

Risk Factors Comparison 2025-03-31 to 2024-03-29 Form: 10-K

Legend: **New Text** ~~Removed Text~~ Unchanged Text **Moved Text** Section

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, 2023 was \$ 354 million. We had \$ ~~25-15~~ **7-1** million of unrestricted cash as of December 31, ~~2023-2024~~ **2024**, and \$ ~~20-6~~ million ~~remaining of available borrowings~~ under a line of credit provided by our chairman, ~~Richard E. Uihlein~~ **Richard E. Uihlein**. ~~Additionally, and in March 2025, we signed a new supplemental line of credit agreement with our chairman for an additional \$ 40-5 million supplemental line of available borrowings credit provided also by our chairman.~~ **Additionally, and in March 2025, we signed a new supplemental line of credit agreement with our chairman for an additional \$ 40-5 million supplemental line of available borrowings credit provided also by our chairman.** The Company believes there is sufficient cash **, including the \$ 11 million under the two lines of credit,** to fund currently planned operations ~~at least through August March 31, 2025.~~ **at least through August March 31, 2025.** We will require more cash to fund our operations after ~~August December 31, 2024-2025~~ **August December 31, 2024-2025** and ~~believe we will be able to obtain additional financing.~~ **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. **Our NAVIGATE trial was our only active clinical trial, and we currently do not have plans or funding to undertake another clinical trial. In December 2024, we presented top- line results of the NAVIGATE clinical trial. The composite endpoint did not reach statistical significance. Because the data from NAVIGATE clinical trial did not reach statistical significance, we may determine not to conduct an additional clinical trial to test the efficacy of our drug candidate, belapectin. Furthermore, it will be difficult for us to raise the capital necessary for another clinical trial. The Company continues to analyze data from the 57 patients that completed 36 months of treatment prior to the ending of the trial in February 2025. While data from this group patient would not change the results of results of the NAVIGATE clinical trial, the Company believes that encouraging results from this group of patients may draw interest from potential strategic partners. There is substantial doubt about our ability to continue as a going concern. In 2024, we experienced net losses of \$ 47. 2 million, had no revenue from operations, and used \$ 41. 8 million in cash to fund our operations. Due to the current level of liquidity at December 31, 2024 and the projected shortfall to cover operating expenses requiring cash for a period of 12 months from the report date of the annual report, management has expressed substantial doubt as to our ability to continue as a going concern .** 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. ~~Index~~ **Index** ~~In~~ **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.

Top-line results from an interim analysis for our Phase 2b/3 clinical study, the NAVIGATE trial, were presented, is expected in the December fourth quarter of 2024. Again, while there was positive data, especially in the 2 mg cohort, the composite endpoint did not reach statistical significance. We may engage others to conduct our clinical trials, including clinical research organizations and, possibly, government-sponsored agencies. Additional clinical trials may not start or be completed as we forecast and may not achieve the desired results. The time required to obtain FDA and other approvals is unpredictable but often can take years following the commencement of clinical trials, depending upon the complexity of the drug candidate. Even if we receive regulatory approval, we may be unable to commercialize our product candidates. Even if 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 (now known as Fortrea), 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. IndexWe 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~~ **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. IndexOur 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. 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. IndexRisks 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. Index

