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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

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**FORM 10-K**

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**ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d)  
OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2021

Commission file number 001-36177

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**GlycoMimetics, Inc.**

(Exact name of Registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**06-1686563**  
(IRS Employer  
Identification No.)

**9708 Medical Center Drive**  
**Rockville, Maryland**  
(Address of principal executive offices)

**20850**  
(Zip Code)

**Registrant's telephone number, including area code: (240) 243-1201**

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

Title of Each Class:	Trading Symbol:	Name of Each Exchange on which Registered
Common Stock, \$0.001 par value	GLYC	The Nasdaq Stock Market

**Securities registered pursuant to Section 12(g) of the Act: None**

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

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

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

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

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

Large Accelerated Filer	<input type="checkbox"/>	Accelerated Filer	<input type="checkbox"/>
Non-accelerated Filer	<input checked="" type="checkbox"/>	Smaller Reporting Company	<input checked="" type="checkbox"/>
		Emerging Growth Company	<input type="checkbox"/>

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.

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

As of June 30, 2021, the last business day of the registrant's last completed second quarter, the aggregate market value of the Common Stock held by non-affiliates of the registrant was approximately \$117.5 million based on the closing price of the registrant's Common Stock, as reported by the Nasdaq Global Market, on such date.

At February 28, 2022, 52,313,894 shares of GlycoMimetics, Inc.'s Common Stock, \$0.001 par value per share, were outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of GlycoMimetics, Inc.'s definitive proxy statement, to be filed pursuant to Regulation 14A under the Securities Exchange Act of 1934, for its 2022 Annual Meeting of Stockholders are incorporated by reference in Part III of this Form 10-K.

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## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, or this Annual Report, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, that involve substantial risks and uncertainties. The forward-looking statements are contained principally in Part I, Item 1. “Business,” Part I, Item 1A. “Risk Factors,” and Part II, Item 7. “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” but are also contained elsewhere in this Annual Report. In some cases, you can identify forward-looking statements by the words “may,” “might,” “will,” “could,” “would,” “should,” “expect,” “intend,” “plan,” “objective,” “anticipate,” “believe,” “estimate,” “predict,” “project,” “potential,” “continue” and “ongoing,” or the negative of these terms, or other comparable terminology intended to identify statements about the future. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Annual Report, we caution you that these statements are based on a combination of facts and factors currently known by us and our expectations of the future, about which we cannot be certain. Forward-looking statements include statements about:

- our plans to develop and commercialize our glycomimetic drug candidates;
- our and our collaborators’ ongoing and planned clinical trials for our drug candidates uproleselan and GMI-1359, including the timing of initiation of and enrollment in the trials, the timing of availability of data from the trials and the anticipated results of the trials;
- the timing of and our ability to obtain and maintain regulatory approvals for our drug candidates;
- the clinical utility of our drug candidates;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our intellectual property position;
- our ability to identify additional drug candidates with significant commercial potential that are consistent with our commercial objectives;
- our estimates regarding future revenues, expenses and needs for additional financing; and
- our beliefs that our capital resources will be sufficient to meet our anticipated cash requirements into the second quarter of 2023.

You should refer to Item 1A. “Risk Factors” section of this Annual Report for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Annual Report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Annual Report.

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## RISK FACTOR SUMMARY

Our business is subject to numerous risks. You should carefully consider the following risks, as well as general economic and business risks, and all of the other information contained in this Annual Report, together with any other documents we file with the SEC. Any of the following risks could have a material adverse effect on our business, operating results and financial condition and cause the trading price of our common stock to decline.

Among these important risks are the following:

- We have incurred significant losses since our inception. We expect to continue to incur losses over the next several years and may never achieve or maintain profitability.
  - We will need substantial additional funding to pursue our business objectives. If we are unable to raise capital when needed, we may not be able to continue as a going concern and could be forced to delay, reduce or eliminate our drug development programs or potential commercialization efforts.
  - Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our drug candidates.
  - We have only one drug candidate in a late-stage clinical trial. If we or our collaborators are unable to commercialize our drug candidates or experience significant delays in doing so, our business will be materially harmed.
  - Clinical drug development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our drug candidates.
  - Our business could be adversely affected by the effects of health epidemics or pandemics, including the ongoing COVID-19 pandemic, in regions where we or third parties on whom we rely have significant manufacturing facilities, clinical trial sites or other business operations.
  - If serious adverse or unacceptable side effects are identified during the development of our drug candidates, we may need to abandon or limit the development of some of our drug candidates.
  - We may expend our limited resources to pursue a particular drug candidate or indication and fail to capitalize on drug candidates or indications that may be more profitable or for which there is a greater likelihood of success.
  - Our success depends in part on current and future collaborations. If we are unable to maintain any of these collaborations, or if these collaborations are not successful, our business could be adversely affected.
  - We expect to rely on third parties to conduct our future clinical trials for drug candidates, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.
  - We contract with third parties for the manufacturing of our drug candidates for preclinical and clinical testing and expect to continue to do so for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our drug candidates or drugs, or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.
  - We, or our third-party manufacturers, may be unable to successfully scale-up manufacturing of our drug candidates in sufficient quality and quantity, which would delay or prevent us from conducting our ongoing and planned clinical trials and developing our drug candidates.
  - Even if any of our drug candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.
  - We face substantial competition, which may result in others discovering, developing or commercializing drugs before or more successfully than we do.
  - If we are unable to obtain and maintain patent protection for our drug candidates, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize drug candidates similar or identical to ours, and our ability to successfully commercialize our drug candidates may be impaired.
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- If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.
  - If we or our collaborators are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we or they will not be able to commercialize our drug candidates and our ability to generate revenue will be materially impaired.
  - Even though we have obtained Orphan Drug designation for several of our drug candidates, we may not be able to obtain orphan drug marketing exclusivity for these or any of our other drug candidates.
  - The FDA fast track designation and additional Breakthrough Therapy designation for uproleselan may not actually lead to a faster development or regulatory review or approval process.
  - Failure to obtain marketing approval in international jurisdictions would prevent our drug candidates from being marketed abroad.
  - A variety of risks associated with developing and marketing our drug candidates internationally could hurt our business.
  - Any drug candidate for which we obtain marketing approval could be subject to post-marketing restrictions or recall or withdrawal from the market, and we may therefore be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our drug candidates, when and if any of them are approved.
  - Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our drug candidates and affect the prices we may obtain.
  - Governments outside the United States tend to impose strict price controls, which may adversely affect our revenue, if any.
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## **PART I**

### **ITEM 1. BUSINESS**

#### **Company Overview**

We are a clinical-stage biotechnology company focused on the discovery and development of novel glycomimetic drugs to address unmet medical needs resulting from diseases in which carbohydrate biology plays a key role. We are developing a pipeline of proprietary glycomimetics, which are small molecules that mimic the structure of carbohydrates involved in important biological processes, to inhibit disease-related functions of carbohydrates such as the roles they play in inflammation, cancer and infection. We believe this represents an innovative approach to drug discovery to treat a wide range of diseases. We are focusing our efforts on drug candidates for diseases that we believe will qualify for Orphan Drug designation.

Our proprietary glycomimetics platform is based on our expertise in carbohydrate chemistry and our understanding of the role carbohydrates play in key biological processes. Most human proteins are modified by the addition of complex carbohydrate structures to the surface of such proteins, which affects the functions of the proteins and their interactions with other molecules. Our research and development efforts have focused on drug candidates targeting selectins, which are proteins that serve as adhesion molecules and bind to carbohydrates that are involved in the inflammatory component and progression of a wide range of diseases, including hematologic disorders, cancer and cardiovascular disease. For example, we believe that members of the selectin family play a key role in tumor metastasis and resistance to chemotherapy. Inhibiting specific carbohydrates from binding to selectins has long been viewed as a potentially attractive approach for therapeutic intervention. The ability to successfully develop drug-like carbohydrate compounds that inhibit binding with selectins, known as selectin antagonists, has historically been limited by their potency and the complexities of carbohydrate chemistry. We believe our expertise in the rational design of potent glycomimetic antagonists with drug-like properties and in carbohydrate chemistry enables us to identify highly effective selectin antagonists and other glycomimetics that may inhibit the disease-related functions of certain carbohydrates in order to develop novel drug candidates to address orphan diseases with high unmet medical need.

#### **Overview of Our Drug Candidates**

Our current drug candidates are summarized below. We have retained the worldwide development and commercialization rights to each of our drug candidates, except with respect to uproleselan and GMI-1687, for which we have exclusively licensed development and commercialization rights to Apollomics (Hong Kong) Limited, or Apollomics, in Mainland China, Hong Kong, Macau and Taiwan, collectively referred to as Greater China.

#### ***Uproleselan***

We are developing uproleselan, a specific E-selectin inhibitor, to be used in combination with chemotherapy to treat patients with acute myeloid leukemia, or AML, a life-threatening hematologic cancer, and potentially other hematologic cancers. Uproleselan has been granted Breakthrough Therapy designation by the U.S. Food and Drug Administration, or FDA, for the treatment of adults with relapsed or refractory AML. In addition, uproleselan has received Orphan Drug designation from the FDA and the European Commission for the treatment of AML.

E-selectin plays a critical role in binding cancer cells within vascular niches in the bone marrow, which prevents the cells from entering circulation where they can be more readily killed by chemotherapy. In animal studies, uproleselan mobilized AML cancer cells out of the bone marrow, making them more sensitive to chemotherapy. In these studies, tumor burden was significantly reduced in the animals treated with a combination of chemotherapy and uproleselan as compared to animals treated with chemotherapy alone. In addition, the combination of uproleselan with chemotherapy resulted in improved survival rates for the treated animals compared to chemotherapy alone. In other animal studies, uproleselan appeared to also protect normal cells from some of the side effects of chemotherapy. Common side effects of chemotherapy include bone marrow toxicity resulting in neutropenia, which is an abnormally low number of neutrophils, the white blood cells that serve as the primary defense against infection, and mucositis, which is the inflammation and sloughing of the mucous membranes lining the digestive tract. Animals treated with uproleselan and chemotherapy had less severe neutropenia and mucositis and lower bone marrow toxicity as compared to animals treated with chemotherapy alone. We believe that treatment with uproleselan results in lower bone marrow toxicity due to its inhibition of E-selectin, which inhibition makes stem cells in the bone marrow divide less frequently, thereby protecting them from chemotherapy agents that target rapidly dividing cells.

We completed an initial Phase 1 trial in healthy volunteers for uproleselan and in 2017 we completed enrollment in a Phase 1/2 clinical trial in patients with either relapsed/refractory or de novo/secondary AML. Final efficacy and safety data from this Phase 1/2 trial were published in the journal *BLOOD* in September 2021, with scientists highlighting an enhanced depth of response following addition of uproleselan to salvage therapy, as indicated by the high remission rates observed in the trial compared to historical experience with salvage chemotherapy alone and 69% rate of minimal residual disease, or MRD, negativity in evaluable trial participants with relapsed/refractory AML.

In 2018, we dosed the first patient in a Phase 3 clinical trial to evaluate uproleselan in adults with relapsed/refractory AML. In November 2021, we completed enrollment in this Phase 3 clinical trial and expect to report top-line data from this pivotal trial after year-end 2022.

In May 2018, we signed a Cooperative Research and Development Agreement, or CRADA, with the NCI, part of the National Institutes of Health. Under the terms of the CRADA, we are collaborating with both the NCI and the Alliance for Clinical Trials in Oncology to conduct a randomized, controlled clinical trial evaluating the addition of uproleselan to a standard cytarabine/daunorubicin chemotherapy regimen (7&3) in older adults with previously untreated AML who are eligible for intensive chemotherapy. The first patient in this Phase 2/3 NCI-sponsored trial was dosed in April 2019. Completion of enrollment of the Phase 2 portion, which occurred in December 2021, sets the stage for a planned interim analysis that will evaluate event-free survival and whether the pre-specified threshold for continuing to Phase 3 has been met. The trial may also provide support for regulatory filings if the results of the planned interim analysis are positive.

#### **GMI-1359**

We are also developing a drug candidate, GMI-1359, that simultaneously targets both E-selectin and a chemokine receptor known as CXCR4. Since E-selectin and CXCR4 are implicated in the retention of cancer cells in the bone and bone marrow, we believe that targeting both E-selectin and CXCR4 with a single compound could improve efficacy in the treatment of cancers that affect the bone and bone marrow, including solid tumors that have a propensity to metastasize to bone. Following a Phase 1 randomized, double-blind, placebo-controlled, single-dose escalation trial of GMI-1359 in healthy volunteers, we conducted a Phase 1b trial of GMI-1359 at Duke University Cancer Center in hormone receptor positive, or HR+, breast cancer patients whose tumors had spread to bone. The goal of this dose escalation trial was to evaluate safety, pharmacokinetics (PK) and pharmacodynamics (PD). Interim data from this Phase 1b study were presented at the American Association of Cancer Research (AACR) 2021 Annual Meeting, with clear evidence of dual antagonism on both E-selectin and CXCR4, key PD markers of biologic activity, being observed for participants treated with GMI-1359. Based on activity levels observed in the trial, we are evaluating potential indications for future development where these overlapping functions play key roles, as well as the funding requirement for any potential development opportunities.

Most recently, at the 63<sup>rd</sup> American Society of Hematology (ASH) Annual Meeting and Exposition in 2021, we presented preclinical data showing that FLT3 inhibitors, such as quizartinib and sorafenib, upregulate the expression of E-selectin ligands and CXCR4, thereby increasing adhesion to protective niches in the bone marrow microenvironment and inducing chemoresistance. Using cells from a relapsed AML patient treated with a FLT3 inhibitor in a murine model, the addition of GMI-1359 to quizartinib broke chemoresistance, which led to a significant reduction in leukemic burden and a statistically significant doubling of median survival time from 79 to 158 days ( $p < 0.0001$ ).

In January 2020, the FDA granted GMI-1359 Orphan Drug designation and Rare Pediatric Disease designation for the treatment of osteosarcoma, a rare cancer affecting approximately 900 adolescents each year in the United States.

#### **GMI-1687**

We have rationally designed an innovative antagonist of E-selectin, GMI-1687, that could be suitable for subcutaneous administration. Initially developed as a potential life-cycle extension to uproleselan, when given by subcutaneous injection in animal models, GMI-1687 has been observed to have equivalent activity to uproleselan, but at an approximately 1,000-fold lower dose. We believe that GMI-1687 could be developed to broaden the clinical usefulness of an E-selectin antagonist to conditions where outpatient treatment is preferred or required.

In September 2020 at the virtual meeting of the Foundation for Sickle Cell Disease Research, or FSCDR, we gave an oral presentation on an abstract containing data on GMI-1687, which included data from a preclinical model showing the drug candidate's potential as a subcutaneously administered treatment for vaso-occlusive crisis, or VOC, a common complication of sickle cell disease, or SCD. We are currently conducting activities and studies with GMI-1687 to support our planned submission in the first half of 2022 of an investigational new drug application, or IND, to the FDA.

### **Galectin Antagonists**

Galectin-3 is a carbohydrate-binding protein whose expression has been shown to play a central role in fibrosis and cancer. Galectin-3 has been linked to a number of biologic processes including inflammation, aberrant cell activation and proliferation (macrophages, neutrophils, and mast cells), fibrogenesis and ultimately, organ dysfunction. Experimental data have implicated galectin-3 in a variety of diseases across a number of organ systems, including liver, kidney, lung, eye and heart. Current research also indicates that galectin-3 has important roles in modulating the immune and inflammatory response to cancer that contributes to neoplastic transformation, tumor cell survival, angiogenesis and metastasis.

Applying our understanding of carbohydrate biology and chemistry, we have rationally designed several high-potency, selective, small-molecule glycomimetic antagonists of galectin-3, including a potential candidate that has demonstrated oral bioavailability. In our preclinical studies, our galectin-3 antagonists have augmented antitumor activity of checkpoint inhibitors and prevented fibrosis following organ damage, which we believe makes them promising therapeutic targets for further evaluation and development.

### **Our Strategy**

Our goal is to be the leader in the discovery, development and commercialization of novel glycomimetic drugs to address unmet medical needs resulting from diseases in which carbohydrate biology plays a key role. Leveraging the potentially broad applicability of our proprietary glycomimetics platform, our initial focus is to internally develop and advance orphan drug candidates targeted at hematologic cancers and other diseases, and to out-license any drug candidates we may develop that are targeted at larger market opportunities. The key elements of our strategy are to:

- **Complete clinical development of and obtain regulatory approval for uproleselan for the treatment of adults with relapsed/refractory AML.** Building on positive Phase 1/2 clinical results, we recently completed enrollment in a randomized, double-blind, placebo-controlled Phase 3 clinical trial to evaluate uproleselan in adults with relapsed/refractory AML. Trial design was aligned with guidance received from the FDA. In this single pivotal trial, we enrolled 388 adult patients with relapsed or refractory AML at centers in the United States, Canada, Europe and Australia. Based on discussions with our external statisticians, we expect to report preliminary data from the trial after year-end 2022. If the results from this Phase 3 clinical trial are positive, we plan to apply for regulatory approval from the FDA and potentially the European Medicines Agency, or EMA.
- **Explore the potential use of uproleselan in other AML patient populations through third-party collaborations.** We are currently collaborating with the National Cancer Institute (NCI) on a Phase 2/3 clinical trial of uproleselan in previously untreated older adults with AML who are fit for intensive chemotherapy. Under the terms of our collaboration, the NCI may fund additional research, including clinical trials of pediatric patients with AML as well as preclinical experiments and clinical trials evaluating alternative chemotherapy regimens.
- **Expand the potential use of our E-selectin inhibitors (uproleselan and GMI-1687) in other select territories through out-licensing arrangements.** In January 2020, we entered into an exclusive collaboration and license agreement with Apollomics for the development and commercialization of uproleselan and GMI-1687 in Greater China. Apollomics will be responsible at its cost for clinical development and commercialization of uproleselan in Greater China, and will work with us to advance the preclinical and clinical development of GMI-1687. We have also entered into separate agreements to provide clinical and commercial supplies of uproleselan and GMI-1687 to Apollomics, and we retain all rights for both compounds in the rest of the world.

- **Advance the development of GMI-1687 for the treatment of acute VOC and hematologic malignancies.** We plan to develop our selectin inhibitors for the treatment of acute VOC in patients with SCD and as a life-cycle extension to uproleselan in additional hematologic malignancies. We are currently conducting IND-enabling activities with GMI-1687 to support our planned submission of an IND for the treatment of acute VOC to the FDA in the first half of 2022.
- **Seek to advance the clinical development of GMI-1359 for the treatment of cancers that affect the bone and bone marrow.** We have recently ended a Phase 1b trial of GMI-1359 in HR+ breast cancer patients whose tumors have spread to bone to evaluate dose escalation as well as safety, PK and PD markers of biologic activity. Based on activity levels observed in the trial, we are evaluating potential indications for future development where these overlapping functions of CXCR4 and e-selectin play key roles, as well as the funding requirement for any potential development opportunities.
- **Apply our insights and our glycomimetics platform to other carbohydrate targets beyond selectins.** We have identified additional opportunities where carbohydrates play critical roles in disease processes and where we believe we can apply our platform to create targeted glycomimetic drugs. We have designed inhibitors that specifically block the binding of galectin-3 to carbohydrate structures. We have identified a highly potent galectin-3 compound that could be administered orally and plan to conduct additional preclinical studies to further characterize the effects of galectin-3 inhibitors on inflammation and fibrosis, as well as immune processes.

### **Our Platform**

Our proprietary glycomimetics platform is based on our expertise in carbohydrate chemistry and our understanding of the role carbohydrates play in key biological processes. Carbohydrate structures on cell surfaces are responsible for complex carbohydrate-protein binding interactions. Inhibiting these binding interactions affects the functions of these proteins and their interactions with other molecules. We believe our expertise enables us to design specific glycomimetic molecules that can mimic carbohydrate structures and thereby inhibit their disease-related functions.

