of Directors, Titan Pharmaceuticals, Inc.

**Elissa J. Schwartz, Ph.D.**,(3) Professor of Biological Sciences and Mathematics at Washington State University

**Harold H. Shlevin, Ph.D.**, former Chief Executive Officer and President Galectin Therapeutics, Inc.

**Richard E. Uihlein**, Chairman of Galectin Therapeutics Board of Directors, Chief Executive Officer, Chairman and Co-Founder of Uline Inc.

**Richard A. Zordani**,(2) Director of Shareholder Services at Uline Inc.

(1) Member of the Compensation Committee
(2) Member of the Audit Committee
(3) Member of the Nominating and Corporate Governance Committee

### ANNUAL MEETING

The 2023 Annual Meeting of Stockholders will be held Virtually via The internet at 11:00 A.M. Eastern Time on Thursday, December 7, 2023.

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**IMPORTANT NOTICE REGARDING THE AVAILABILITY OF PROXY MATERIALS FOR THE SHAREHOLDER MEETING ON DECEMBER 7,2023. OUR PROXY STATEMENT AND 2022 ANNUAL REPORT TO SHAREHOLDERS ARE AVAILABLE FOR VIEWING AT:**
www.galectintherapeutics.com

Shareholders may obtain financial reports, and other documents of interest in the Investor Relations portion of the Company's website www.galectintherapeutics.com at no charge or upon written request to:

Galectin Therapeutics Inc.
Investor Relations
4960 Peachtree Industrial Blvd., Suite 240
Norcross, GA 30071

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