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~~ **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 \$ 35,967,000 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. IndexOur 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 16.64% of our outstanding common stock as of February 29-28, 2024-2025 (which does not include any shares issuable upon exercise of options and warrants **nor shares issuable upon conversion of convertible notes and lines of credit**) and the 10X Fund, LP, which now owns 9.64% of the issued and outstanding shares of common stock of the Company as of February 29-28, 2024-2025 (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. Uihlein 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. A pandemic similar to the COVID-19 pandemic, or the reemergence of the COVID-19 pandemic could adversely impact our business, including our preclinical studies and clinical trials. The occurrence of a pandemic similar to the COVID-19 pandemic, or the reemergence of the COVID-19 pandemic could cause disruptions that could severely impact our business and our clinical trials 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 a contagious illness, 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; Index • 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. In addition, the trading prices for our common stock and other biopharmaceutical companies could experience extreme volatility during a pandemic. The extent to which a pandemic may impact our business, preclinical studies and clinical trials will depend on factors that we cannot predict or control, 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. **Comments**. Item 1C. Cybersecurity Risk management and strategy We have policies and processes designed to protect our information technology systems, which are managed by outside consultants. Our cybersecurity consultants resolve issues in a timely manner in the event of a cybersecurity threat or incident. As part of our broader risk management framework, from time to time, we seek to identify potential cybersecurity risks to our business and improve our policies and processes to address such risks. We have designed our business applications to minimize the impact that cybersecurity incidents could have on our business and have identified back-up systems where appropriate. We seek to further mitigate cybersecurity risks through a combination of monitoring and detection activities, use of anti-malware applications, employee training, quality reviews and communication and reporting structures, among other processes. We have an incident response plan in place that outlines containment, eradication and recovery plans in the event of a cybersecurity threat or incident. We engage a third-party consultant to assist us with designing controls and our cybersecurity risk management framework. We are also engaging with a third party to perform penetration testing. We also retain third parties to assist with the monitoring and detection of cybersecurity threats and responding to any cybersecurity threats or incidents. With respect to third parties that manage or use our information technology or data, we obtain reports to assess the security of their systems and processes. We engage in ongoing monitoring of third-party providers to ensure compliance with our cybersecurity standards. We have not encountered cybersecurity threats or incidents that have had a material impact on our business. Cybersecurity Governance Our Nomination and Corporate Governance Committee has specific oversight responsibility for cybersecurity. The Nomination and Corporate Governance Committee reviews and discusses with management our policies, practices and risks related to information security and cybersecurity. Our chief financial officer has primary responsibility for assessing, monitoring and managing cybersecurity risks. We utilize cybersecurity consultants to monitor and report cybersecurity threats or incidents to our chief financial officer and to resolve issues arising from such threats or incidents. Our chief financial officer updates the Nomination and Corporate Governance Committee on any risks related to cybersecurity as needed. 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. Index 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 29, 2024, there were 138 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 a pandemic or the reemergence of COVID-19, which delayed our clinical trial and development efforts, as well as the impact that such a pandemic 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 belapeetin (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. Belapeetin 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, 2023 and 2022

Research and Development Expense Year ended December 31, 2023 as Compared to 2022

2023	2022	\$ Change	% Change
\$ 32,130	\$ 31,737	\$ 393	1.2%

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, belapeetin and GM-CT-01; however only belapeetin is in active development. Our research and development expenses were as follows:

Year Ended December 31, 2023	Year Ended December 31, 2022	\$ Change	% Change
\$ 32,130	\$ 31,737	\$ 393	1.2%
Direct external expenses: (in thousands)			
Clinical programs	\$ 23,942	\$ 26,746	11.2%
Pre-clinical activities	3,021	1,262	41.7%
Other research and development expenses: Payroll and other including stock-based compensation	5,167	3,727	72.2%

Clinical programs expenses decreased in the year ended December 31, 2023 over the year ended December 31, 2022 primarily due to costs related to our the NAVIGATE clinical trial activities and a decrease in costs related to contract manufacturing of belapeetin. Pre-clinical activities increased due to activities incurred in support of the 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, 2023 as Compared to 2022

2023	2022	\$ Change	% Change
\$ 5,942	\$ 6,615	\$ (673)	(10.2%)

General and administrative expenses consist primarily of salaries including

stock-based compensation, legal and accounting fees, insurance, investor relations, business development and other office related expenses. The primary reasons for the decrease for the year ended December 31, 2023, as compared to the same period for 2022 are due to a decrease in non-cash stock-based compensation of \$ 624,000. Other Income and Expense During the year ended December 31, 2023, other income and expense consisted of \$ 230,000 of interest income offset by interest expense and amortization of debt discounts on convertible notes payable and convertible line of credit of \$ 2,792,000 and change in fair value of derivatives of \$ 432,000. During the year ended December 31, 2022, other income and expense consisted of \$ 52,000 of interest income and change in fair value of derivatives of \$ 557,000 offset by interest expense and amortization of debt discounts on convertible notes payable and convertible line of credit of \$ 1,033,000. 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 %)
\$ 31,737	\$ 23,818	\$ 7,919	%