Our initial focus is on selectin antagonists, which we believe have the potential to address unmet medical needs in a number of orphan and large market opportunities. Selectins have been shown to play a key role in a wide range of diseases, including hematologic disorders, inflammatory diseases, infection, cancer and cardiovascular disease.

Our initial drug design efforts are focused on a naturally occurring, three-dimensional complex carbohydrate core structure known as the Lewis structure. This core structure is naturally modified in a variety of ways to form many different functional carbohydrates. These variations determine the biological functions of the carbohydrates, including functions related to conditions defined above. Accordingly, we believe that this structure provides the foundation for the design of glycomimetic drug candidates that could be used to address a variety of diseases.

Once we identify a carbohydrate structure involved in a disease pathway, we design molecules that mimic that carbohydrate structure and inhibit its disease-related functions by binding to the carbohydrate's target receptor, thereby blocking the binding by the native carbohydrate itself. For example, one of the naturally modified Lewis structures binds to selectins, which play a key role in adhesion of AML blasts to the vasculature of the bone marrow. Uproleselan mimics that carbohydrate structure and accordingly binds to selectins, which we believe thereby inhibits the adhesion of AML blasts and renders them more susceptible to killing with cytotoxic chemotherapies. In addition, our glycomimetic molecules are designed to have greater affinity to the carbohydrate's target receptor than does the native carbohydrate. This means that the glycomimetic molecules possess stronger intermolecular forces between themselves and the target receptors, and thus "outcompete" the native carbohydrates in binding to the relevant target receptors, thereby inhibiting their disease-related functions. Using our glycomimetics platform, we have designed and synthesized a proprietary library of these structures targeting different biological processes.

Our glycomimetics platform includes intellectual property, know-how, expertise, proprietary biological information and biochemical assays, all of which support the rational design of potent glycomimetic compounds. These include:

- Know-how to successfully mimic the Lewis structure, which is common to a number of functional carbohydrates.

- Use of empirical methods to determine critical interactions between variations of a particular functional carbohydrate and its target molecule.
- Application of the empirically determined bioactive structure of the functional carbohydrate for docking into the binding area of the crystal structure of the target molecule.
- Expertise in stabilizing the bioactive core of glycomimetic compounds and increasing the number of interaction contact points to improve affinity.
- Experience and technology in synthetic organic chemistry required for the specialized synthesis of carbohydrates and their modifications.
- Proprietary assays to determine the binding characteristics, inhibitory activity and biological activity of glycomimetic compounds.

### Our Pipeline

We have discovered our drug candidates internally through a rational drug design approach that couples our expertise in carbohydrate chemistry with our knowledge of carbohydrate biology. We are actively developing glycomimetic drug candidates based on this expertise. Our drug candidates and their target indications and development status are summarized in the chart below.



### Uproleselan —Targeting the Bone Marrow Microenvironment to Treat Hematologic Cancers

We are developing uproleselan, a specific E-selectin antagonist, to be used adjunctively with standard chemotherapy to treat AML and other hematologic cancers. We believe that uproleselan may be used as first-line treatment for elderly patients with AML or for patients with relapsed or refractory AML. Uproleselan targets interactions between cancer cells and the bone marrow microenvironment. In preclinical studies, combining uproleselan with chemotherapy made cancer cells more sensitive to chemotherapy. In other preclinical studies, uproleselan also reduced some of the toxic effects of chemotherapy, including neutropenia and mucositis, on normal cells.

Uproleselan received Orphan Drug designation from the FDA in 2015 for the treatment of patients with AML. In 2016, uproleselan received Fast Track designation from the FDA for the treatment of adult patients with relapsed or refractory AML and elderly patients aged 60 years or older with AML. In 2017, uproleselan received Breakthrough Therapy designation from the FDA for the treatment of adult patients with relapsed or refractory AML. In 2017, the European Commission, based on a favorable recommendation from the EMA Committee for Orphan Medicinal Products, granted Orphan Designation for uproleselan for the treatment of patients with AML. In January 2021, the China National Medical Products Administration Center for Drug Evaluation granted Breakthrough Therapy designation to uproleselan for the treatment of relapsed/refractory AML.

### **Acute Myeloid Leukemia**

AML, a hematologic cancer that is characterized by the rapid growth of abnormal white blood cells that accumulate in the bone marrow and interfere with the production of normal blood cells, is a relatively rare disease, but one that accounts for the largest number of annual deaths from leukemia in the United States. According to the Surveillance, Epidemiology, and End Results Program managed by the NCI, there were an estimated 20,240 new cases of AML diagnosed in 2021 in the United States. AML caused an estimated 11,400 deaths in 2021 in the United States.

AML is more commonly present in elderly patients, with a median age at diagnosis of 68 years old according to the NCI. In a review published in the *Journal of Clinical Oncology*, the median overall survival of patients 60 years old or older was nine months. The overall five-year relative survival rate for all AML patients from 2011 to 2017 was 29.5%. Relative survival is a statistical measure of net survival that is calculated by comparing observed survival with expected survival from a comparable set of people who do not have AML, in order to measure the excess mortality that is associated with the AML diagnosis.

A number of published studies indicate that only some AML patients who receive chemotherapy achieve a complete response, which is defined as the disappearance of all signs of AML, and that most patients with a complete response will eventually relapse. Patients who do not enter remission are referred to as refractory, meaning that they are resistant to the chemotherapy treatment.

We believe there is a need for new treatment options for elderly patients with AML, as well as those AML patients who relapse or develop refractory disease. Most AML patients with relapsed or refractory disease have limited established treatment options and, accordingly, may be referred for participation in clinical studies of potential new therapies. For patients who elect not to participate or are unable to participate, treatment options typically include chemotherapy regimens, hypomethylating agents and supportive care. Further, many elderly patients with AML are too frail to undergo chemotherapy as a result of other medical conditions, and may only be able to tolerate pain comfort or control measures. Without treatment, however, AML is uniformly fatal.

#### ***Role of E-selectin in AML***

E-selectin has been shown to play important roles in the progression of AML and its contribution to cell extrinsic chemoresistance. This has been observed in several studies, which have shown that levels of E-selectin correlate with tumor infiltration and relapse in AML. We therefore believe that our E-selectin antagonist, uproleselan, has the potential to improve the current treatment of patients with AML.

#### ***Uproleselan Preclinical Development***

Leukemia cells can bind to E-selectin in the bone marrow where they are relatively protected from the effects of chemotherapy. This phenomenon is now known as environment-mediated drug resistance, or EMDR. We believe that E-selectin inhibition disrupts the cell adhesion involved in EMDR and mobilizes blasts out of the bone marrow and into the bloodstream, making them more susceptible to chemotherapy. We believe that this mechanism of action may allow uproleselan to improve chemotherapy response rates, duration of remission and, ultimately, survival in patients with hematologic cancers such as AML.

In one in vivo study in a mouse model of AML, combining uproleselan with chemotherapy, mobilized AML blast cells and significantly reduced tumor burden as compared to treatment with chemotherapy alone. In an in vitro study, AML cells once bound to E-selectin were more resistant to chemotherapy. In a related study, when treated with uproleselan, the resistance of such cells to chemotherapy was reduced. Tumor cells of patients who have relapsed AML, when tested in the laboratory, bound significantly higher levels of E-selectin than tumor cells of patients at initial diagnosis. Additional preclinical studies in mouse models of AML, in which E-selectin was observed to be upregulated, suggest that AML cells binding to E-selectin have increased chemo-resistance. This is due to the induction of tumor cell survival signaling pathways as a consequence of E-selectin binding. This effect within the bone marrow microenvironment is unique to E-selectin as compared to other vascular adhesion molecules and can be blocked by uproleselan. The results of these preclinical studies were published in the journal *Nature Communications* in April 2020, and we believe the findings provide important information about how treatment with uproleselan may improve sensitivity to chemotherapy.

As uproleselan disrupts the interactions between cancer cells and bone marrow microenvironment, its mechanism of action is not limited to a single tumor type. In addition to our studies in AML, we have also tested the drug candidate

in other cancer models. In *in vivo* studies involving animal models of multiple myeloma, chronic myelogenous leukemia and acute lymphoblastic leukemia, uproleselan, as an adjunct to standard-of-care chemotherapy, decreased tumor burden and improved survival over chemotherapy alone.

In addition to its anti-tumor effects, uproleselan, in animal models, has shown protection against some of the toxicities of chemotherapy. In particular, animals treated with uproleselan in combination with chemotherapy had less severe neutropenia and mucositis and lower bone marrow toxicity as compared to animals treated with chemotherapy alone. We believe that treatment with uproleselan results in lower bone marrow toxicity due to its inhibition of E-selectin, thereby making hematopoietic stem cells divide less frequently and protecting them from chemotherapy agents that target rapidly dividing cells. Hematopoietic stem cells are blood cells that give rise to all other types of blood cells and are heavily concentrated in the bone marrow. Based on these reductions in some of the toxicities of chemotherapy, we are evaluating these effects as secondary efficacy endpoints in our clinical trials.

#### *Expanding the Utility of E-selectin antagonists*

At the 2018 annual ASH meeting, we reported on the preclinical development of a highly potent antagonist of E-selectin, GMI-1687, which demonstrated significant activity in animal models previously reported for uproleselan but at an approximately 1,000-fold lower dose. This level of activity was obtained following injections under the skin and could alleviate the need for intravenous infusions. Based on these compound characteristics, we believe GMI-1687 could potentially be used in outpatient settings where an E-selectin antagonist has therapeutic relevance. We are currently conducting IND-enabling studies of GMI-1687 and plan to file an IND in the first half of 2022.

In 2020, we reported on expanded preclinical studies with GMI-1687 in which the subcutaneous administration of GMI-1687 was effective in restoring blood flow in occluded blood vessels in two mouse models of SCD. We believe that these data support our planned development of GMI-1687 for subcutaneous use and self-administration with the potential for use in the early intervention of VOC.

#### ***Uproleselan Clinical Trials***

In 2014, we completed a Phase 1 trial of uproleselan in healthy volunteers. The single-site Phase 1 trial was a randomized, double-blind, placebo-controlled, single ascending intravenous dose trial. In the trial, we evaluated the safety, tolerability and PK of uproleselan. Twenty-eight healthy adult subjects were enrolled in cohorts to receive study drug at three dose levels. In the trial, we observed that the subjects tolerated uproleselan well, and that the PK for uproleselan was consistent with what was predicted based on preclinical data.

In 2015, we commenced a multinational Phase 1/2, open-label trial of uproleselan as an adjunct to standard chemotherapy in patients with AML. This trial in males and females with AML was conducted at a number of academic institutions in the United States, Ireland and Australia. The trial consisted of two parts. In the Phase 1 portion, escalation testing was performed to determine a recommended uproleselan dose in combination with standard chemotherapy to be used in the Phase 2 portion. In the Phase 2 portion of the trial, dose expansion was performed at the recommended dose of 10 mg/kg uproleselan in combination with standard chemotherapy. The primary objective of the trial was to evaluate the safety of uproleselan in combination with chemotherapy. Secondary objectives were to characterize PK and PD and to observe anti-leukemic activity. A total of 19 patients with relapsed or refractory AML were enrolled and dosed with a single cycle of treatment with uproleselan and chemotherapy in the Phase 1 portion of the trial. In the Phase 2 portion, one cohort of 25 patients over 60 years of age with newly diagnosed AML and a second cohort of 47 patients with relapsed or refractory AML were enrolled. Unlike in the Phase 1 portion, some of the patients in the Phase 2 portion were eligible to receive multiple cycles of uproleselan with chemotherapy.

In December 2018, we presented final efficacy and correlative results from the Phase 1/2 trial at the annual ASH meeting. Key highlights from the Phase 1/2 clinical data include the following:

- Relapsed/Refractory (R/R) AML Cohort: There were 66 patients in the R/R cohort, of which 54 were in the recommended Phase 2 dose (RP2D) group. At the RP2D, CR (complete remission)/CRi (complete remission with incomplete blood count recovery) rate was 41%, median overall survival, or OS, was 8.8 months (95% CI 5.7-11.4) and 69% of evaluable patients (11/16) achieved minimal residual disease, or MRD, negativity as assessed by either flow and/or DNA-based methods such as reverse transcription polymerase chain reaction (RT-PCR). OS will be the primary outcome measure in our ongoing Phase 3 trial in relapsed/refractory AML patients. In historical controls, OS of approximately 5.2-5.4 months has been observed in this population with this treatment approach. If we are able to achieve OS results in the Phase 3 trial comparable to those observed

in the Phase 1/2 clinical trial, it could be a significant improvement over the results observed in these historical controls.

- Newly Diagnosed AML Cohort: At the RP2D, CR/CRi rate was 72%, median overall survival was 12.6 months (95% CI 9.9-not reached), event-free survival (EFS) was 9.2 months (95% CI 3.0-12.6) and 56% of evaluable patients (5 out of 9) achieved MRD negativity as assessed by either flow and/or DNA-based methods such as RT-PCR. Of note, the EFS data (primary outcome measure for the interim analysis in the NCI-sponsored clinical trial in newly diagnosed AML patients) compares favorably to a range of 2.0-6.5 months for EFS in historical controls, which generally included lower risk patient populations than those treated in our Phase 1/2 trial.
- An analysis of E-selectin ligand expression on leukemic cells demonstrated that detectable levels were present on leukemic blasts for every patient tested, providing clinical evidence of biological relevance of the E-selectin ligand in this disease setting. In bone marrow samples, leukemic stem cell expression of E-selectin ligand correlated with leukemic blast E-selectin ligand expression ( $p < 0.0001$ ), consistent with the hypothesis that E-selectin-mediated interactions are a mechanism of chemoresistance. Additionally, investigators assessed the association between baseline E-selectin ligand expression on leukemic blasts and clinical outcomes using a log-rank test. In the R/R cohort of patients treated with uproleselan and evaluated for E-selectin ligand expression at baseline, this analysis demonstrated that  $\geq 10\%$  E-selectin ligand expression was correlated with prolonged survival ( $p < 0.01$ ) compared to  $< 10\%$  E-selectin ligand expression. We believe this observation is important because in patients not treated with uproleselan the scientific literature has instead observed that high levels of E-selectin ligand correlated with a worse clinical prognosis. The addition of uproleselan in our study appears to have reversed this trend toward worsened prognosis, and we believe this result may be achieved through the restoration of chemosensitivity.

Based on these results, we are conducting a randomized, double-blind, placebo-controlled Phase 3 clinical trial to evaluate uproleselan in individuals with relapsed/refractory AML, with a trial design aligned with guidance received from the FDA. The primary efficacy endpoint is overall survival, and the FDA has advised us that data on overall survival will not need to be censored for transplant in the primary efficacy analysis, meaning that patients who proceed to transplant will continue to be included as part of the survival analysis.

All patients are being treated with standard chemotherapy of either MEC (mitoxantrone, etoposide and cytarabine) or FAI (fludarabine, cytarabine and idarubicin), with approximately half of the patients randomized to receive uproleselan in addition to chemotherapy. Patients receiving uproleselan are dosed for one day prior to initiation of chemotherapy, twice a day through the chemotherapy regimen, and then for two days after the end of chemotherapy, which was the same schedule as in the Phase 2 portion of the Phase 1/2 trial. The dose regimen is fixed, rather than weight-based, which we believe simplifies administration, and we are offering up to three cycles of consolidation therapy in both arms of the trial for patients who achieve remission. We believe that multiple cycles of treatment in patients who respond may drive an even deeper response in patients treated with uproleselan. If this is the case, it could lengthen the duration of remission with potential for additional benefit on survival. Key secondary endpoints of the Phase 3 trial include the incidence of severe mucositis and remission rate, which will be assessed in a hierarchical fashion to provide supportive data.

Enrollment in this pivotal trial began in the fourth quarter of 2018, and we completed enrollment of the trial with a total of 388 patients in November 2021 at centers in the United States, Canada, Europe and Australia. Based on discussions with our external statisticians who are overseeing the results from the trial, we expect to report preliminary data from this trial after year-end 2022.

In 2018, we signed a CRADA with the NCI. Under the terms of the CRADA, we are collaborating with both the NCI and the Alliance for Clinical Trials in Oncology to conduct a Phase 2/3 randomized, controlled clinical trial testing the addition of uproleselan to a standard cytarabine/daunorubicin chemotherapy regimen (7&3) in older adults with previously untreated AML who are fit for intensive chemotherapy. Following completion of enrollment of the Phase 2 portion of the study, which occurred in December 2021, there will be an interim analysis of EFS. The full trial is expected to enroll approximately 670 patients with a primary endpoint is overall survival, which is defined as the time from the date of randomization to death from any cause. Under the terms of the CRADA, the NCI may also fund additional research, including clinical trials involving pediatric patients with AML as well as preclinical experiments and clinical trials evaluating alternative populations and chemotherapy regimens. We will supply uproleselan as well as

provide financial support to augment data analysis and monitoring for the Phase 2/3 program. Completion of enrollment now sets the stage for a planned evaluation of the Phase 2 portion of the trial to determine whether the prespecified threshold for continuing to Phase 3 has been met based on EFS results.

Uproleselan is also being studied in multiple investigator-sponsored trials (ISTs). In May 2021, clinicians at the Washington University School of Medicine in St. Louis dosed the first patient in a Phase 2 IST evaluating uproleselan as a prophylactic agent to reduce gastrointestinal (GI) toxicities and improve clinical outcomes in patients receiving high-dose melphalan in autologous hematopoietic cell transplantation (auto-HCT) for multiple myeloma. Up to 50 patients will be enrolled, and we anticipate a preliminary/interim data readout from the trial in 2022.

In July 2021, clinicians at the University of California (UC) Davis Comprehensive Cancer Center initiated dosing of the first patient in a clinical study of uproleselan combined with venetoclax and azacitidine for the treatment of older or unfit patients with treatment-naïve AML. The goal of the two-part IST is first to determine a recommended Phase 2 dose, and then to explore efficacy in a dose expansion cohort. We are providing uproleselan for the IST. Up to 31 patients will be enrolled, and a preliminary/interim readout is expected in 2022.

In July 2021, clinicians at the University of Texas MD Anderson Cancer Center treated the first patient in a Phase 1b/2 study evaluating uproleselan, added to cladribine plus low dose cytarabine, in patients with treated secondary AML (ts-AML). Considered a distinct high-risk subset of AML with an adverse prognosis, ts-AML is defined as AML arising from a previously treated antecedent myeloid neoplasm (myelodysplastic syndrome or myeloproliferative neoplasm). We are providing uproleselan for the IST. The Phase 1b/2 single-arm trial is enrolling patients 18 years or older, with a diagnosis of ts-AML who have not received therapy for their AML. Clinicians plan to enroll approximately 25 patients in the trial and a preliminary/interim readout is expected in 2022.

In November 2021, clinicians at the University of Michigan initiated dosing of the first patient in a clinical study of uproleselan in patients with severe COVID-19 pneumonia. Soluble E-selectin is a significant biomarker for acute respiratory distress syndrome (ARDS). Soluble E-selectin also has pro-inflammatory properties further releasing cytokines and promoting its synthesis and the continued influx of neutrophils. The goal of the study is to evaluate the safety of uproleselan in this patient population to determine if treatment with E-selectin inhibitors can reduce the progression of ARDS. Clinicians plan to enroll approximately 15 patients in the trial and a preliminary/interim readout is expected in 2022.

#### ***GMI-1359 - Drug Candidate Targeting E-selectin and CXCR4***

The chemokine CXCR4 has emerged as an important pro-inflammatory cytokine that is involved in cell migration throughout the body. Like E-selectin, tumor cells may also use the CXCR4 cellular pathway, contributing to chemoresistance, metastatic disease and ultimately decreased survival. We are developing GMI-1359 that simultaneously targets both E-selectin and CXCR4. Since E-selectin and CXCR4 are implicated in keeping cancer cells in the bone marrow, we believe that targeting both E-selectin and CXCR4 with a single compound could improve efficacy in the treatment of cancers that affect the bone marrow, such as hematologic cancers, including AML and multiple myeloma, metastases of certain solid tumors, such as breast and prostate cancer, and primary tumors of the bone such as osteosarcoma, a rare cancer affecting about 900 adolescents a year in the United States, as compared to targeting CXCR4 alone.

Leukemic cells and circulating tumor cells derived from adenocarcinomas home to and are retained in the bone marrow via defined sinusoidal vascular gateways that express E-selectin and soluble mediators such as C-X-C motif chemokine 12 (CXCL12, also known as stem cell-derived factor 1). This homing and retention occurs through an interaction with E-selectin ligands and the chemokine receptor for CXCL12, CXCR4, which is expressed on tumor cells. Interrupting E-selectin-mediated cell activation, adhesion and homing and CXCR4-mediated homing and cell migration and retention may be synergistic and could have therapeutic benefit in many malignancies with unmet medical need. We believe the use of an E-selectin/CXCR4 dual antagonist as an adjunct to chemotherapy and possibly immunotherapy could improve response and remission rates, remission duration, and, ultimately, survival, particularly in malignancies where bone involvement is a primary hallmark of cancer growth and metastasis.

In one in vivo mouse model of bone metastatic prostate carcinoma, combining GMI-1359 with docetaxel significantly reduced tumor burden and attenuated bone destruction compared to docetaxel alone. In two mouse models of primary osteosarcoma, administration of GMI-1359 resulted in inhibition of both tumor growth and spread to the lung.

These results were presented during the 2015 and 2018 meetings of the American Association of Cancer Research. In both mouse models, GMI-1359 showed single agent activity.

GMI-1359 has completed a Phase 1 single-dose escalation trial in healthy volunteers. In this trial, volunteer participants received a single injection of GMI-1359, after which they were evaluated for safety, tolerability, PK and PD. This randomized, double-blind, placebo-controlled, dose-escalation trial was conducted at a single site in the United States. GMI-1359 was generally well tolerated in this trial, with no subjects experiencing serious adverse events. We initiated a Phase 1b trial of GMI-1359 in the fourth quarter of 2019 at the Duke University Cancer Center in HR+ breast cancer patients whose tumors have spread to bone. The trial evaluated safety and PK and PD markers of biologic activity in these patients. The first patient was dosed in January 2020, and the trial ended in the fourth quarter of 2021. Evidence of on-target effects of GMI-1359 was observed in patients, including CD34+ mobilization and decreased soluble E-selectin levels following drug dosing. This data was presented during the 2021 meeting of the American Association of Cancer Research. In January 2020, the FDA granted GMI-1359 Orphan Drug designation and Rare Pediatric Disease designation for the treatment of osteosarcoma. Based on activity levels observed in the trial, we are evaluating potential indications for future development where these overlapping functions play key roles, as well as the funding requirement for any potential development opportunities.

### ***GMI-1687***

We have rationally designed an innovative antagonist of E-selectin, GMI-1687, that could be suitable for subcutaneous administration. Initially developed as a potential life-cycle extension to uproleselan, when given by subcutaneous injection in animal models, GMI-1687 has been observed to have equivalent activity to uproleselan, but at an approximately 1,000-fold lower dose. We believe that GMI-1687 could be developed to broaden the clinical usefulness of an E-selectin antagonist to conditions where outpatient treatment is preferred or required.

In September 2020 at the virtual meeting of the FSCDR, we gave an oral presentation on an abstract containing data on GMI-1687, which included data from a preclinical model showing the drug candidate's potential as a subcutaneously administered treatment for VOC, a common complication of SCD. We are currently conducting activities and studies with GMI-1687 to support our planned submission of an IND to the FDA in the first half of 2022.

### ***Galectin Inhibitors***

Using our glycomimetics platform, we have designed galectin-3 inhibitors that specifically block the binding of galectin-3 to carbohydrate structures. Galectin-3 is a protein that is known to play critical roles in many pathological processes, including fibrosis, checkpoints in T-cell exhaustion during cancer immunotherapy, chemotherapy resistance and cardiovascular disease. We continue to optimize these compounds and conduct additional preclinical experiments to further characterize the effects of our galectin-3 inhibitors on immune processes, fibrotic-associated disease progression and to determine if these compounds can be orally bioavailable. One such compound, GMI-2093, has been observed to be 30% bioavailable through oral administration. Another compound, GMI-1757, is a dual antagonist of both E-selectin and galectin-3 and inhibited thrombus formation in a vena cava model and fibrosis in a corneal neovascularization model. These results were presented at ASH in 2018.

### ***Our Collaboration and License Agreement with Apollomics for Uproleselan and GMI-1687***

In January 2020, we entered into an exclusive collaboration and license agreement with Apollomics for the development and commercialization of uproleselan and GMI-1687 for all fields and all uses in Greater China. Apollomics will be responsible for all clinical development and commercialization activities in Greater China. We and Apollomics will also collaborate to advance the preclinical and clinical development of GMI-1687. As part of the agreement, we received an upfront cash payment of \$9.0 million and will be eligible to receive potential milestone payments totaling approximately \$180.0 million based on the achievement of specified development, regulatory and commercial milestones, as well as tiered royalties ranging from the high single digits to 15% based on net sales. In September 2020, we received a non-refundable \$1.0 million development milestone payment upon acceptance by Chinese regulatory authorities of a Phase 3 bridging study design to support registration in China. Apollomics will be responsible for all costs related to development, regulatory approvals and commercialization in Greater China for

uproleselan and GMI-1687. We retain all rights for both compounds in the rest of the world and have agreed to supply uproleselan and GMI-1687 to Apollomics pursuant to clinical and commercial supply agreements.

In June 2020, we entered into a clinical supply agreement with Apollomics under which we will manufacture and supply uproleselan product to Apollomics at agreed upon prices. Apollomics has the option to begin manufacture after appropriate material transfer requirements are met.

In September 2020, the China National Medical Products Administration (NMPA) Center for Drug Evaluation (CDE) granted IND approval for uproleselan (also referred to as APL-106), enabling the initiation of a Phase 1 PK and tolerability study. The IND approval also includes acceptance of a Phase 3 bridging study of APL-106 in combination with chemotherapy in relapsed/refractory AML. In January 2021, APL-106 was granted Breakthrough Therapy designation from the China NMPA CDE for the treatment of relapsed/refractory acute myeloid leukemia. In March 2021, Apollomics enrolled the first patient in the Phase 1 study.

We and Apollomics have established a joint development committee to oversee activities under the collaboration and license agreement. The collaboration and license agreement will terminate on a region-by-region basis upon the expiration of the royalty term for each region, unless earlier terminated by either party. Either party may terminate the collaboration and license agreement upon prior written notice, subject to specified conditions, including uncured material breach, or upon bankruptcy or insolvency of the other party. Apollomics may terminate the collaboration and license agreement upon prior written notice for any reason.

### **Intellectual Property**

We strive to protect the intellectual property that we believe is important to our business, including seeking and maintaining patent protection intended to cover the composition of matter of our drug candidates and their methods of use. We have issued patents which cover uproleselan and methods of use that are expected to expire between 2032 and 2033. In addition, we have several pending patent applications covering uproleselan and/or methods of using it, the last expiring of which, if issued, currently would be predicted to expire in 2041. We also have an issued patent covering GMI-1359 and methods of use that is expected to expire in 2036. In addition, we have several pending patent applications covering GMI-1359 and/or methods of using it, the last expiring of which, if issued, currently would be predicted to expire in 2041. We also have an issued patent covering GMI-1687 that is expected to expire in 2037. In addition, we have several pending patent applications covering GMI-1687 and/or methods of using it, the last expiring of which, if issued, currently would be predicted to expire in 2041. We also have several pending patent applications directed to our lead galectin antagonist compounds and their methods of use, the last of which, if issued, currently would be predicted to expire in 2041. We also rely on trade secret protection for our confidential and proprietary information and careful monitoring of such information to protect aspects of our business.

Our success will depend significantly on our ability to obtain and maintain patent and other proprietary protection for commercially important inventions and know-how related to our business, defend and enforce our patents, preserve the confidentiality of our trade secrets and operate without infringing the valid and enforceable patents and other proprietary rights of third parties. We also rely on know-how and continuing technological innovation to develop, strengthen and maintain our proprietary position in the field of glycomimetics.

A third party may hold intellectual property, including patent rights that are important or necessary to the development of our drug candidates. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our drug candidates, in which case we would be required to obtain a license from these third parties. If we are not able to obtain such a license, or are not able to obtain such a license on commercially reasonable terms, our business could be materially harmed.

We plan to continue to expand our intellectual property estate by filing patent applications directed to additional glycomimetic compounds and their derivatives, compositions and formulations containing them and methods of using them. Additionally, we will seek patent protection in the United States and internationally for novel compositions of matter covering the compounds and their use in a variety of therapies.

The patent positions of biotechnology companies like us are generally uncertain and involve complex legal, scientific and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance, including where a reissue application is filed in relation to an issued patent to correct issues or errors arising during prosecution that may render claims of the issued patent either wholly or partially invalid or unenforceable. Consequently, we do not know whether any of our drug

candidates will be protectable or remain protected by enforceable patents. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. Any patents that we hold may be challenged, circumvented or invalidated by third parties.

Because patent applications in the United States and certain other jurisdictions are maintained in secrecy for 18 months, and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain of the priority of inventions covered by pending patent applications. Moreover, we may have to participate in interference proceedings declared by the U.S. Patent and Trademark Office, or USPTO, or a foreign patent office to determine priority of invention or in post-grant challenge proceedings, such as oppositions, that challenge priority of invention or other features of patentability. Such proceedings could result in substantial cost, even if the eventual outcome is favorable to us.

### **Manufacturing**

We do not have any manufacturing facilities or personnel. We currently rely, and expect to continue to rely, on third parties for the manufacturing of our drug candidates for preclinical and clinical testing, as well as for commercial manufacturing if our drug candidates receive marketing approval. We anticipate continuing to manage process development, scale-up and manufacturing under contracts with third parties. For uproleselan, we expect a significant increase in manufacturing as we prepare for potential regulatory filings for marketing approval.

All of our drug candidates are small molecules and are manufactured in reliable and reproducible synthetic processes from readily available starting materials. The chemistry does not require unusual equipment in the manufacturing process. We expect to continue to develop drug candidates that can be produced cost-effectively at contract manufacturing facilities.

### **Commercialization**

We have not yet established a sales, marketing or drug distribution infrastructure. We generally expect to retain commercial rights in the United States for our current drug candidates, all of which are still in preclinical or clinical development. We believe that it will be possible for us to access the U.S. market for those drug candidates through a focused, specialized, key account sales force. With respect to uproleselan and GMI-1687, we have granted Apollomics exclusive commercialization rights in Greater China, and we may grant similar rights to third parties for our drug candidates in other jurisdictions around the world.

Subject to receiving marketing approvals, we expect to commence commercialization activities by building or outsourcing a focused sales, marketing and key account management organization in the United States to sell our drugs. We believe that such an organization will be able to target the community of physicians who are the key specialists in treating the patient populations for which our drug candidates are being developed. Outside the United States, we expect to enter into distribution and other marketing arrangements with third parties for any of our drug candidates that obtain marketing approval.

We also plan to build a marketing and sales management organization to create and implement marketing strategies for any drugs that we market through our own sales organization and to oversee and support our sales force. The responsibilities of the marketing organization would include developing educational initiatives with respect to approved drugs and establishing relationships with thought leaders in relevant fields of medicine.

### **Competition**

The key competitive factors affecting the success of all of our drug candidates, if approved, are likely to be their safety, efficacy, convenience, price, the level of generic competition and the availability of coverage and reimbursement from government and other third-party payors.

As the treatment landscape for AML changes, there is substantial risk that uproleselan might not provide additional benefit over other existing therapies. A key consideration in the treatment of relapsed/refractory AML patients is the patient's suitability for intensive salvage chemotherapy. The patient population being studied in our ongoing Phase 3 clinical trial of uproleselan includes AML patients deemed able to tolerate salvage chemotherapy. While there is no commonly accepted single standard approach for salvage chemotherapy, existing options for the treatment of relapsed/refractory AML patients who can tolerate salvage chemotherapy include cytarabine-based combinations. In addition, we are aware of several other products and product candidates that are commercially available or are in

development as potential treatment options for AML patients. Some of the patient populations being studied for these product candidates in development overlap with the patient population being studied in our Phase 3 clinical trial of uproleselan. The existence of established treatment options and the development of competing therapies for relapsed/refractory AML patients could negatively impact our ability to successfully commercialize uproleselan.

The following therapies have been approved by the FDA for the treatment of AML:

- RYDAPT® (midostaurin), an oral prescription medicine commercialized by Novartis to be used in combination with certain chemotherapy medicines to treat adults with newly diagnosed AML who have a defect in a gene called FLT3;
- IDHIFA® (enasidenib), a prescription medicine commercialized by Celgene intended to treat people with AML with an isocitrate dehydrogenase-2 (IDH2) mutation whose disease has come back or has not improved after previous treatments;
- VYXEOS™ (daunorubicin and cytarabine), commercialized by Jazz Pharmaceuticals, which is indicated for the treatment of adults with newly-diagnosed therapy-related AML (t-AML) or AML with myelodysplasia-related changes (AML-MRC);
- MYLOTARG™ (gemtuzumab ozogamicin), commercialized by Pfizer, which is indicated for the treatment for the treatment of newly-diagnosed CD33-positive AML in adults (in combination with daunorubicin and cytarabine) and for treatment of relapsed or refractory CD33-positive AML in adults and in pediatric patients aged 2 years and older as a stand-alone treatment;
- TIBSOVO® (ivosidenib), a prescription medicine commercialized by Agios intended to treat people with AML with an isocitrate dehydrogenase-1 (IDH1) mutation whose disease has come back or has not improved after previous treatments;
- XOSPATA® (gilteritinib), an oral prescription medicine commercialized by Astellas intended to treat people with AML with a FLT3 gene mutation whose disease has come back or has not improved after previous treatments;
- DAURISMO (glasdigib), an oral prescription medicine commercialized by Pfizer to be used in combination with low-dose cytarabine, for the treatment of newly-diagnosed AML in adult patients who are ≥75 years old or who have comorbidities that preclude use of intensive induction chemotherapy;
- VENCLEXTA® (venetoclax), an oral prescription medicine commercialized by AbbVie/Genentech to be used in combination with azacitidine, or decitabine, or low-dose cytarabine to treat adults with newly-diagnosed AML who are either 75 years of age or older, or have other medical conditions that prevent the use of standard chemotherapy; and
- ONUREG® (Azacitidine), an oral prescription medicine for continued treatment of adult patients with AML who achieved CR or CRi following intensive induction chemotherapy and are not able to complete intensive curative therapy.

While many chemotherapies and targeted therapies, either approved or in development for hematologic malignancies, will likely be complementary to uproleselan, there are also therapies in development that could be directly competitive with uproleselan. In particular, Pfizer has recently initiated Phase 1 development of an E-selectin antibody (PF-07209326). While the initial target indication for this biologic is SCD, it is possible Pfizer could expand development to AML and other hematologic malignancies. Additionally, there are a number of CXCR4 antagonists in clinical development that target the bone marrow microenvironment in order to mobilize and sensitize cancer cells to chemotherapy or other therapies, including candidates developed by Sanofi-Aventis (Mozobil), Bristol Myers Squibb (BMS-936564), NOXXON Pharma (NOX-A12), Eli Lilly (LY2510924) and BioLine RX (BL-8040).

Many of the companies against which we are competing, or against which we may compete in the future, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early stage companies may also prove to be significant

competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

### **Government Regulation and Product Approval**

Government authorities in the United States, at the federal, state and local levels, and in other countries, extensively regulate, among other things, the research, development, testing, manufacture, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, import and export of pharmaceutical products, such as those we are developing. The processes for obtaining regulatory approvals in the United States and in foreign countries, along with subsequent compliance with applicable statutes and regulations, require the expenditure of substantial time and financial resources.

#### ***United States Government Regulation***

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable United States requirements at any time during the drug development process, approval process or after approval, may subject an applicant to a variety of administrative or judicial sanctions, such as the FDA's refusal to approve pending new drug applications, or NDAs, withdrawal of an approval, imposition of a clinical hold, issuance of warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties.

The process required by the FDA before a drug may be marketed in the United States generally involves:

- completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's good laboratory practice, or GLP, regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, at each clinical site before each trial may be initiated;
- performance of human clinical trials, including adequate and well-controlled clinical trials, in accordance with good clinical practices, or GCP, to establish the safety and efficacy of the proposed drug for each indication;
- submission to the FDA of an NDA;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with current good manufacturing practices, or cGMP, and to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity, as well as satisfactory completion of an FDA inspection of selected clinical sites to determine GCP compliance; and
- FDA review and approval of the NDA.

#### ***Preclinical Studies***

Preclinical studies include laboratory evaluation of product chemistry, toxicity and formulation, as well as animal studies to assess potential safety and efficacy. An IND sponsor must submit the results of the preclinical studies, together with manufacturing information, analytical data and any available clinical data or literature, among other things, to the FDA as part of an IND. Some preclinical testing may continue even after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

### *Clinical Trials*

Clinical trials involve the administration of the investigational new drug to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, an IRB at each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must continue to oversee the clinical trial while it is being conducted. Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health, or NIH, for public dissemination on their ClinicalTrials.gov website.

Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined. In Phase 1, the drug is initially introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an initial indication of its effectiveness. In Phase 2, the drug typically is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage. In Phase 3, the drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the safety and efficacy of the product for approval, to establish the overall risk-benefit profile of the product and to provide adequate information for the labeling of the product.

Progress reports detailing the results of the clinical trials must be submitted, at least annually, to the FDA, and more frequently if serious adverse events occur. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements, or if the drug has been associated with unexpected serious harm to patients.

A sponsor may request a Special Protocol Assessment, or SPA, the purpose of which is to reach agreement with the FDA on the Phase 3 clinical trial protocol design and analysis that will form the primary basis of an efficacy claim. According to the FDA's published guidance on the SPA process, a sponsor that meets the prerequisites may make a specific request for an SPA and provide information regarding the design and size of the proposed clinical trial. The FDA is supposed to evaluate the protocol within 45 days of the request to assess whether the protocol design and planned analysis of the trial are acceptable to support regulatory approval of the product candidate with respect to effectiveness of the indication studied, and that evaluation may result in discussions and a request for additional information. An SPA request must be made before the proposed trial begins, and all open issues must be resolved before the trial begins for an SPA to be approved. If a written agreement is reached, it will be documented in an SPA letter or the minutes of a meeting between the sponsor and the FDA and made part of the administrative record.

Even if the FDA agrees to the design, execution and analyses proposed in protocols reviewed under the SPA process, the FDA may revoke or alter its agreement under the following circumstances:

- public health concerns emerge that were unrecognized at the time of the protocol assessment, or the director of the review division determines that a substantial scientific issue essential to determining safety or efficacy has been identified after testing has begun;
- a sponsor fails to follow a protocol that was agreed upon with the FDA; or
- the relevant data, assumptions, or information provided by the sponsor in a request for SPA change are found to be false statements or misstatements, or are found to omit relevant facts.

A documented SPA may be modified, and such modification will be deemed binding on the FDA review division, except under the circumstances described above, if the FDA and the sponsor agree in writing to modify the protocol and such modification is intended to improve the study. An SPA, however, does not guarantee that a trial will be successful.

### *Marketing Approval*

Assuming successful completion of the required clinical testing, the results of the preclinical and clinical studies, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the product for one or more indications. In most cases, the submission of an NDA is subject to a substantial application user fee. Under the Prescription Drug User Fee Act, or PDUFA, guidelines that are currently in effect, the FDA has agreed to certain performance goals regarding the timing of its review of an application.

In addition, under the Pediatric Research Equity Act, an NDA or supplement to an NDA must contain data that are adequate to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan designation.

The FDA also may require submission of a risk evaluation and mitigation strategy, or REMS, plan to mitigate any identified or suspected serious risks. The REMS plan could include medication guides, physician communication plans, assessment plans and elements to assure safe use, such as restricted distribution methods, patient registries or other risk minimization tools.

The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA reviews an NDA to determine, among other things, whether the drug is safe and effective and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, quality and purity.