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, belapeetin and GM-CT-01; however only belapeetin is in active development. Our research and development expenses were as follows: Year Ended December 31, 2022

2022	2021	\$ Change	% Change (in thousands, except %)
\$ 26,748	\$ 20,830	\$ 5,918	%

Pre-clinical activities 1,262 Other research and development expenses: Payroll and other including stock-based compensation 3,727 2,426 \$ 31,737 \$ 23,818

Index 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 %)
\$ 6,615	\$ 6,361	\$ 254	%

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. 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, 2023, we raised a net total of \$ 284.5 million from these offerings. At December 31, 2023, the Company had \$ 25.7 million of unrestricted cash and cash equivalents in addition to \$ 30 million available under two lines of credit provided by our chairman available to fund future operations. The Company believes there is sufficient cash to fund currently planned operations through March 31, 2025. We will require more cash to fund our operations after March 31, 2025 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. 2023 compared to 2022

2023	2022	\$ Change
\$ 1,909,000	\$ 32,965,000	\$ 31,056,000

Net cash used in operations increased by \$ 1,909,000 to \$ 32,965,000 for 2023, as compared to \$ 31,056,000 for 2022. 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 2023 or 2022. Net cash provided by financing activities was \$ 40,033,000 during 2023 as compared to \$ 10,000,000 during 2022, due primarily to the transactions described below. In 2023, we received \$ 30,000,000 in proceeds under a convertible line of credit provided by our chairman in addition to \$ 10 million in proceeds from stock purchase warrants exercised by our chairman. In 2022, we received proceeds of \$ 10,000,000 under a convertible line of credit provided by our chairman. 2022 compared to 2021

2022	2021	\$ Change
\$ 31,056,000	\$ 24,308,000	\$ 6,748,000

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. Index 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, 2023 and 2022. Index 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, 2023. Our management has concluded, based on their evaluation, that our disclosure controls and procedures were effective as of December 31, 2023 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, 2023. (c) Changes in Internal Control Over Financial Reporting There was no change in our internal control over financial reporting that occurred during the fourth quarter of 2023 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. Index Item 9B. Other Information Supplemental Line of Credit On March 29, 2024, the Company and Richard E. Uihlein (the "Lender") entered into a Supplemental Line of Credit Letter Agreement (the "Supplemental Credit Agreement"), pursuant to which the Lender shall provide the Company a line of credit of up to \$ 10.0 million (the "Supplemental Line of Credit") to finance the Company's working capital needs. The Company may draw upon the Supplemental Line of Credit through March 31, 2025. Each advance made pursuant to the Supplemental 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 March 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 Supplemental Credit Agreement, the Company agreed to issue the Lender warrants to purchase up to an aggregate of 200,000 shares of the Company's common stock, par value \$ 0.001 per share (collectively, the "Warrants"). The Company shall issue to the Lender Warrants ratably, upon borrowings under the Supplemental Line of Credit, 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 securities referred to in this Item 9B are being issued by the Company to the Lender in reliance upon the exemption from the registration requirements of the Securities Act of 1933, as amended (the "Securities Act"), pursuant to Section 4 (a) (2) thereof and Regulation D thereunder. The Company relied, in part, upon representations from the Lender that the Lender is an accredited investor as defined in Regulation D under the Securities Act. Securities Trading Plans of Directors and Executive Officers No officers or directors, as defined in Rule 16a-1 (f), adopted or terminated a "Rule 10b5-1 trading arrangement" or a "non-Rule 10b5-1 trading arrangement," as defined in Regulation S-K Item 408, during the fiscal quarter ended December 31, 2023. Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections Not applicable. Index 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 2023 Annual Meeting of Stockholders. The following table sets forth the certain biographical information about our directors as of February 28, 2024, 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) Benjamin S. Carson, Sr., M. D. Kary Eldred (1) Kevin D. Freeman (1) (2) (3) Joel Lewis Gilbert S. Omenn, M. D., Ph. D. (2) Mare Rubin, M. D. (3) Elissa J. Schwartz, Ph. D. (3) Harold H. Shlevin, Ph. D. Richard E. Uihlein, Chairman Richard A. Zordani (1) (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. Dr. Benjamin S. Carson, Sr., a director since 2023, served as the 17th Secretary of the U. S. Department of Housing and Urban Development ("HUD") from 2017 to 2021. Dr. Carson is a world-renowned neurosurgeon who prior to serving as HUD Secretary was involved with more than 15,000 surgical procedures and was the recipient of numerous awards, including the Presidential Medal of Freedom, more than 70 honorary doctorate degrees and the Spingarn Medal, the NAACP's highest honor. Dr. Carson serves on the Board of Directors for D. R. Horton, Inc. (NYSE: DHI), Covenant Logistics Group, Inc. (NASDAQ: CVLG), and Sinclair Broadcast Group, Inc. (NASDAQ: SBGI). In addition, Dr. Carson previously served on the Board of Directors of both The Kellogg Company (NYSE: K) and Costco Wholesale Corporation (NASDAQ: COST). Dr. Carson is the founder and current Chairman of the American Cornerstone Institute. Dr. Carson is on the Board of Directors of the Carson Scholars Fund, an organization he and his wife, Mrs. Candy Carson, founded in 1994. Throughout his distinguished career, Dr. Carson contributed to the field of medicine through the thousands of surgeries he performed and the many leadership positions he held, including serving as Director of the Division of Pediatric Neurosurgery at The Johns Hopkins Medical Institutions from 1984 to 2013 as well as a Professor of Neurological Surgery, Oncology, Plastic Surgery, and Pediatrics at The Johns Hopkins Medical Institutions from 1999 to 2013. The Board believes that Dr. Carson's extensive medical, management, director, leadership, financial, and information security experience make him highly qualified to serve as a member of our Board. 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. IndexJoel 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 Oneofusion 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 eum laude from Princeton University, M. D. magna eum 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. Index 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 Altshuler, 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 PolicyThe SEC adopted final rules implementing the incentive-based compensation recovery provisions of the Dodd-Frank Act, and Nasdaq has adopted listing standards consistent with the SEC rules. In compliance with those standards, we have adopted an incentive-compensation recoupment policy, or "clawback" policy, which applies to our executive officers, within the meaning of Section 10D of the Exchange Act and Rule 10D-1 promulgated thereunder, who were employed by the Company during the applicable recovery period. Under the policy, in the event that the financial results upon which a cash or equity-based incentive award was predicated become the subject of a financial restatement that is required because of material non-compliance with financial reporting requirements, the Compensation Committee will conduct a review of awards covered by the policy and recoup any erroneously awarded incentive-based compensation to ensure that the ultimate payout gives retroactive effect to the financial results as restated. The Company may not indemnify any such covered officer against the loss of such recovered compensation.

Director NominationsNo material changes have been made to the procedures by which security holders may recommend nominees to our board of directors.

Audit CommitteeThe 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 ManagementThe 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.

INDEX EXECUTIVE OFFICERS

Joel Lewis, see above under directors.

Pol F. Boudes, M.D., age 66, 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. Callieutt, age 56, became our Chief Financial Officer on July 1, 2013. From August 2011 through June 2012, Mr. Callieutt was the Chief Financial Officer of REACH Health, Inc., a telemedicine technology company headquartered in Alpharetta, GA. From April 2010 through August 2012, Mr. Callieutt 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. Callieutt 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. Callieutt 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. Callieutt 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 ComplianceSection 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, 2023, except as set forth below.

Delinquent Section 16 (a) ReportsOne of our directors, Dr. Benjamin S. Carson, Sr. did not timely file one initial ownership report on Form 3.

Item 11. Executive Compensation

COMPENSATION PHILOSOPHY DISCUSSIONThe 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 2023 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. Callieutt 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.