The FDA typically refers questions regarding novel drugs to an external advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical trial sites to assure compliance with GCP.

The testing and approval process for an NDA requires substantial time, effort and financial resources, and could take several years to complete. Data obtained from preclinical and clinical testing are not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The FDA may not grant approval of an NDA on a timely basis, or at all.

After evaluating the NDA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a complete response letter. A complete response letter generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA and may require additional clinical or preclinical testing in order for the FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

### *Special FDA Expedited Review and Approval Programs*

The FDA has various programs, including fast track designation, accelerated approval, priority review, and breakthrough therapy designation, which are intended to expedite or simplify the process for the development and the FDA review of drugs that are intended for the treatment of serious or life threatening diseases or conditions and demonstrate the potential to address unmet medical needs. The purpose of these programs is to provide important new drugs to patients earlier than under standard FDA review procedures.

To be eligible for a fast track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need. The FDA will determine that a product will fill an unmet medical need if it will provide a therapy where none exists or provide a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. The FDA may review sections of the NDA for a fast track product on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

The FDA may give a priority review designation to drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists. A priority review means that the goal for the FDA to review an application is six months, rather than the standard review of ten months under current PDUFA guidelines. These six and ten month review periods are measured from the “filing” date rather than the receipt date for NDAs for new molecular entities, which typically adds approximately two months to the timeline for review and decision from the date of submission. Most products that are eligible for fast track designation are also likely to be considered appropriate to receive a priority review.

In addition, products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may be eligible for accelerated approval and may be approved on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require a sponsor of a drug receiving accelerated approval to perform post-marketing studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoint, and the drug may be subject to accelerated withdrawal procedures.

A sponsor can also request designation of a product candidate as a “breakthrough therapy.” A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs designated as breakthrough therapies are also eligible for accelerated approval. The FDA must take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. We may explore some of these opportunities for our product candidates as appropriate.

### *Post-Approval Requirements*

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications, manufacturing changes or other labeling claims, are subject to further testing requirements and prior FDA review and approval. There also are continuing annual user fee requirements for any marketed products, as well as application fees for supplemental applications with clinical data.

Even if the FDA approves a product, it may limit the approved indications for use of the product, require that contraindications, warnings or precautions be included in the product labeling, including a boxed warning, require that

post-approval studies, including Phase 4 clinical trials, be conducted to further assess a drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms under a REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market.

Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in mandatory revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Although physicians, in the practice of medicine, may prescribe approved drugs for unapproved indications, pharmaceutical companies generally are required to promote their drug products only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. However, physicians may, in their independent medical judgment, prescribe legally available products for off-label uses. The FDA does not regulate the behavior of physicians in their choice of treatments but the FDA does restrict manufacturer's communications on the subject of off-label use of their products.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution.

#### *Federal and State Fraud and Abuse, Data Privacy and Security, and Transparency Laws and Regulations*

In addition to FDA restrictions on marketing of pharmaceutical products, federal and state healthcare laws and regulations restrict business practices in the biopharmaceutical industry. These laws include, but are not limited to, anti-kickback and false claims laws and regulations, data privacy and security, and transparency laws and regulations.

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for or

recommending the purchase, lease or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term “remuneration” has been broadly interpreted to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers and formulary managers on the other. Although there are a number of statutory exemptions and regulatory safe harbors protecting some common activities from prosecution, the exemptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Several courts have interpreted the statute’s intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated.

The reach of the federal Anti-Kickback Statute was also broadened by the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively PPACA, which, among other things, amended the intent requirement of the federal Anti-Kickback Statute such that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act or the civil monetary penalties statute, which imposes penalties against any person or entity who is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

Federal false claims laws, including the federal civil False Claims Act, prohibit any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. A claim includes “any request or demand” for money or property presented to the U.S. government. Pharmaceutical and other healthcare companies have been prosecuted under these laws for, among other things, allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Companies also have been prosecuted for causing false claims to be submitted because of the companies’ marketing of products for unapproved, and thus non-reimbursable, uses. The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created additional federal criminal statutes that prohibit, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Also, many states have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

In addition, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their respective implementing regulations, including the Final HIPAA Omnibus Rule published on January 25, 2013, imposes specified requirements on certain types of individuals and entities relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA’s security standards directly applicable to “business associates,” defined as independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney’s fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which are not pre-empted by HIPAA, differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners) and

teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by the physicians and their immediate family members.

We may also be subject to state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, as well as state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures.

Because of the breadth of these laws and the narrowness of available statutory and regulatory exemptions, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the federal and state laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including administrative, criminal and significant civil monetary penalties, damages, fines, disgorgement, imprisonment, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm, diminished profits and future earnings, disgorgement, exclusion from participation in government healthcare programs and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. To the extent that any of our products are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

#### *Coverage and Reimbursement*

The future commercial success of our drug candidates or any of our collaborators' ability to commercialize any approved drug candidates successfully will depend in part on the extent to which governmental payor programs at the federal and state levels, including Medicare and Medicaid, private health insurers and other third-party payors provide coverage for and establish adequate reimbursement levels for our drug candidates. Government health administration authorities, private health insurers and other organizations generally decide which drugs they will pay for and establish reimbursement levels for healthcare. In particular, in the United States, private health insurers and other third-party payors often provide reimbursement for products and services based on the level at which the government, through the Medicare or Medicaid programs, provides reimbursement for such treatments. In the United States, the European Union, or EU, and other potentially significant markets for our drug candidates, government authorities and third party payors are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which often has resulted in average selling prices lower than they would otherwise be. Further, the increased emphasis on managed healthcare in the United States and on country and regional pricing and reimbursement controls in the EU will put additional pressure on product pricing, reimbursement and usage, which may adversely affect our future product sales and results of operations. These pressures can arise from rules and practices of managed care groups, judicial decisions and laws and regulations related to Medicare, Medicaid and healthcare reform, pharmaceutical coverage and reimbursement policies and pricing in general.

Third-party payors are increasingly imposing additional requirements and restrictions on coverage and limiting reimbursement levels for medical products. For example, federal and state governments reimburse covered prescription drugs at varying rates generally below average wholesale price. These restrictions and limitations influence the purchase of healthcare services and products. Third-party payors may limit coverage to specific drug products on an approved list, or formulary, which might not include all of the FDA-approved drug products for a particular indication. Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain the FDA approvals. Our drug candidates may not be considered medically necessary or cost-effective. A payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a drug product does not assure that other payors will also provide coverage for the drug product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in drug development. Legislative proposals to reform healthcare or reduce costs under government insurance programs may result in lower reimbursement for our drugs and drug candidates or exclusion of our drugs and drug candidates from coverage. The cost containment measures that healthcare payors and providers are instituting and any healthcare reform could significantly reduce our

revenues from the sale of any approved drug candidates. We cannot provide any assurances that we will be able to obtain and maintain third party coverage or adequate reimbursement for our drug candidates in whole or in part.

*Impact of Healthcare Reform on our Business*

The United States and some foreign jurisdictions are considering enacting or have enacted a number of additional legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts, which include major legislative initiatives to reduce the cost of care through changes in the healthcare system, including limits on the pricing, coverage, and reimbursement of pharmaceutical and biopharmaceutical products, especially under government-funded health care programs, and increased governmental control of drug pricing.

There have been several U.S. government initiatives over the past few years to fund and incentivize certain comparative effectiveness research, including creation of the Patient-Centered Outcomes Research Institute under PPACA. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payors, it is not clear what effect, if any, the research will have on the sales of any product, if any such product or the condition that it is intended to treat is the subject of a study. It is also possible that comparative effectiveness research demonstrating benefits in a competitor's product could adversely affect the sales of our product candidates. If third-party payors do not consider our drug candidates to be cost-effective compared to other available therapies, they may not cover our drug candidates, once approved, as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our drugs on a profitable basis. PPACA became law in March 2010 and substantially changed the way healthcare is financed by both governmental and private insurers. Among other measures that may have an impact on our business, PPACA established an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents; a new Medicare Part D coverage gap discount program; and a new formula that increases the rebates a manufacturer must pay under the Medicaid Drug Rebate Program. Additionally, PPACA extends manufacturers' Medicaid rebate liability, expands eligibility criteria for Medicaid programs, and expands entities eligible for discounts under the Public Health Service pharmaceutical pricing program. There remain judicial and Congressional challenges to certain aspects of PPACA, as well as efforts by the executive branch at various times to repeal or replace certain aspects of the PPACA.

Since January 2017, two Executive Orders were signed that were designed to delay the implementation of any certain provisions of the PPACA or otherwise circumvent some of the requirements for health insurance mandated by the PPACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the PPACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the PPACA have been signed into law. The Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the PPACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the PPACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. The Bipartisan Budget Act of 2018, or the BBA, among other things, amended the ACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." For example, on June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how any such challenges and healthcare reform measures of the Biden administration will impact ACA and our business.

In addition, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed

federal and proposed and enacted state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration used several means to propose implementing drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that seek to implement several of the administration's proposals. As a result, the FDA released a final rule and guidance on September 24, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the U.S. Department of Health and Human Services finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed pending review by the Biden administration until January 1, 2023. On November 20, 2020, the Centers for Medicare & Medicaid Services, or CMS, issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries. As a result of litigation challenging the Most Favored Nation model, on December 27, 2021, CMS published a final rule that rescinded the Most Favored Nation model interim final rule. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. No legislation or administrative actions have been finalized to implement these principles. In addition, Congress is considering drug pricing as part of other reform initiatives. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

As a result of PPACA, Medicare payments are increasingly tied to quality of care and value measures, and reporting of related data by providers such as physicians and hospitals. So called "value based reimbursement" measures may present challenges as well as potential opportunities for biopharmaceutical manufacturers. Medicare incentives for providers meeting certain quality measures may ultimately prove beneficial for manufacturers that are able to establish that their products may help providers to meet such measures. However, manufacturers' ability to market their drug products based on quality or value is highly regulated and not always permissible. In addition, the potentially decreased Medicare reimbursement to those providers that fail to adequately comply with quality reporting requirements could translate to decreased resources available to purchase products and may negatively impact marketing or utilization of our drug candidates if they are approved for marketing. We cannot predict at this time what impact, if any, the longer-term shift towards value based reimbursement will have on any of our drug candidates in either the Medicare program, or in any other third party payor programs that may similarly tie payment to provider quality.

In addition, other legislative changes have been proposed and adopted since PPACA was enacted. In August 2011, the President signed into law the Budget Control Act of 2011, as amended, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee on Deficit Reduction did not achieve its targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reductions to several government programs. These reductions include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which began in 2013 and, following passage of the Bipartisan Budget Act of 2015, will continue through 2031, except for a temporary suspension from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic, unless additional Congressional action is taken. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 3% in the final fiscal year of this sequester. On March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover

overpayments to providers from three to five years. Additional legislative proposals to reform healthcare and government insurance programs, along with the trend toward managed healthcare in the United States, could influence the purchase of medicines and reduce reimbursement and/or coverage of our product candidates, if approved.

#### *Exclusivity and Approval of Competing Products*

##### *Hatch-Waxman Patent Listing*

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent with claims that cover the applicant's product or a method of using the product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors in support of approval of an abbreviated new drug application, or ANDA, or 505(b)(2) NDA. Generally, an ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths, dosage form and route of administration as the listed drug and has been shown to be bioequivalent through *in vitro* or *in vivo* testing or otherwise to the listed drug. ANDA applicants are not required to conduct or submit results of preclinical or clinical tests to prove the safety or efficacy of their drug product, other than the requirement for bioequivalence testing. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug, and can often be substituted by pharmacists under prescriptions written for the original listed drug. 505(b)(2) NDAs generally are submitted for changes to a previously approved drug product, such as a new dosage form or indication.

The ANDA or 505(b)(2) NDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book, except for patents covering methods of use for which the ANDA applicant is not seeking approval. Specifically, the applicant must certify with respect to each patent that:

- the required patent information has not been filed;
- the listed patent has expired;
- the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or
- the listed patent is invalid, unenforceable or will not be infringed by the new product.

Generally, the ANDA or 505(b)(2) NDA cannot be approved until all listed patents have expired, except when the ANDA or 505(b)(2) NDA applicant challenges a listed drug. A certification that the proposed product will not infringe the already approved product's listed patents or that such patents are invalid or unenforceable is called a Paragraph IV certification. If the applicant does not challenge the listed patents or indicate that it is not seeking approval of a patented method of use, the ANDA or 505(b)(2) NDA application will not be approved until all the listed patents claiming the referenced product have expired.

If the ANDA or 505(b)(2) NDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the application has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the receipt of notice of the Paragraph IV certification automatically prevents the FDA from approving the ANDA or 505(b)(2) NDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the ANDA applicant.

##### *Hatch-Waxman Non-Patent Exclusivity*

Market and data exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications for competing products. The FDCA provides a five-year period of non-patent data exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the activity of the drug substance. During the exclusivity period, the FDA may not accept for review an ANDA or a 505(b)(2) NDA submitted by another company that contains the previously approved active moiety. However, an ANDA or 505(b)(2) NDA may be submitted after four years if it contains a certification of patent invalidity or noninfringement.

The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA or 505(b)(2) NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant, are deemed by the FDA to be essential to the approval of the application or supplement. Three-year exclusivity may be awarded for changes to a previously approved drug product, such as new indications, dosages, strengths or dosage forms of an existing drug. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and, as a general matter, does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for generic versions of the original, unmodified drug product. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

#### *Orphan Drug Exclusivity*

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a drug or biological product available in the United States for this type of disease or condition will be recovered from sales of the product. Orphan designation must be requested before submitting an NDA or biologics license application. Orphan designation does not convey any advantage in or shorten the duration of the regulatory review and approval process. We have received Orphan Drug designation for uproleselan and GMI-1359, as well as for our prior drug candidate rivipansel, and we intend to seek Orphan Drug designation and exclusivity for our other drug candidates whenever it is available.

If a product that has orphan designation subsequently receives the first FDA approval for such drug for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug or biological product for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity. Competitors, however, may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. If a drug or biological product designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan product exclusivity. Orphan drug status in the EU has similar, but not identical, benefits.

#### *Pediatric Exclusivity*

Pediatric exclusivity is another type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity, including the non-patent and orphan drug exclusivity periods described above. This six-month exclusivity may be granted if an NDA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or Orange Book listed patent protection cover the drug are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve an ANDA or 505(b)(2) application owing to regulatory exclusivity or listed patents. If any of our drug candidates is approved, we anticipate seeking pediatric exclusivity when it is appropriate.

#### **Foreign Regulation**

In order to market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our drug candidates. For example, in the EU, we must obtain authorization of a clinical trial application, or CTA, in each member state in which we intend to conduct a clinical trial. Whether or not we obtain FDA approval for a drug, we would need to obtain the necessary approvals by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the drug in those countries. The approval process varies from country to country and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country does not ensure regulatory

approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others.

### **Employees and Human Capital Resources**

As of December 31, 2021, we had 52 employees, all of whom are full-time and located in the United States. None of our employees is represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees. The principal purposes of our equity incentive plans are to attract, retain and reward high performing employees through the granting of equity-based compensation awards in order to increase shareholder value and the success of our company by motivating employees to perform to the best of their abilities and achieve our company objectives. We monitor our compensation, benefits, and exit interview data and make changes as needed to enable the ongoing recruitment and selection of talented new employees, as well as to retain existing talent. Our Core Values underpin our mission on how we build our drug development pipeline, and how we establish relationships with employees, patients, healthcare providers, researchers and stakeholders.

### **Legal Proceedings**

We are not currently a party to any material legal proceedings, and we are not aware of any pending or threatened legal proceeding against us that we believe could have a material adverse effect on our business, operating results or financial condition.

### **Corporate Information**

We were incorporated under the laws of the State of Delaware in April 2003 and commenced operations in May 2003. Our principal executive offices are located at 9708 Medical Center Drive, Rockville, Maryland 20850. Our telephone number is (240) 243-1201.

“GlycoMimetics,” the GlycoMimetics logo and other trademarks or service marks of GlycoMimetics, Inc. appearing in this Annual Report are the property of GlycoMimetics, Inc. This Annual Report contains additional trade names, trademarks and service marks of others, which are the property of their respective owners.

### **Available Information**

Our internet website address is [www.glycomimetics.com](http://www.glycomimetics.com). In addition to the information contained in this Annual Report, information about us can be found on our website. Our website and information included in or linked to our website are not part of this Annual Report.

Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, are available free of charge through our website as soon as reasonably practicable after they are electronically filed with or furnished to the Securities and Exchange Commission, or SEC. Additionally the SEC maintains an internet site that contains reports, proxy and information statements and other information. The address of the SEC’s website is [www.sec.gov](http://www.sec.gov).

## ITEM 1A. RISK FACTORS

*Our business is subject to numerous risks. You should carefully consider the following risks, as well as general economic and business risks, and all of the other information contained in this Annual Report, together with any other documents we file with the SEC. Any of the following risks could have a material adverse effect on our business, operating results and financial condition and cause the trading price of our common stock to decline.*

### **Risks Related to Our Financial Position and Capital Needs**

***We have incurred significant losses since our inception. We expect to continue to incur losses over the next several years and may never achieve or maintain profitability.***

We have incurred significant losses since our inception in 2003 and, as of December 31, 2021, we had an accumulated deficit of \$372.9 million. In recent years, we have financed our operations with proceeds from registered public offerings of our common stock and upfront and milestone payments under our license and collaboration agreements.

We have devoted substantially all of our financial resources and efforts to research and development, including preclinical studies and clinical trials. We are still in the early stages of development of our drug candidates, and we have not completed development of any drugs. We expect to continue to incur significant expenses and operating losses over the next several years. Our net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially and our negative cash flows from operating activities will continue over the next 12 months and beyond as we:

- conduct our ongoing clinical trials and initiate additional clinical trials of our drug candidates, including the completion of our planned Phase 3 clinical trial of uproleselan;
- continue the research and preclinical development of our drug candidates;
- seek to discover and develop additional drug candidates;
- seek regulatory approvals for any drug candidates that successfully complete clinical trials;
- ultimately establish a sales, marketing and distribution infrastructure and scale up external manufacturing capabilities to commercialize any drugs for which we may obtain regulatory approval;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, quality control, regulatory and scientific personnel;
- add operational, financial and management information systems and personnel, including personnel to support our drug development and planned future commercialization efforts; and
- incur legal, accounting, insurance and other expenses in operating as public company.

To become and remain profitable, we must succeed in developing and eventually commercializing drugs that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our drug candidates, obtaining regulatory approval for these drug candidates and manufacturing and commercializing any drugs for which we may obtain regulatory approval, as well as discovering additional drug candidates. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenue that is significant enough to achieve profitability.

In the case of uproleselan and GMI-1687, our ability to generate revenue is partially dependent upon the achievement of development, regulatory and commercial milestones and sales sufficient to generate royalties under our license agreement with Apollomics, and the achievement of such milestones is largely out of our control. If Apollomics fails, or chooses not to continue, to further develop, to seek regulatory approval for or to commercialize uproleselan in Greater China, our ability to generate revenue with respect to uproleselan may be significantly reduced or eliminated.

Because of the numerous risks and uncertainties associated with drug development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. If we are

required by regulatory authorities to perform studies in addition to those currently expected, or if there are any delays in completing our clinical trials or the development of any of our drug candidates, our expenses could increase.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts or even continue our operations. A decline in the value of our company could also result in significant harm to our financial position and adversely affect our stock price.

***We will need substantial additional funding to pursue our business objectives. If we are unable to raise capital when needed, we may not be able to continue as a going concern and could be forced to delay, reduce or eliminate our drug development programs or potential commercialization efforts.***

We believe that our cash and cash equivalents as of December 31, 2021 will enable us to fund our operating expenses and capital expenditure requirements into the second quarter of 2023. However, we will need to obtain substantial additional funding in connection with our continuing operations. Our future capital requirements will depend on many factors, including:

- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our drug candidates;
- the number and development requirements of other drug candidates that we may pursue;
- the costs, timing and outcome of regulatory review of our drug candidates;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our drug candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sales of our drug candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims; and
- the extent to which we acquire or in-license other drug candidates and technologies.

Our management must periodically evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern. Based on our current cash position, our ongoing significant operating losses and the fact that we do not have any committed sources of revenue or cash flows other than potential payments from our license and collaboration agreements, management believes that, given our current cash position, there is substantial doubt about our ability to continue as a going concern beyond the date that is one year from the date that the financial statements included in this Annual Report were issued.

Identifying potential drug candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we or any current or future collaborators may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. In addition, our drug candidates, if approved, may not achieve commercial success. Our commercial revenue, if any, will be derived from the sale of drugs that we do not expect to be commercially available for several years, if at all. Accordingly, our ability to fund our operations is dependent upon management's plans, which include raising additional capital in the near term primarily through a combination of equity and debt financings, collaborations and strategic alliances. There can be no assurances that new financings or other transactions will be available to us on commercially acceptable terms, or at all. Our ability to raise additional capital may also be adversely impacted by global economic conditions and disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic. If we are unable to raise capital to fund our operations when needed or on attractive terms, we could be forced to delay, reduce the scope of or eliminate our research and development programs or any future commercialization efforts, which would have a material adverse effect on our business, financial condition, results of operations and ability to operate as a going concern.

***Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our drug candidates.***

Until such time, if ever, as we can generate substantial revenue from the sale of our drugs, we expect to finance our cash needs through a combination of equity offerings, debt financings and license and development agreements. We do not currently have any committed external source of funds other than possible milestone payments and possible royalties under our license agreement with Apollomics. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that could adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our research programs or drug candidates or grant licenses on terms that may not be favorable to us or that may be at less than the full potential value of such rights. If we are unable to raise additional funds through equity or debt financings or other arrangements with third parties when needed, we may be required to delay, limit, reduce or terminate our drug development or future commercialization efforts or grant rights to third parties to develop and market drug candidates that we would otherwise prefer to develop and market ourselves.

***Our operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.***

We commenced operations in 2003, and our operations to date have been largely focused on raising capital, developing our expertise in carbohydrate chemistry and knowledge of carbohydrate biology, identifying potential drug candidates, undertaking preclinical studies and conducting clinical trials. We have not yet demonstrated our ability to successfully complete later stage clinical trials, obtain regulatory approvals, manufacture a commercial scale drug, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization.

We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. We will need to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

We expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance

***Our ability to use net operating losses to offset future taxable income may be subject to limitations.***

As of December 31, 2021, we had federal and state net operating loss carryforwards of \$290.0 million, research and development tax credit carryforwards of \$10.3 million and \$37.7 million of orphan drug tax credit carryforwards. The federal and state net operating loss carryforwards will begin to expire, if not utilized, beginning in 2026, the research and development tax credits in 2023 and the orphan drug tax credit in 2033. These net operating loss and tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under federal income tax laws, federal net operating losses incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an “ownership change,” which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation’s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We could experience ownership changes in the future that would limit our ability to use our net operating loss carryforwards.

## **Risks Related to the Discovery and Development of Our Drug Candidates**

***Our research and development is focused on discovering and developing novel glycomimetic drugs, and we are taking an innovative approach to discovering and developing drugs, which may never lead to marketable drugs.***

A key element of our strategy is to use and expand our platform to build a pipeline of novel glycomimetic drug candidates and progress these drug candidates through clinical development for the treatment of a variety of diseases. The discovery of therapeutic drugs based on molecules that mimic the structure of carbohydrates is an emerging field, and the scientific discoveries that form the basis for our efforts to discover and develop drug candidates are relatively new. The scientific evidence to support the feasibility of developing drug candidates based on these discoveries is both preliminary and limited. Although our research and development efforts to date have resulted in a pipeline of glycomimetic drug candidates, we may not be able to develop drug candidates that are safe and effective. Even if we are successful in continuing to build our pipeline, the potential drug candidates that we identify may not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be drugs that will receive marketing approval and achieve market acceptance. If we do not successfully develop and commercialize drug candidates based upon our glycomimetics platform, we will not be able to obtain product revenue in future periods, which likely would result in significant harm to our financial position and adversely affect our stock price.

***We have only one drug candidate in a late-stage clinical trial. All of our other drug candidates are still in Phase 1 clinical trials or in preclinical development. If we or our collaborators are unable to commercialize our drug candidates or experience significant delays in doing so, our business will be materially harmed.***

Uproleselan is our only drug candidate that is in a Phase 2 or Phase 3 clinical trial. Our other drug candidates are still in Phase 1 clinical trials or in preclinical development. We have not completed the development of any drug candidates, we currently generate no revenue from the sale of any drugs and we may never be able to develop a marketable drug. We have invested substantially all of our efforts and financial resources in the development of our glycomimetics platform, the identification of potential drug candidates using that platform and the development of our drug candidates. Our ability to generate revenue from our other drug candidates, which we do not expect to occur for many years, if ever, will depend heavily on their successful development and eventual commercialization. The success of those drug candidates will depend on several factors, including:

- successful completion of preclinical studies and clinical trials;
- receipt of marketing approvals from applicable regulatory authorities;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our drug candidates;
- making arrangements with third-party manufacturers for, or establishing, commercial manufacturing capabilities;
- launching commercial sales of the drugs, if and when approved, whether alone or in collaboration with others;
- acceptance of the drugs, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- obtaining and maintaining healthcare coverage and adequate reimbursement;
- protecting our rights in our intellectual property portfolio; and
- maintaining a continued acceptable safety profile of the drugs following approval.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our drug candidates, which would materially harm our business.

***Clinical drug development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our drug candidates.***

The risk of failure of our drug candidates is high. It is impossible to predict when or if any of our drug candidates will prove safe or effective in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any drug candidate, we or a collaborator must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of the drug candidate in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of development. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. In addition, changes in patient treatment options over time may make the relevance of historical control data for a given indication less relevant to the drug candidate being studied, which could impact the success of the trial or, even if successful, the desirability of a successful drug candidate versus other available treatment options. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their drug candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their drugs.

We or our current or future collaborators may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our or their ability to receive marketing approval or commercialize our drug candidates, including:

- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- clinical trials of our drug candidates may produce negative or inconclusive results, including failure to demonstrate statistical significance, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon drug development programs;
- the number of patients required for clinical trials of our drug candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our drug candidates may be greater than we anticipate;
- the supply or quality of our drug candidates or other materials necessary to conduct clinical trials of our drug candidates may be insufficient or inadequate; and
- our drug candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or institutional review boards to suspend or terminate the trials.

If we are required to conduct additional clinical trials or other testing of our drug candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our drug candidates or other testing, if the results of these clinical trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our drug candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;

- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements; or
- have the drug removed from the market after obtaining marketing approval.

Our drug development costs will also increase if we experience delays in testing or marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant preclinical study or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our drug candidates or allow our competitors to bring drugs to market before we do, and thereby impair our ability to successfully commercialize our drug candidates.

***Our business could be adversely affected by the effects of health epidemics or pandemics, including the ongoing COVID-19 pandemic, in regions where we or third parties on whom we rely have significant manufacturing facilities, clinical trial sites or other business operations.***

Our business could be adversely affected by health epidemics or pandemics in regions where we have concentrations of clinical trial sites or other business operations, and could cause significant disruption in the operations of third-party collaborators, manufacturers and CROs upon whom we rely.

In response to the ongoing COVID-19 pandemic, in 2020 we implemented a work-from-home policy for most of our employees, and we have recently adopted a hybrid home-office work policy. The effects of our policy may negatively impact productivity, disrupt our business and delay our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, operating results and financial condition.

Quarantines, shelter-in-place, stay-at-home, executive and similar government orders—or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur—related to COVID-19 or other infectious diseases, could impact personnel at third-party manufacturing facilities in the United States and other countries, or the availability or cost of materials, which would disrupt our supply chain. For example, any manufacturing supply interruption of uproleselan, which is currently manufactured at facilities in Switzerland and China, could adversely affect our ability to conduct ongoing and future clinical trials of uproleselan.

In addition, our clinical trials may be affected by the COVID-19 pandemic due to prioritization of hospital resources toward the COVID-19 pandemic. Some patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, the pandemic may impact our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 and adversely impact our clinical trial operations.

The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by, and the duration of, the COVID-19 pandemic may be difficult to assess or predict, a further prolonged pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity.

The global pandemic of COVID-19 continues to rapidly evolve. The ultimate impact of the COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, healthcare systems or the global economy as a whole. However, these effects could have a material impact on our operations, and we will continue to monitor the situation closely.

***If serious adverse or unacceptable side effects are identified during the development of our drug candidates, we may need to abandon or limit the development of some of our drug candidates.***

If our drug candidates are associated with undesirable side effects in clinical trials or have characteristics that are unexpected, we may need to abandon their development or limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Many drug candidates that initially showed promise in early stage testing have later been found to cause side effects that prevented their further development.

***We may expend our limited resources to pursue a particular drug candidate or indication and fail to capitalize on drug candidates or indications that may be more profitable or for which there is a greater likelihood of success.***

Because we have limited financial and management resources, we focus on a limited number of research programs and drug candidates. As a result, we may forego or delay pursuit of opportunities with other drug candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial drugs or profitable market opportunities. Our spending on current and future research and development programs and drug candidates for specific indications may not yield any commercially viable drugs. If we do not accurately evaluate the commercial potential or target market for a particular drug candidate, we may relinquish valuable rights to that drug candidate through collaboration, licensing or other arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights.

#### **Risks Related to Our Dependence on Third Parties**

***Our success depends in part on current and future collaborations. If we are unable to maintain any of these collaborations, or if these collaborations are not successful, our business could be adversely affected.***

We have limited capabilities for drug development and do not yet have any capabilities for sales, marketing or distribution. We cannot assure you that our current or future collaborators will develop our drug candidates in a timely manner, or at all, or, if regulatory approval for a drug candidate is achieved, that such collaborator will successfully commercialize the candidate.

Any collaborations we might enter into may pose a number of risks, including:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue the commercialization of any drug candidates that achieve regulatory approval or may elect not to pursue, continue or renew development or commercialization of drug candidates based on clinical trial results, changes in such collaborators' strategic focus or available funding or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a drug candidate, repeat or conduct new clinical trials or require a new formulation of a drug candidate for clinical testing;
- collaborators could experience delays in initiating or conducting clinical trials for any number of reasons;
- collaborators could independently develop, or develop with third parties, drugs that compete directly or indirectly with our drugs or drug candidates if such collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- drug candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own drug candidates or drugs, which may cause such collaborators to cease to devote resources to the commercialization of our drug candidates;
- a collaborator with marketing and distribution rights to one or more of our drug candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such drug or drugs;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of drug candidates, might lead to additional responsibilities for us with respect to drug candidates or might result in litigation or arbitration, any of which would be time consuming and expensive;
- collaborators may not properly maintain or defend our or their intellectual property rights or may use our or their proprietary information in such a way as to invite litigation that could jeopardize or invalidate such intellectual property or proprietary information or expose us to potential litigation;

- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable drug candidates.

If any collaborations we might enter into do not result in the successful development and commercialization of drugs, or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. For example, in February 2020, Pfizer terminated its license agreement with us for the worldwide development and commercialization of our prior drug candidate rivipansel, thereby eliminating our right to receive any future development or commercialization milestones or royalty payments for sales of that drug candidate. In addition, even if we are eligible to receive any such payments from a collaborator, they could be substantially delayed. If we do not receive the funding we expect under these agreements, the development of our drug candidates could be delayed and we may need additional resources to develop our drug candidates. All of the risks relating to drug development, regulatory approval and commercialization described in this report also apply to the activities of our collaborators.

If a current or future collaborator of ours is involved in a business combination, the collaborator might deemphasize or terminate development or commercialization of any drug candidate licensed to it by us. If one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our reputation in the business and financial communities could be adversely affected. We may in the future determine to collaborate with pharmaceutical and biotechnology companies for their development and potential commercialization of our drug candidates. We face significant competition in seeking appropriate collaborators. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of a collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a drug candidate, reduce or delay its development or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our drug candidates or bring them to market, which would impair our business prospects.

***We expect to rely on third parties to conduct our future clinical trials for drug candidates, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.***

We have engaged a third-party contract research organization, or CRO, to conduct our ongoing and planned clinical trials for uproleselan and expect to engage CROs with respect to any of our other drug candidates that may progress to clinical development. We expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct those clinical trials. Agreements with such third parties might terminate for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements, that would delay our drug development activities.

Our reliance on these third parties for research and development activities will reduce our control over these activities, but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as good clinical practices, or GCPs, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and significant civil and criminal sanctions.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or

conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our drug candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our drug candidates.

We also expect to rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our drug candidates or commercialization of our drugs, producing additional losses and depriving us of potential revenue.

***We contract with third parties for the manufacturing of our drug candidates for preclinical and clinical testing and expect to continue to do so for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our drug candidates or drugs, or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.***

We do not have any manufacturing facilities or personnel. We rely, and expect to continue to rely, on third parties for the manufacturing of our drug candidates for preclinical and clinical testing, as well as for commercial manufacture if any of our drug candidates receives marketing approval. Disruption to our supply arrangements may arise from unforeseeable events that impact such third parties, including the ongoing COVID-19 pandemic. Our reliance on third parties increases the risk that we will not have sufficient quantities of our drug candidates or drugs, or such quantities at an acceptable cost or quality, which could delay, prevent or impair our ability to timely conduct our clinical trials or our other development or commercialization efforts.

We also expect to rely on third-party manufacturers or third-party collaborators for the manufacturing of commercial supply of any other drug candidates for which we or our collaborators obtain marketing approval. We may be unable to establish any agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or non-renewal of the agreement by the third party at a time that is costly or inconvenient for us.

Third-party manufacturers may not be able to comply with current good manufacturing practices, or cGMP, regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of drug candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our drugs.

In addition, in the event that any of our third-party manufacturers fails to comply with such requirements or to perform its obligations to us in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to manufacture the materials ourselves, for which we currently do not have the capabilities or resources, or enter into an agreement with another third party, which we may not be able to do on commercially reasonable terms, if at all. We do not currently have arrangements in place for redundant supply or a second source for bulk drug substance. If our current contract manufacturers cannot perform as agreed, we may be required to replace such manufacturers and we may incur added costs and delays in identifying and qualifying any such replacement. Any replacement of our manufacturers could require significant effort and expertise because there may be a limited number of qualified replacements. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop our drug candidates in a timely manner or within budget.

Our current and anticipated future dependence upon others for the manufacturing of our drug candidates or drugs may adversely affect our future profit margins and our ability to commercialize any drugs that receive marketing approval on a timely and competitive basis.

***We, or our third-party manufacturers, may be unable to successfully scale-up manufacturing of our drug candidates in sufficient quality and quantity, which would delay or prevent us from conducting our ongoing and planned clinical trials and developing our drug candidates.***

In order to conduct our ongoing and planned clinical trials of our drug candidates, we will need to manufacture them in large quantities. We, or our manufacturing partners, may be unable to successfully increase the manufacturing capacity for any of our drug candidates in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities. If we or our manufacturing partners are unable to successfully scale up the manufacture of our drug candidates in sufficient quality and quantity, the development, testing and clinical trials of that drug candidate may be delayed or become infeasible, and marketing approval or commercial launch of any resulting drug may be delayed or not obtained, which could significantly harm our business.

#### **Risks Related to the Commercialization of Our Drug Candidates**

***Even if any of our drug candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.***

If any of our drug candidates receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If our drug candidates do not achieve an adequate level of acceptance, we may not generate significant revenue from drug sales and we may not become profitable. The degree of market acceptance of our drug candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and potential advantages compared to alternative treatments;
- our ability to offer our drugs for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our drugs together with other medications.

***If we are unable to establish sales, marketing and distribution capabilities for our drug candidates, we may not be successful in commercializing those drug candidates if and when they are approved.***

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of pharmaceutical drugs. To achieve commercial success for any drug candidate for which we may obtain marketing approval, we will need to establish a sales and marketing organization to market or co-promote such drugs. There are risks involved with establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a drug candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our drugs on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future drugs;
- the lack of complementary drugs to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more products; and

- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we are unable to establish our own sales, marketing and distribution capabilities and enter into arrangements with third parties to perform these services, our revenue and our profitability, if any, are likely to be lower than if we were to sell, market and distribute any drugs that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute our drug candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our drugs effectively. If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our drug candidates.

***We face substantial competition, which may result in others discovering, developing or commercializing drugs before or more successfully than we do.***

The development and commercialization of new drugs is highly competitive. We face competition with respect to our current drug candidates, and we will face competition with respect to any drug candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies, biotechnology companies, academic institutions, governmental agencies and public and private research institutions. Should any competitors' drug candidates receive regulatory or marketing approval prior to ours, they may establish a strong market position and be difficult to displace or diminish the need for our drug candidates.

The key competitive factors affecting the success of all of our drug candidates, if approved, are likely to be their safety, efficacy, convenience, price, the level of generic competition and the availability of coverage and reimbursement from government and other third-party payors. As described above under "Business—Competition," we expect that our drug candidates will compete with approved therapies and those currently in development by other companies. To the extent that competitive drugs or drug candidates developed by others are successful in treating our target indications, it could reduce the market opportunity for our drug candidates.

Many of the companies against which we are competing, or against which we may compete in the future, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize drugs that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any drugs that we may develop. Our competitors also may obtain FDA or other regulatory approval for their drugs more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

In addition, because we have no patents with respect to our glycomimetics platform, our competitors may use our methods, or acquire similar expertise, in order to develop glycomimetic drug candidates and progress these drug candidates through clinical development and commercialization, which could impair our ability to successfully commercialize our drug candidates or otherwise limit our commercial opportunities.

***Even if we or our collaborators are able to commercialize any of our drug candidates, the drugs may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies.***

Our and our collaborators' ability to commercialize any of our drug candidates successfully will depend, in part, on the extent to which coverage and adequate reimbursement for these drugs and related treatments will be available from government payor programs at the federal and state levels authorities, including Medicare and Medicaid, private health insurers, managed care plans and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement

for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for drugs. Coverage and reimbursement may not be available for any drug that we or our collaborators commercialize and, even if these are available, the level of reimbursement may not be satisfactory. Inadequate reimbursement levels may adversely affect the demand for, or the price of, any drug candidate for which we or our collaborators obtain marketing approval. Obtaining and maintaining adequate reimbursement for our drugs may be difficult. We may be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement relative to other therapies. If coverage and adequate reimbursement are not available or reimbursement is available only to limited levels, we or our collaborators may not be able to successfully commercialize any drug candidates for which marketing approval is obtained.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the indications for which the drug is approved by the FDA or similar regulatory authorities outside the United States. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution expenses. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. However, one payor's determination to provide coverage for a drug does not assure that other payors will also provide coverage for the drug. Our or our collaborators' inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved drugs that we develop could adversely affect our operating results, our ability to raise capital needed to commercialize drugs and our overall financial condition.

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drugs vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we or our collaborators might obtain marketing approval for a drug in a particular country, but then be subject to price regulations that delay commercial launch of the drug, possibly for lengthy time periods, and negatively impact our ability to generate revenue from the sale of the drug in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more drug candidates, even if our drug candidates obtain marketing approval.

There can be no assurance that our drug candidates, if they are approved for sale in the United States or in other countries, will be considered medically reasonable and necessary for a specific indication, that they will be considered cost-effective by third-party payors, that coverage or an adequate level of reimbursement will be available or that third-party payors' reimbursement policies will not adversely affect our ability to sell our drug candidates profitably if they are approved for sale.

***Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any drugs that we may develop.***

We face an inherent risk of product liability exposure related to the testing of our drug candidates in human clinical trials, and will face an even greater risk if we commercially sell any drugs that we may develop. If we cannot successfully defend ourselves against claims that our drug candidates or drugs caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any drug candidates or drugs that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;

- substantial monetary awards paid to trial participants or patients;
- loss of revenue;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize any drugs that we may develop.

We carry clinical trial insurance coverage in an amount that we believe is sufficient in relation to our clinical trials being conducted in the United States and in foreign countries where we have or plan to have sites as part of our clinical trials for uproleselan. The use of our drug candidates in clinical trials may result in liability claims for which our current insurance would not be adequate to cover all liabilities that we may incur. In addition, we may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our drug candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

#### **Risks Related to Our Intellectual Property**

***If we are unable to obtain and maintain patent protection for our drug candidates, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize drug candidates similar or identical to ours, and our ability to successfully commercialize our drug candidates may be impaired.***

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our drug candidates. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our drug candidates.

The patent prosecution process is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. We may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the rights to patents licensed to third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States, or vice versa. For example, European patent law restricts the patentability of methods of treatment of the human body more than U.S. law does. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or, in some cases, not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued that protect our drug candidates, in whole or in part, or which effectively prevent others from commercializing competitive drug candidates. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The U.S. Patent and Trademark Office recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

Moreover, we may be subject to a third-party preissuance submission of prior art to the U.S. Patent and Trademark Office, or become involved in opposition, derivation, reexamination, *inter partes* review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our drug candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize drugs without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future drug candidates.

Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patents by developing similar or alternative drug candidates in a non-infringing manner.

In addition, the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical drug candidates, or limit the duration of the patent protection of our drug candidates. Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing drugs similar or identical to ours.

***We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful.***

Competitors may infringe our issued patents or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly.

***We may need to license intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.***

A third party may hold intellectual property, including patent, rights that are important or necessary to the development of our drug candidates. It may be necessary for us to use patented or proprietary technology of third parties to commercialize our drug candidates, in which case we would be required to obtain a license from these third parties on commercially reasonable terms, or our business could be harmed, possibly materially.

***Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.***

Our commercial success depends upon our ability, and the ability of our collaborators, to develop, manufacture, market and sell our drug candidates without infringing the proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our drug candidates, including interference or derivation proceedings before the U.S. Patent and Trademark Office. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future.

If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our drug candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing drug. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our drug candidates or force us to cease some of our business

operations. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

***We may be subject to claims by third parties asserting that we or our employees have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.***

Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these employees or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims.

In addition, while it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our and their assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management.

***Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.***

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

***If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.***

In addition to seeking patents for our drug candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. For example, our platform is based on trade secrets that consist largely of expertise in carbohydrate chemistry and knowledge of carbohydrate biology. We do not believe that we can obtain patent protection for our platform. Thus, our competitors may use our methods, or acquire similar expertise, in order to develop glycomimetic drug candidates and progress these drug candidates through clinical development and commercialization, which could impair our ability to successfully commercialize our drug candidates.

We seek to protect our trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

## **Risks Related to Regulatory Approval of Our Drug Candidates and Other Legal Compliance Matters**

***If we or our collaborators are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we or they will not be able to commercialize our drug candidates and our ability to generate revenue will be materially impaired.***

Our drug candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by the EMA and similar regulatory authorities outside the United States. Failure to obtain marketing approval for a drug candidate will prevent us or our collaborators from commercializing the drug candidate. We have not received approval to market any of our drug candidates from regulatory authorities in any jurisdiction. We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party CROs to assist us in this process. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the drug candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, applicable regulatory authorities. Our drug candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our ability to obtain marketing approval or prevent or limit commercial use. If any of our drug candidates receives marketing approval, the accompanying label may limit the approved use of our drug, which could limit sales of the drug.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive and may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the drug candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations or changes in regulatory review for each submitted drug application may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application, or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a drug candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved drug not commercially viable.

If we experience delays in obtaining approval or if we fail to obtain approval of our drug candidates, the commercial prospects for our drug candidates may be harmed and our ability to generate revenue will be materially impaired.

***Even though we have obtained Orphan Drug designation for several of our drug candidates, we may not be able to obtain orphan drug marketing exclusivity for these or any of our other drug candidates.***

Regulatory authorities in some jurisdictions, including the United States and the European Union, or EU, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States. We have obtained Orphan Drug designation from the FDA for uproseselan for the treatment of AML, as well as for GMI-1359 for the treatment of osteosarcoma. However, in order to obtain marketing exclusivity in a particular jurisdiction, we must receive the first marketing approval of the drug for its intended indication. In addition, the orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process.

Generally, if a drug with an orphan designation subsequently receives the first marketing approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the FDA or the EMA from approving another marketing application for the same drug for the same indication for that time period. The applicable period is seven years in the United States and 10 years in the EU. The EU exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or the EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

Even if we obtain orphan drug exclusivity for a drug candidate, that exclusivity may not effectively protect the candidate from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve another drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

***The FDA fast track designation and additional breakthrough therapy designation for uproleselan may not actually lead to a faster development or regulatory review or approval process.***

If a drug is intended for the treatment of a serious or life-threatening disease or condition and the drug demonstrates the potential to address unmet medical needs for this disease or condition, the drug sponsor may apply for the FDA fast track designation. If fast track designation is obtained, the FDA may initiate review of sections of a new drug application, or NDA, before the application is complete. This “rolling review” is available if the applicant provides, and the FDA approves, a schedule for submission of the individual sections of the application.

Although we have obtained a fast track designation from the FDA for uproleselan to treat AML and breakthrough therapy designation for uproleselan to treat AML, we may not experience a faster development process, review or approval compared to conventional FDA procedures. Our fast track designation may be withdrawn by the FDA if it believes that the designation is no longer supported by data from our clinical development programs. Our fast track designation does not guarantee that we will qualify for or be able to take advantage of the expedited review procedures or that we will ultimately obtain regulatory approval of uproleselan.

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

In order to market and sell our drugs in the EU and any other jurisdictions, we or our collaborators 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 drug be approved for reimbursement before it can be approved for sale in that country. We or our collaborators 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. However, failure to obtain approval in one jurisdiction may impact our ability to obtain approval elsewhere. We or our collaborators may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our drugs in any market.

***A variety of risks associated with developing and marketing our drug candidates internationally could hurt our business.***

We or our collaborators may seek regulatory approval for uproleselan and our other drug candidates outside of the United States and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including:

- differing regulatory requirements in foreign countries;
- the potential for so-called parallel importing, which is what happens when a local seller, faced with high or higher local prices, opts to import goods from a foreign market with low or lower prices rather than buying them locally;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations related to doing business in another country;

- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the Foreign Corrupt Practices Act or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from pandemic, epidemic or disease outbreaks or geo-political actions, including war and terrorism.

Pursuant to the terms of our collaboration and license agreement, Apollomics is responsible for the clinical development and commercialization of uproleselan and GMI-1687 in Greater China. The continuation of COVID-19 in China could have a material adverse effect on Apollomics' ability to develop these drug candidates in a timely manner due to disruptions in the region, travel restrictions, temporary closures of businesses and suspension of services and supplies. Any such delay or disruptions in clinical development could result in the delay of any potential milestone payments to us under the license and collaboration agreement, which could have a material adverse effect on our financial position and results of operations.

***Any drug candidate for which we obtain marketing approval could be subject to post-marketing restrictions or recall or withdrawal from the market, and we may therefore be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our drug candidates, when and if any of them are approved.***

Any drug candidate for which we obtain marketing approval, along with manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such drug candidate, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. Even if marketing approval of a drug candidate is granted, the approval may be subject to limitations on the indicated uses for which the drug may be marketed or to the conditions of approval, including the requirement to implement a risk evaluation and mitigation strategy. If any of our drug candidates receives marketing approval, the accompanying label may limit the approved use of our drug, which could limit its sales.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the drug. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use, and if we do not market our drugs for their approved indications, we may be subject to enforcement action for off-label marketing. Violations of the Federal Food, Drug, and Cosmetic Act relating to the promotion of prescription drugs may lead to investigations alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws.

In addition, later discovery of previously unknown adverse events or other problems with our drugs, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may have negative consequences, including:

- restrictions on such drugs, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a drug;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters;

- recall or withdrawal of the drugs from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- clinical holds;
- fines, restitution or disgorgement of revenue or profit;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our drugs;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

Non-compliance with the EU requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of drugs for the pediatric population, can also result in significant financial penalties. Similarly, failure to comply with the EU's requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

***Our current and future business and relationships with customers and third-party payors in the United States and elsewhere may be subject, directly or indirectly, to applicable anti-kickback, fraud and abuse, false claims, transparency, health information privacy and security and other healthcare laws and regulations, which could expose us to significant penalties, including criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.***

Healthcare providers and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any drug candidates for which we obtain marketing approval. Our current and future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, which may constrain the business or financial arrangements and relationships through which we conduct clinical research, sell, market and distribute any drugs for which we obtain marketing approval. In addition, we may be subject to transparency laws and patient data privacy and security regulation by the U.S. federal and state governments and by governments in foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal healthcare programs, such as Medicare and Medicaid;
- federal civil and criminal false claims laws, including the federal False Claims Act, which impose criminal and civil penalties, including civil whistleblower or qui tam actions, and civil monetary penalty laws that prohibit individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose obligations on covered healthcare providers, health plans, and healthcare clearinghouses, as well as their business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal Open Payments program, pursuant to the Physician Payments Sunshine Act, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to “payments or other transfers of value” made to physicians, which is defined to include doctors, dentists, optometrists, podiatrists and chiropractors, other healthcare professionals (such as physician assistants and nurse practitioners) and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by the physicians and their immediate family members, with disclosure of such information to be made by CMS on a publicly available website; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state and local laws requiring the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, individual imprisonment, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm, diminished profits and future earnings, disgorgement, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, which could have a material adverse effect on our business. If any of the physicians or other healthcare providers or entities with whom we expect to do business, including our collaborators, is found not to be in compliance with applicable laws, it may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government healthcare programs, which could also materially affect our business.

***Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our drug candidates and affect the prices we may obtain.***

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our drug candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any drug candidates for which we obtain marketing approval.

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts, which include major legislative initiatives to reduce the cost of care through changes in the healthcare system, including limits on the pricing, coverage, and reimbursement of pharmaceutical and biopharmaceutical products, especially under government-funded health care programs, and increased governmental control of drug. In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively PPACA, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, improve quality of care, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

Among the provisions of PPACA of importance to our business and potential drug candidates are:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers and enhanced penalties for non-compliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for a manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- the new requirements under the federal Open Payments program and its implementing regulations;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

There remain judicial and Congressional challenges to certain aspects of PPACA, as well as efforts by the Trump administration to repeal or replace certain aspects of the PPACA. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the PPACA or otherwise circumvent some of the requirements for health insurance mandated by the PPACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the PPACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017, or Tax Act, included a provision which repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the PPACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". In addition, the 2020 federal spending package permanently eliminates, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. The Bipartisan Budget Act of 2018, or the BBA, among other things, amended the ACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." For example, on June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA.

It is unclear how any such challenges and healthcare reform measures of the Biden administration will impact ACA and our business.

In addition, other legislative changes have been proposed and adopted since PPACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which began in 2013, pursuant to the Budget Control Act of 2011. On March 1, 2013, the President signed an executive order implementing the 2% Medicare payment reductions, and on April 1, 2013, these reductions went into effect. Pursuant to the Bipartisan Budget Act of 2015, these reductions will stay in effect through 2031, except for a temporary suspension from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic, unless additional Congressional action is taken. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 3% in the final fiscal year of this sequester. On March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Additional legislative proposals to reform healthcare and government insurance programs, along with the trend toward managed healthcare in the United States, could influence the purchase of medicines and reduce reimbursement and/or coverage of our product candidates, if approved.

Current and future healthcare reform measures may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved drug. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payors. There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration used several means to propose implementing drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that seek to implement several of the administration's proposals. As a result, the FDA released a final rule and guidance on September 24, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the U.S. Department of Health and Human Services finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed pending review by the Biden administration until January 1, 2023. On November 20, 2020, the Centers for Medicare & Medicaid Services, or CMS, issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries. As a result of litigation challenging the Most Favored Nation model, on December 27, 2021, CMS published a final rule that rescinded the Most Favored Nation model interim final rule. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. No legislation or administrative actions have been finalized to implement these principles. In addition, Congress is considering drug pricing as part of other reform initiatives. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our drugs.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for drugs. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our drug candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's

approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

***Governments outside the United States tend to impose strict price controls, which may adversely affect our revenue, if any.***

In some countries, particularly in the EU, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a drug. To obtain coverage and reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our drug candidate to other available therapies. If reimbursement of our drugs is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

***If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.***

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

#### **Risks Related to Employee Matters and Managing Our Growth**

***Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.***

We are highly dependent on the management, research and development, clinical, financial and business development expertise of Harout Semerjian, our President and Chief Executive Officer; John Magnani, our Senior Vice President of Research and Chief Scientific Officer; Armand Girard, our Senior Vice President and Chief Business Officer; and Brian Hahn, our Senior Vice President of Finance and Chief Financial Officer, as well as the other members of our scientific and clinical teams. In particular, we are dependent upon Dr. Magnani for key expertise in carbohydrate chemistry and knowledge of carbohydrate biology with respect to our glycomimetics platform, and the loss of his services would materially impair our future drug discovery efforts. Although we have entered into employment agreements with our executive officers, each of them may currently terminate their employment with us at any time. We do not maintain "key person" insurance for any of our executives or employees.

Recruiting and retaining qualified scientific and clinical personnel and, if we progress the development of our drug pipeline toward scaling up for commercialization, sales and marketing personnel, will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval for and commercialize our drug candidates. Competition to hire qualified personnel in our industry is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar

personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

***We expect to expand our development and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.***

As our development progresses, we expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of research, drug development, regulatory affairs and, if any of our drug candidates receives marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

***Our employees and employees of our collaborators may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.***

We and our collaborators are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with the FDA regulations, to provide accurate information to the FDA, to comply with manufacturing standards we have established, to comply with federal and state healthcare fraud and abuse laws and regulations, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent improper activities may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, or any such actions are instituted against any of our collaborators, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions and diminished royalties.

#### **General Risks Related to Ownership of Our Common Stock**

***An active trading market for our common stock may not be sustained.***

Although our common stock is listed on The Nasdaq Global Market, we cannot assure you that an active trading market for our shares will be sustained. If an active market for our common stock is not sustained, it may be difficult for investors in our common stock to sell shares without depressing the market price for the shares or to sell the shares at all.

***The trading price of our common stock has been and is likely to continue to be volatile.***

Our stock price from time to time has been volatile. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the price paid for the shares. The market price for our common stock may be influenced by many factors, including:

- announcements relating to development, regulatory approvals or commercialization of our drug candidates;

- actual or anticipated variations in our operating results;
- changes in financial estimates by us or by any securities analysts who might cover our stock;
- conditions or trends in our industry;
- changes in laws or other regulatory actions affecting us or our industry, such as drug pricing and reimbursement;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biopharmaceutical industry;
- announcements by us or our competitors of significant acquisitions, strategic partnerships or divestitures;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- capital commitments;
- investors' general perception of our company and our business;
- disputes concerning our intellectual property or other proprietary rights;
- recruitment or departure of key personnel; and
- sales of our common stock, including sales by our directors and officers or specific stockholders.

In addition, the stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many companies, including recently in connection with the COVID-19 pandemic, which has resulted in volatile stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. These fluctuations have often been unrelated or disproportionate to the operating performance of those companies. Broad market and industry factors, including potentially worsening economic conditions and other adverse effects or developments relating to the COVID-19 pandemic, political, regulatory and other market conditions, may negatively affect the market price of shares of our common stock, regardless of our actual operating performance.

In addition, in the past, stockholders have initiated class action lawsuits against pharmaceutical and biotechnology companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources from our business.

***If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline.***

The trading market for our common stock is influenced by the research and reports that equity research analysts publish about us and our business. We have only limited research coverage by equity research analysts. Equity research analysts may elect not to initiate or continue to provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. Even if we have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline.

***The issuance of additional stock in connection with financings, acquisitions, investments, our stock incentive plan, our employee stock purchase plan or otherwise will dilute all other stockholders.***

Our certificate of incorporation authorizes us to issue up to 100,000,000 shares of common stock and up to 5,000,000 shares of preferred stock with such rights and preferences as may be determined by our board of directors. Subject to compliance with applicable rules and regulations, we may issue our shares of common stock or securities convertible into our common stock from time to time in connection with a financing, acquisition, investment, our stock incentive plan, our employee stock purchase plan or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and cause the trading price of our common stock to decline.

***If a substantial number of our total outstanding shares are sold into the market, or if the market perceives that such sales may occur, it could cause the market price of our common stock to drop significantly, even if our business is doing well.***

Sales of a substantial number of shares of our common stock in the public market could occur at any time. If our stockholders sell, or if the market perceives that our stockholders intend to sell, substantial amounts of our common stock in the public market, the market price of our common stock could decline significantly. All of our outstanding shares of common stock are available for sale in the public market, subject only to the restrictions of Rule 144 under the Securities Act in the case of our affiliates.

In addition, we have filed registration statements on Form S-8 registering the issuance of shares of common stock subject to options or other equity awards issued or reserved for future issuance under our equity incentive plans. Shares registered under these registration statements are available for sale in the public market subject to vesting arrangements and exercise of options, as well as Rule 144 in the case of our affiliates. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

***Provisions in our corporate charter documents and under Delaware law may prevent or frustrate attempts by our stockholders to change our management and hinder efforts to acquire a controlling interest in us, and the market price of our common stock may be lower as a result.***

There are provisions in our certificate of incorporation and bylaws that may make it difficult for a third party to acquire, or attempt to acquire, control of our company, even if a change in control was considered favorable by some or all of our stockholders. For example, our board of directors has the authority to issue up to 5,000,000 shares of preferred stock. The board of directors can fix the price, rights, preferences, privileges and restrictions of the preferred stock without any further vote or action by our stockholders. The issuance of shares of preferred stock may delay or prevent a change in control transaction. As a result, the market price of our common stock and the voting and other rights of our stockholders may be adversely affected. An issuance of shares of preferred stock may result in the loss of voting control to other stockholders.

Our charter documents also contain other provisions that could have an anti-takeover effect, including:

- only one of our three classes of directors is elected each year;
- stockholders are not entitled to remove directors other than by a 66 2/3% vote and only for cause;
- stockholders are not permitted to take actions by written consent;
- stockholders cannot call a special meeting of stockholders; and
- stockholders must give advance notice to nominate directors or submit proposals for consideration at stockholder meetings.

In addition, we are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which regulates corporate acquisitions by prohibiting Delaware corporations from engaging in specified business combinations with particular stockholders of those companies. These provisions could discourage potential acquisition proposals and could delay or prevent a change in control transaction. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock.

Our certificate of incorporation also provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders.

***If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.***

We are subject to the reporting requirements of the Securities Exchange Act of 1934, the Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 and the rules and regulations of The Nasdaq Global Market. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting and perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal

control over financial reporting. This requires that we incur substantial additional professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts.

We may in the future discover areas of our internal financial and accounting controls and procedures that need improvement. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are unable to maintain proper and effective internal controls in the future, we may not be able to produce timely and accurate financial statements, and we may conclude that our internal controls over financial reporting are not effective. If that were to happen, the market price of our stock could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities.

***We do not anticipate paying any cash dividends on our common stock in the foreseeable future and our stock may not appreciate in value.***

We have not declared or paid cash dividends on our common stock to date. We currently intend to retain our future earnings, if any, to fund the development and growth of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. There is no guarantee that shares of our common stock will appreciate in value or that the price at which our stockholders have purchased their shares will be able to be maintained.

***We incur increased costs and demands upon management as a result of being a public company.***

As a public company listed in the United States, we incur, and will continue to incur now that we have ceased to be an "emerging growth company," significant legal, accounting and other costs. These costs could negatively affect our financial results. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including regulations implemented by the SEC and Nasdaq, may increase legal and financial compliance costs and make some activities more time-consuming. These laws, regulations and standards are subject to varying interpretations and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies.

We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If we do not comply with new laws, regulations and standards, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

Failure to comply with these rules might also make it more difficult for us to obtain some types of insurance, including director and officer liability insurance, and we might be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on committees of our board of directors or as members of senior management.

#### **ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

#### **ITEM 2. PROPERTIES**

Our principal offices occupy approximately 42,000 square feet of leased office space in Rockville, Maryland, pursuant to a lease agreement that expires in October 2023. We believe that our properties are generally in good condition, well maintained, suitable and adequate to carry on our business. We believe our capital resources are sufficient to lease any additional facilities required to meet our expected growth needs.

#### **ITEM 3. LEGAL PROCEEDINGS**

From time to time, we are subject to litigation and claims arising in the ordinary course of business. We are not currently a party to any material legal proceedings and we are not aware of any pending or threatened legal proceeding

against us that we believe could have a material adverse effect on our business, operating results, cash flows or financial condition.

**ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

**PART II**

**ITEM 5. MARKET FOR REGISTRANT’S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES**

**Market Information for Common Stock**

Our common stock is listed on The Nasdaq Global Market under the symbol “GLYC.”

**Dividend Policy**

We have never declared or paid any dividends on our common stock. We anticipate that we will retain all of our future earnings, if any, for use in the operation and expansion of our business and do not anticipate paying cash dividends in the foreseeable future.

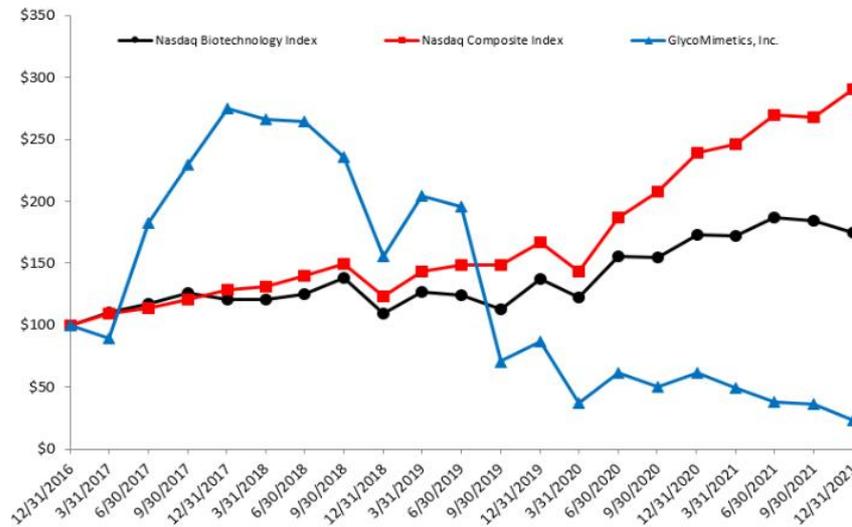
**Stockholders**

As of February 28, 2022, we had 52,313,894 shares of common stock outstanding held by 24 holders of record. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

**Performance Graph**

The following graph compares the five-year cumulative total return of our common stock with the Nasdaq Composite Index (U.S.) and the Nasdaq Biotechnology Index. The comparison assumes a \$100 investment on December 31, 2016 in our common stock, the stocks comprising the Nasdaq Composite Index, and the stocks comprising the Nasdaq Biotechnology Index, and assumes reinvestment of the full amount of all dividends, if any. Historical stockholder return is not necessarily indicative of the performance to be expected for any future periods.

**Comparison of Cumulative Total Return  
Among GlycoMimetics, Inc., the Nasdaq Composite Index and the Nasdaq Biotechnology Index**



The performance graph shall not be deemed to be incorporated by reference by means of any general statement incorporating by reference this Form 10-K into any filing under the Securities Act of 1933, as amended or the Exchange Act, except to the extent that we specifically incorporate such information by reference, and shall not otherwise be deemed filed under such acts.

**Recent Sales of Unregistered Securities**

None.

**Purchases of Equity Securities by the Issuer and Affiliated Parties**

None.

**ITEM 6. [RESERVED]**

## **ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

*You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes and other financial information included elsewhere in this Annual Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. You should review Item 1A. "Risk Factors" and "Special Note Regarding Forward-Looking Statements" in this Annual Report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.*

For the discussion of our financial condition and results of operations and cash flows for the year ended December 31, 2020 compared to the year ended December 31, 2019, please refer to Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the year ended December 31, 2020 filed with the SEC on March 2, 2021.

### **Overview**

We are a clinical-stage biotechnology company focused on the discovery and development of novel glycomimetic drugs to address unmet medical needs resulting from diseases in which carbohydrate biology plays a key role. We are developing a pipeline of proprietary glycomimetics, which are small molecules that mimic the structure of carbohydrates involved in important biological processes, to inhibit disease-related functions of carbohydrates such as the roles they play in inflammation, cancer and infection. We believe this represents an innovative approach to drug discovery to treat a wide range of diseases. We are focusing our efforts on drug candidates for diseases that we believe will qualify for orphan drug designation.

Our proprietary glycomimetics platform is based on our expertise in carbohydrate chemistry and our understanding of the role carbohydrates play in key biological processes. Most human proteins are modified by the addition of complex carbohydrate structures to the surface of such proteins, which affects the functions of the proteins and their interactions with other molecules. Our initial research and development efforts have focused on drug candidates targeting selectins, which are proteins that serve as adhesion molecules and bind to carbohydrates that are involved in the inflammatory component and progression of a wide range of diseases, including hematologic disorders, cancer and cardiovascular disease. For example, we believe that members of the selectin family play a key role in tumor metastasis and resistance to chemotherapy. Inhibiting specific carbohydrates from binding to selectins has long been viewed as a potentially attractive approach for therapeutic intervention. The ability to successfully develop drug-like carbohydrate compounds that inhibit binding with selectins, known as selectin antagonists, has historically been limited by their potency and the complexities of carbohydrate chemistry. We believe our expertise in the rational design of potent glycomimetic antagonists with drug-like properties and in carbohydrate chemistry enables us to identify highly effective selectin antagonists and other glycomimetics that may inhibit the disease-related functions of certain carbohydrates in order to develop novel drug candidates to address orphan diseases with high unmet medical need.

Our lead glycomimetic drug candidate, uproleselan, is a specific E-selectin inhibitor that we are developing to be used in combination with chemotherapy to treat patients with acute myeloid leukemia, or AML, a life-threatening hematologic cancer, and potentially other hematologic cancers. In 2021, we completed enrollment of patients in a randomized, double-blind, placebo-controlled Phase 3 pivotal clinical trial to evaluate uproleselan in individuals with relapsed/refractory AML, the design of which was based on guidance received from the U.S. Food and Drug Administration, or FDA. Based on discussions with our external statisticians for the trial, we expect to report preliminary data from the trial after year end 2022.

We have also entered into a Cooperative Research and Development Agreement, or CRADA, with the National Cancer Institute, or NCI, part of the National Institutes of Health, to conduct a Phase 2/3 randomized, controlled clinical trial testing the addition of uproleselan to a standard chemotherapy regimen. Enrollment of the Phase 2 portion was completed in December 2021. There will be a planned interim analysis that will evaluate event-free survival and whether the pre-specified threshold for continuing to Phase 3 has been met. The trial may also provide support for regulatory filings, if the results of the planned interim analysis are positive.

Uproleselan is also being studied in multiple investigator-sponsored trials, with data readouts from these trial expected in 2022.

We have rationally designed an innovative antagonist of E-selectin, GMI-1687, that could be a subcutaneously administered treatment. Initially developed as a potential life-cycle extension to uproleselan, we believe that GMI-1687 could be developed to broaden the clinical usefulness of an E-selectin antagonist to conditions where outpatient treatment is preferred or required. We are currently conducting preclinical activities and studies with GMI-1687 to support our planned submission of an investigational new drug application, or IND, to the FDA in the first half of 2022.

We are also developing a drug candidate, GMI-1359, that simultaneously targets both E-selectin and a chemokine receptor known as CXCR4. In the fourth quarter of 2021, we ended a Phase 1b trial of GMI-1359 in hormone receptor positive breast cancer patients whose tumors have spread to bone. We are also advancing other preclinical-stage programs, including small-molecule glycomimetic compounds that inhibit the protein galectin-3, that could be an orally administered treatment, which we believe may have potential to be used for the treatment of fibrosis, cancer and cardiovascular disease.

We have financed our operations primarily through private placements of our securities, up-front and milestone payments under our license and collaboration agreements and the net proceeds from public offerings of common stock, including sales of common stock under at-the-market sales facilities with Cowen and Company LLC, or Cowen. We have no approved drugs currently available for sale, and substantially all of our revenue to date has been revenue from up-front and milestone payments under license and collaboration agreements.

Since inception, we have incurred significant operating losses. We had an accumulated deficit of \$372.9 million as of December 31, 2021 and we expect to continue to incur significant expenses and operating losses over at least the next several years. Our net losses may fluctuate significantly from quarter to quarter and year to year, depending on the timing of our clinical trials and our expenditures on other research and development activities. We anticipate that our expenses will increase substantially as we:

- initiate and conduct our planned clinical trials of uproleselan and GMI-1687, including fulfilling our funding and supply commitments related to the ongoing clinical trials of uproleselan;
- conduct NDA-enabling activities related to manufacture, toxicology and clinical pharmacology for our product candidates;
- manufacture additional uproleselan drug supplies for validation and prepare for commercialization;
- seek to discover and develop additional drug candidates;
- seek regulatory approvals for any drug candidates that successfully complete clinical trials;
- ultimately establish a sales, marketing and distribution infrastructure and scale up external manufacturing capabilities to commercialize any drug candidates for which we may obtain regulatory approval;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, quality control, regulatory and scientific personnel;
- maintain sufficient level of insurance including product liability and directors, officers and corporate liability insurance policies; and
- add operational, financial and management information systems and personnel, including personnel to support our drug development and potential future commercialization efforts.

To fund further operations, we will need to raise capital. We may obtain additional financing in the future through the issuance of our common stock, through other equity or debt financings, potentially including the use of our at-the-market sales facility with Cowen, or through collaborations or partnerships with other companies. We may not be able to raise additional capital on terms acceptable to us, or at all, and any failure to raise capital as and when needed could compromise our ability to execute on our business plan. For example, the current global COVID-19 pandemic presents material uncertainty and its disruption of the capital markets may have a material adverse impact on our ability to raise additional capital if we decide to do so. Although it is difficult to predict future liquidity requirements, we believe that our existing cash and cash equivalents will be sufficient to fund our operations into the second quarter of 2023 without

giving effect to potential business development opportunities, such as upfront or milestone payments under license and collaboration agreements, or additional financing activities including the potential sale of common stock. However, our ability to successfully transition to profitability will be dependent upon achieving a level of revenues adequate to support our cost structure. We cannot assure you that we will ever be profitable or generate positive cash flow from operating activities.

### ***Impact of COVID-19 on Our Business***

The imposition of “lockdown,” “social distancing” and “shelter in place” directives by state and federal governments in the United States as well as governments in other regions of the world in response to the COVID-19 pandemic, including in locations in which our Phase 3 clinical trial of uproleselan is being conducted, resulted in slowed clinical site initiation, patient recruitment and enrollment rates early in the pandemic. Enrollment rates returned to forecasted rates from the beginning of the lockdowns and we completed enrollment in November 2021. However, we cannot at this time fully assess the effect of the COVID-19 pandemic on our completion of the clinical trial. We continue to closely monitor the COVID-19 situation and any potential impact to our planned activities.

We have also implemented business continuity plans designed to address and mitigate the impact of the COVID-19 pandemic on our employees and our business. While to date we have experienced limited impacts beyond the earlier delays in recruitment in our ongoing uproleselan Phase 3 clinical trial, given the global economic slowdown, the overall disruption of global healthcare systems and the other risks and uncertainties associated with the pandemic, our business, financial condition, results of operations and growth prospects could be materially adversely affected. We continue to closely monitor the COVID-19 situation as we evolve our business continuity plans and response strategy. In March 2020, our workforce transitioned to working remotely in accordance with federal and state declarations. We have reopened our offices pursuant to a hybrid return to office policy with a focus on employee safety and optimal work environment.

### **Our Collaboration and License Agreements**

#### ***Apollomics***

In January 2020, we entered into an exclusive collaboration and license agreement with Apollomics (Hong Kong) Limited, or Apollomics, for the development and commercialization of uproleselan and GMI-1687 in Mainland China, Hong Kong, Macau and Taiwan, also known as Greater China. Under the terms of the agreement, Apollomics will be responsible for clinical development and commercialization in Greater China. We will also collaborate with Apollomics to advance the preclinical and clinical development of GMI-1687. We received an upfront cash payment of \$9.0 million and in September 2020 received a \$1.0 million development milestone payment. Subject to the terms of the agreement, we will be eligible to receive potential further milestone payments totaling approximately \$179.0 million, as well as tiered royalties ranging from the high single digits to 15%, as a percentage of net sales. Apollomics will be responsible for all costs related to development, regulatory approvals, and commercialization activities for uproleselan and GMI-1687 in Greater China, and we and Apollomics expect to enter into clinical and commercial supply agreements with respect to our provision of uproleselan and GMI-1687 to Apollomics. We retain all rights for both compounds in the rest of the world.

In September 2020, the China National Medical Products Administration (NMPA) Center for Drug Evaluation (CDE) granted IND approval for uproleselan (also known as APL-106), enabling the initiation of a Phase 1 pharmacokinetics and tolerability study and a planned Phase 3 bridging study of APL-106 in combination with chemotherapy in relapsed/refractory AML. In January 2021, APL-106 was granted Breakthrough Therapy Designation from the China NMPA CDE for the treatment of relapsed/refractory AML. In March 2021, Apollomics enrolled the first patient in the Phase 1 study.

In June 2020, we entered into a clinical supply agreement with Apollomics under which we will manufacture and supply uproleselan product to Apollomics at agreed upon prices. Apollomics has the option to begin manufacture after appropriate material transfer requirements are met. During the year ended December 31, 2021, we recognized \$1.1 million in revenue from the sale of clinical supplies to Apollomics under the clinical supply agreement.

## Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of these financial statements requires us to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities as of the dates of the balance sheets and the reported amounts of revenue and expenses during the reporting periods. In accordance with GAAP, we base our estimates on historical experience and on various other assumptions that we believe are reasonable under the circumstances at the time such estimates are made. Actual results may differ materially from our estimates and judgments under different assumptions or conditions. We periodically review our estimates in light of changes in circumstances, facts and experience. The effects of material revisions in estimates are reflected in our financial statements prospectively from the date of the change in estimate.

We define our critical accounting policies as those accounting principles generally accepted in the United States that require us to make subjective estimates and judgments about matters that are uncertain and are likely to have a material impact on our financial condition and results of operations, as well as the specific manner in which we apply those principles. While our significant accounting policies are more fully described in Note 3 to our financial statements appearing elsewhere in this Annual Report, we believe the following are the critical accounting policies used in the preparation of our financial statements that require significant judgments and estimates.

### Revenue Recognition

We apply Accounting Standards Codification, or ASC, Topic 606, *Revenue from Contracts with Customers*, to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration agreements and financial instruments. Under Topic 606, an entity recognizes revenue when its customer obtains control of promised goods and services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods and services. To determine revenue recognition for an arrangement that an entity determines is within the scope of Topic 606, we perform the following five steps: (i) identify the contract(s) with the customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligation in the contract; and (v) recognize revenue when (or as) we satisfy a performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer. At contract inception, once the contract is determined to be within the scope of Topic 606, we assess the goods or services promised within each contract and identify, as a performance obligation, and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

We enter into licensing agreements which are within the scope of Topic 606, under which we license certain of our product candidates' rights to third parties. The terms of these arrangements typically include payment of one or more of the following: non-refundable, up-front license fees; development, regulatory and commercial milestone payments; and royalties on net sales of the licensed product. In determining the appropriate amount of revenue to be recognized as we fulfill our obligation under our agreements, we perform the five steps described above. As part of the accounting for these arrangements, we must develop assumptions that require judgment to determine the stand-alone selling price, which may include forecasted revenues, development timelines, reimbursement of personnel costs, discount rates and probabilities of technical and regulatory success.

*Licensing of Intellectual Property:* If the license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we will recognize revenue from non-refundable, up-front fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front-fees. We evaluate the measure of progress each reporting period, and, if necessary, adjust the measure of performance and related revenue recognition.

*Milestone Payments:* At the inception of each arrangement that includes development milestone payments, we evaluate whether the milestones are considered probable of being reached and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal will not occur,

the associated milestone value is included in the transaction price. Milestone payments that are not within our control or the licensee's control, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which we recognize revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, we re-evaluate the probability of achievement of such development milestones and any related constraint, and if necessary, adjust our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect license, collaboration and other revenues and earnings in their period of adjustment.

**Royalties:** For arrangements that include sales-based royalties, including milestone payments based on the level of sales, for which the license is deemed to be the predominant item to which royalties relate, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some of all of the royalty has been allocated has been satisfied (or partially satisfied). To date, we have not recognized any royalty revenue from our license agreements.

**Manufacturing and Supply:** Our agreements may include providing clinical and commercial manufacturing products to the counterparties. The services are generally determined to be distinct from the other promises or performance obligations identified in the arrangement. We recognize the transaction price allocated to these services as revenue at a point in time when transfer of control of the related products to the customer occurs.

### **Stock-Based Compensation**

We issue stock-based compensation awards to our employees and non-employee directors, including stock options. We measure stock-based compensation expense related to these awards based on the fair value of the award, utilizing the Black-Scholes-Merton option pricing model, on the date of grant and recognize stock-based compensation expense on a straight-line basis over the requisite service period of the awards, which generally equals the vesting period. We account for forfeitures as they occur. We grant stock options with exercise prices equal to the estimated fair value of our common stock on the date of grant. The Black-Scholes-Merton option pricing model requires the input of various assumptions that require management to apply judgment and make assumptions and estimates, including:

**Risk-Free Interest Rate**—The risk-free interest rate assumption is based on observed interest rates for constant maturity U.S. Treasury securities consistent with the expected life of our employee stock options.

**Expected Term**—The expected life represents the period of time the stock options are expected to be outstanding and is based on the simplified method. Under the simplified method, the expected life of an option is presumed to be the midpoint between the vesting date and the end of the contractual term. We used the simplified method due to the lack of sufficient historical exercise data to provide a reasonable basis upon which to otherwise estimate the expected life of the stock options.

**Expected Volatility**—Volatility is a measure of the amount by which a financial variable such as share price has fluctuated (historical volatility) or is expected to fluctuate (expected volatility) during a period. We base the expected volatility on the historical volatility of our publicly traded common stock.

**Expected Dividend Yield**—We have assumed no dividend yield because we do not expect to pay dividends in the future, which is consistent with our history of not paying dividends.

### **Accruals for Clinical Trial Expenses**

Clinical trial costs primarily consist of expenses incurred under agreements with contract research organizations (CROs), investigative sites, laboratory testing expenses, data management and consultants that conduct our clinical trials. Clinical trial expenses are a significant component of research and development expenses, and we outsource a significant portion of these clinical trial activities to third parties. The accrual for site and patient costs includes inputs such as estimates of patient enrollment, patient cycles incurred, clinical site activations, estimated project duration and other pass-through costs. These inputs are required to be estimated due to a lag in receiving the actual clinical information from third parties. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected on the balance sheets as prepaid assets or accrued expenses. These third-party agreements are generally cancellable, and related costs are recorded as research and development expenses as incurred. Except for payments made in advance of services, clinical trial costs are expensed as incurred. Non-refundable advance clinical payments for goods or services that will be used or rendered for future research and development

activities are recorded as a prepaid asset and recognized as expense as the related goods are delivered or the related services are performed. When evaluating the adequacy of the accrued expenses, management assessments include: (i) an evaluation by the project manager of the work that has been completed during the period; (ii) measurement of progress prepared internally and/or provided by the third-party service provider; (iii) analyses of data that justify the progress; and (iv) our judgment. Significant judgments and estimates may be made in determining the accrued balances at the end of any reporting period. Actual results could differ from the estimates made. Our historical clinical accrual estimates have not been materially different from the actual costs. Clinical trial accruals that are due longer than one year are classified as noncurrent accrued expenses.

## **Components of Operating Results**

### ***Revenue***

To date, we have not generated any revenue from the sale of our drug candidates and do not expect to generate any revenue from the sale of drugs in the near future. Substantially all of our historical revenue consisted of upfront and milestone payments under license and collaboration agreements.

### ***Research and Development***

Research and development expenses consist of expenses incurred in performing research and development activities, including compensation and benefits for full-time research and development employees, facilities expenses, overhead expenses, cost of laboratory supplies, clinical trial and related clinical manufacturing expenses, fees paid to CROs and other consultants and other outside expenses. Other preclinical research and platform programs include activities related to exploratory efforts, target validation, lead optimization for our earlier programs and our proprietary glycomimetics platform. Our research and development expenses relate primarily to the development of uproleselan and our other drug candidates.

We do not currently utilize a formal time allocation system to capture expenses on a project-by-project basis because we are organized and record expense by functional department and our employees may allocate time to more than one development project. Accordingly, we only allocate a portion of our research and development expenses by functional area and by drug candidate.

Research and development costs are expensed as incurred. Non-refundable advance payments for goods or services to be received in the future for use in research and development activities are deferred and capitalized. The capitalized amounts are expensed as the related goods are delivered or the services are performed.

Research and development activities are central to our business model. Drug candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later stage clinical trials. We expect our research and development expenses to increase over the next several years as we seek to progress uproleselan, GMI-1687 and our other drug candidates into and through clinical development. However, it is difficult to determine with certainty the duration and completion costs of our current or future preclinical studies and clinical trials of our drug candidates, or if, when or to what extent we will generate revenues from the commercialization and sale of any of our drug candidates that obtain regulatory approval. We may never succeed in achieving regulatory approval for any of our drug candidates.

The duration, costs and timing of clinical trials and development of our drug candidates will depend on a variety of factors that include:

- per patient trial costs;
- the number of patients that participate in the trials;
- the number of sites included in the trials;
- the countries in which the trial is conducted;
- the length of time required to enroll eligible patients;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;

- potential additional safety monitoring or other studies requested by regulatory agencies;
- the duration of patient follow-up; and
- the safety and efficacy profile of the drug candidate.

In addition, the probability of success for each drug candidate will depend on numerous factors, including competition, manufacturing capability and commercial viability. We will determine which programs to pursue and how much to fund each program in response to the scientific and clinical success of each drug candidate, as well as an assessment of each drug candidate's commercial potential.

#### **General and Administrative**

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in executive, finance, accounting, business development and human resources functions. Other significant costs include facility costs not otherwise included in research and development expenses, legal fees relating to patent and corporate matters and fees for accounting and consulting services. We anticipate that our general and administrative expenses will increase in the future as we start to build upon our commercialization efforts for uproleselan and continue to support our research and development activities.

#### **Interest Income**

Other income consists of interest income earned on our cash and cash equivalents.

#### **Results of Operations**

The following table sets forth our results of operations:

(dollars in thousands)	Year Ended December 31,		Increase/(Decrease)	
	2021	2020		
Revenue	\$ 1,160	\$ 10,163	\$ (9,003)	(89)%
Costs and expenses:				
Research and development expense	47,492	44,929	2,563	6 %
General and administrative expense	17,115	16,743	372	2 %
Total costs and expenses	64,607	61,672	2,935	5 %
Loss from operations	(63,447)	(51,509)	(11,938)	23 %
Interest income	20	482	(462)	(96)%
Net loss and comprehensive loss	\$ (63,427)	\$ (51,027)	\$ (12,400)	24 %

#### **Revenue**

During the year ended December 2021 and 2020, revenue was \$1.2 million and \$10.2 million, respectively, all of which was the result of payments received under our license and collaboration agreement with Apollomics for the development and commercialization of uproleselan and GMI-1687 in Greater China. During the year ended December 31, 2021, we recognized \$1.1 million in revenue from the sale of clinical supplies to Apollomics under a clinical supply agreement. In January 2020, we recognized \$9.0 million in revenue from an upfront milestone payment, and in September 2020, we recognized a \$1.0 million clinical development milestone payment.

**Research and Development Expense**

The following table summarizes our research and development expense by functional area:

(dollars in thousands)	Year Ended		Increase/(Decrease)	
	December 31,			
	2021	2020		
Clinical development	\$ 19,689	\$ 18,321	\$ 1,368	7 %
Manufacturing and formulation	12,307	9,221	3,086	33 %
Contract research services, consulting and other costs	2,163	1,907	256	13 %
Laboratory costs	2,140	2,066	74	4 %
Personnel-related	8,978	10,467	(1,489)	(14)%
Stock-based compensation	2,215	2,947	(732)	(25)%
Research and development expense	<u>\$ 47,492</u>	<u>\$ 44,929</u>	<u>\$ 2,563</u>	<u>6 %</u>

The following table summarizes our research and development expense by drug candidate:

(dollars in thousands)	Year Ended		Increase/(Decrease)	
	December 31,			
	2021	2020		
Uproleselan	\$ 29,781	\$ 27,189	\$ 2,592	10 %
GMI-1359	555	467	88	19 %
Other research and development	5,963	3,859	2,104	55 %
Personnel-related and stock-based compensation	11,193	13,414	(2,221)	(17)%
Research and development expense	<u>\$ 47,492</u>	<u>\$ 44,929</u>	<u>\$ 2,563</u>	<u>6 %</u>

Our research and development expense for the year ended December 31, 2021 increased by \$2.6 million compared to the year ended December 31, 2020 primarily due to:

- increased clinical trial and development costs related to our ongoing global Phase 3 clinical trial of uproleselan in individuals with relapsed/refractory AML;
- increased manufacturing costs for the uproleselan validation batches; and
- increased costs for toxicity studies of GMI-1687 included in other research and development in the drug candidate summary table above.

These increases were partially offset by:

- decreased personnel-related and stock-based compensation due to a lower number of research and development employees.

**General and Administrative Expense**

The following table sets forth the components of our general and administrative expense:

(dollars in thousands)	Year Ended		Increase/(Decrease)	
	December 31,			
	2021	2020		
Personnel-related	\$ 5,788	\$ 6,275	\$ (487)	(8)%
Stock-based compensation	3,872	3,955	(83)	(2)%
Legal, consulting and other professional expenses	6,652	5,819	833	14 %
Other	803	694	109	16 %
General and administrative expense	<u>\$ 17,115</u>	<u>\$ 16,743</u>	<u>\$ 372</u>	<u>2 %</u>

General and administrative expense increased for the year ended December 31, 2021 by \$372,000, or 2%, compared to 2020. Personnel-related expenses decreased due to a reversal of accruals for performance and retention bonuses that our prior Chief Executive Officer was eligible to receive but which were forfeited upon her cessation of

service in that role in 2021. These decreases were offset by higher recruiting, consulting and legal expenses incurred in the year ended December 31, 2021 as compared to 2020.

#### ***Interest Income***

During the year ended December 31, 2021, interest income decreased by \$462,000, compared to the same period in 2020, due to lower average cash balances and lower interest rates on those balances.

#### **Liquidity and Capital Resources**

##### ***Sources of Liquidity***

We have historically financed our operations primarily through public offerings and private placements of our capital stock, including sales agreements with Cowen, and upfront and milestone payments from our license and collaboration agreements. As of December 31, 2021, we had \$90.3 million in cash and cash equivalents.

In October 2020, we filed a prospectus supplement to a shelf registration statement that we filed in May 2019 and entered into an at-the-market sales agreement, or the 2020 Sales Agreement, with Cowen. Under the 2020 Sales Agreement, we may sell up to \$100.0 million of our common stock registered under the shelf registration statement that we filed in May 2019. During the year ended December 31, 2020, we sold 1,024,760 shares of common stock under the 2020 Sales Agreement at a weighted average price of \$3.74 per share, for aggregate net proceeds of \$3.7 million, after deducting commissions and offering expenses. During the year ended December 31, 2021, we sold an additional 3,092,603 shares of common stock under the 2020 Sales Agreement at a weighted average price of \$3.57 per share, for aggregate net proceeds of \$10.7 million, after deducting commissions and offering expenses. As of December 31, 2021, we have approximately \$85.1 million remaining available to be sold under the terms of the 2020 Sales Agreement. Subsequent to December 31, 2021, there have been no additional sales under the 2020 Sales Agreement.

We entered into a collaboration and license agreement with Apollomics in January 2020 and are potentially eligible to earn milestone payments and royalties under that agreement. In January 2020, Apollomics made an upfront payment to us of \$9.0 million. We also received a non-refundable payment of \$1.0 million in September 2020 as a clinical development milestone payment. Our ability to earn additional milestone payments and potential royalty payments and their timing will be dependent upon the outcome of Apollomics' activities and is therefore uncertain at this time.

##### ***Funding Requirements***

Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, third-party clinical research and development services, laboratory and related supplies, clinical costs, legal and other regulatory expenses and general overhead costs.

As of December 31, 2021, our significant contractual obligations consisted solely of rent obligations under a non-cancelable lease, as amended, for our current office space in Rockville, Maryland, which has a term through October 2023. Total remaining obligations under this lease as of December 31, 2021 were \$2.0 million. We have no other fixed long-term obligations and we do not have significant capital expenditure requirements.

We have also entered into various agreements for services with third-party vendors, including agreements to conduct clinical trials, to manufacture products, and for consulting and other contracted services. These agreements include cancellable terms and we accrue the costs of these agreements based on estimates of work completed to date.

The successful development of any of our drug candidates is highly uncertain. As such, at this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the remainder of the development of uproleselan or our other drug candidates. We are also unable to predict when, if ever, material net cash inflows will commence from uproleselan or our other drug candidates. This is due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- successful enrollment in, and completion of, clinical trials;
- receipt of marketing approvals from applicable regulatory authorities;

- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for drug candidates;
- launching commercial sales of drugs, if and when approved, whether alone or in collaboration with others; and
- obtaining and maintaining healthcare coverage and adequate reimbursement.

A change in the outcome of any of these variables with respect to the development of any of our drug candidates would significantly change the costs and timing associated with the development of that drug candidate. Because our drug candidates are in various stages of clinical and preclinical development and the outcome of these efforts is uncertain, we cannot estimate the actual amounts necessary to successfully complete the development and commercialization of our drug candidates or whether, or when, we may achieve profitability. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity or debt financings and collaboration arrangements, including our existing license agreement with Apollomics. Except for amounts that we may sell under our 2020 Sales Agreement with Cowen, and Apollomics' conditional obligations to make milestone and royalty payments to us under our license agreement, we do not have any committed external source of liquidity.

To the extent that we raise additional capital through the future sale of equity or debt, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing common stockholders. If we raise additional funds through the issuance of convertible debt securities, these securities could contain covenants that would restrict our operations.

We may require additional capital beyond our currently anticipated amounts. Additional capital may not be available on reasonable terms, or at all. If we raise additional funds through collaboration arrangements in the future, we may have to relinquish valuable rights to our drug candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our drug development or future commercialization efforts or grant rights to develop and market drug candidates that we would otherwise prefer to develop and market ourselves.

### ***Going Concern***

The accompanying financial statements included in this Annual Report have been prepared assuming that we will continue as a going concern within one year after the date that the financial statements are issued. During 2021, we incurred a net loss of \$63.4 million and had net cash flows used in operating activities of \$57.5 million. At December 31, 2021, we had \$90.3 million in cash and cash equivalents and had no committed source of additional funding from either debt or equity financings. Management believes that given our current cash position and forecasted negative cash flows from operating activities over the next twelve months as we continue our product development activities, including the completion of our planned Phase 3 clinical trial of uproleselan, there is substantial doubt about our ability to continue as a going concern beyond the date that is one year from the date that these financial statements are issued, without obtaining additional financing or entering into another form of non-equity or debt arrangement.

### ***Outlook***

Based on our research and development plans and our timing expectations related to the progress of our programs, we expect that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements into the second quarter of 2023. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we expect. Additionally, the process of testing drug candidates in clinical trials is costly, and the timing of progress in these trials is uncertain.

### Cash Flows

The following table summarizes our cash flows:

(in thousands)	Year Ended December 31,	
	2021	2020
Net cash provided by (used in):		
Operating activities	\$ (57,489)	\$ (39,242)
Investing activities	(15)	(68)
Financing activities	10,724	18,144
Net change in cash and cash equivalents	<u>\$ (46,780)</u>	<u>\$ (21,166)</u>

In assessing cash used in operating activities, we consider several principal factors: (i) net loss for the period; (ii) adjustments for non-cash charges including stock-based compensation expense and depreciation and amortization of property and equipment; and (iii) the extent to which receivables, accounts payable and other liabilities, or other working capital components increase or decrease.

#### Operating Activities

Net cash used in operating activities was \$57.5 million during the year ended December 31, 2021 compared to \$39.2 million during the year ended December 31, 2020. For the years ended December 31, 2021 and 2020, we received \$1.1 million and \$10.2 million, respectively, in revenue under our agreements with Apollomics for the development and commercialization of uproleselan and GMI-1687 in Greater China. For the year ended December 31, 2021, there was increased spending in clinical development and manufacturing expenses as a result of ongoing costs associated with our uproleselan clinical development programs in our global Phase 3 clinical trial and the NCI-sponsored Phase 2/3 trial.

#### Investing Activities

Net cash used in investing activities, consisting of purchases of scientific equipment and computers, was \$15,000 for the year ended December 31, 2021 compared to \$68,000 during the year ended December 31, 2020.

#### Financing Activities

Net cash provided by financing activities of \$10.7 million and \$18.1 million during the years ended December 31, 2021 and 2020, respectively, consisted primarily of the net proceeds received from our at-the-market facility with Cowen. During the year ended December 31, 2020, we also received \$319,000 in proceeds from stock option exercises.

### ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The market risk inherent in our financial instruments and in our financial position represents the potential loss arising from adverse changes in interest rates. As of December 31, 2021 and 2020, we had cash and cash equivalents of \$90.3 million and \$137.0 million, respectively. We generally hold our cash in interest-bearing money market accounts. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Due to the short-term maturities of our cash equivalents and the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash equivalents.

### ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements and related financial statement schedules required to be filed are listed in Part IV, Item 15 of this Form 10-K.

### ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

**ITEM 9A. CONTROLS AND PROCEDURES**

*Evaluation of Disclosure Controls and Procedures*

Under the supervision of and with the participation of our management, including our chief executive officer, who is our principal executive officer, and our chief financial officer, who is our principal financial officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures as of December 31, 2021, the end of the period covered by this Annual Report. The term “disclosure controls and procedures,” as set forth in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to provide reasonable assurance that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the rules and forms promulgated by the SEC. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2021, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

*Management’s Report on Internal Control over Financial Reporting and Attestation Report of the Registered Public Accounting Firm*

Our management is responsible for establishing and maintaining an adequate system of internal control over financial reporting, as defined in the Exchange Act Rule 13a-15(f). Management conducted an assessment of our internal control over financial reporting based on the original framework established in 2013 by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control—Integrated Framework. Based on the assessment, management concluded that, as of December 31, 2021, our internal control over financial reporting was effective.

This Annual Report does not include an attestation report of our registered public accounting firm regarding the effectiveness of internal control over financial reporting as required by Section 404(b) of the Sarbanes-Oxley Act of 2002. Management’s report was not subject to attestation by our registered public accounting firm pursuant to rules of the SEC that permit smaller reporting companies to provide only management’s report in this Annual Report.

*Changes in Internal Control over Financial Reporting*

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended December 31, 2021 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**ITEM 9B. OTHER INFORMATION**

None

**ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS**

Not applicable.

### **PART III**

We will file a definitive proxy statement for our 2022 annual meeting of stockholders, or the 2022 Proxy Statement, with the SEC, pursuant to Regulation 14A, not later than 120 days after the end of our fiscal year. Accordingly, certain information required by Part III has been omitted under General Instruction G(3) to Form 10-K. Only those sections of the 2022 Proxy Statement that specifically address the items set forth herein are incorporated by reference.

#### **ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

The information required by Item 10 is hereby incorporated by reference to the relevant information to be included in the 2022 Proxy Statement under the captions “Information Regarding the Board of Directors and Corporate Governance,” “Election of Directors” and “Executive Officers.”

#### **ITEM 11. EXECUTIVE COMPENSATION**

The information required by Item 11 is hereby incorporated by reference to the relevant information to be included in the 2022 Proxy Statement under the captions “Executive Compensation” and “Non-Employee Director Compensation.”

#### **ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

The information required by Item 12 is hereby incorporated by reference to the relevant information to be included in the 2022 Proxy Statement under the captions “Security Ownership of Certain Beneficial Owners and Management” and “Securities Authorized for Issuance under Equity Compensation Plans.”

#### **ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE**

The information required by Item 13 is hereby incorporated by reference to the relevant information to be included in the 2022 Proxy Statement under the captions “Transactions with Related Persons” and “Independence of the Board of Directors.”

#### **ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES**

The information required by Item 14 is hereby incorporated by reference to the relevant information to be included in the 2022 Proxy Statement under the caption “Ratification of Selection of Independent Auditors.”

**PART IV**

**ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES**

(a) The following documents are filed as part of this Annual Report on Form 10-K:

(1) Financial Statements:

<a href="#">Report of Ernst &amp; Young LLP, Independent Registered Public Accounting Firm</a>	73
<a href="#">Balance Sheets</a>	75
<a href="#">Statements of Operations and Comprehensive Loss</a>	76
<a href="#">Statements of Stockholders' Equity</a>	77
<a href="#">Statements of Cash Flows</a>	78
<a href="#">Notes to Financial Statements</a>	79

(2) Financial Statement Schedules:

All financial statement schedules have been omitted because they are not applicable, not required or the information required is shown in the financial statements or the notes thereto.

(3) Exhibits

<b>Exhibit Number</b>	<b>Description of Document</b>
3.1(1)	<a href="#">Amended and Restated Certificate of Incorporation.</a>
3.2(2)	<a href="#">Amended and Restated Bylaws.</a>
4.1(3)	<a href="#">Specimen stock certificate evidencing shares of Common Stock.</a>
4.2(4)	<a href="#">Description of Certain of Registrant's Securities.</a>
10.1+(5)	<a href="#">2003 Stock Incentive Plan, as amended.</a>
10.2+(6)	<a href="#">Form of Incentive Stock Option Agreement under 2003 Stock Incentive Plan.</a>
10.3+(7)	<a href="#">Form of Nonqualified Stock Option Agreement under 2003 Stock Incentive Plan.</a>
10.4+(8)	<a href="#">2013 Equity Incentive Plan.</a>
10.5+(9)	<a href="#">Form of Stock Option Grant Notice and Stock Option Agreement under 2013 Equity Incentive Plan.</a>
10.6+(10)	<a href="#">Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement under 2013 Equity Incentive Plan.</a>
10.7+(11)	<a href="#">2013 Employee Stock Purchase Plan.</a>
10.8+(12)	<a href="#">Form of Indemnification Agreement.</a>
10.9+(13)	<a href="#">Executive Employment Agreement, dated as of August 3, 2021, by and between the Registrant and Harout Semerjian.</a>
10.10+(14)	<a href="#">Amended and Restated Executive Employment Agreement, dated as of July 30, 2019, by and between the Registrant and Brian Hahn.</a>
10.11+(15)	<a href="#">Amended and Restated Executive Employment Agreement, dated as of July 30, 2019, by and between the Registrant and John Magnani.</a>
10.12+(16)	<a href="#">Amended and Restated Executive Employment Agreement, dated as of July 30, 2019, by and between the Registrant and Armand Girard.</a>
10.13+	<a href="#">Consulting Agreement, dated as of August 31, 2021, by and between the Registrant and Rachel King.</a>
10.14+	<a href="#">Amended and Restated Non-Employee Director Compensation Policy.</a>

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<b>Exhibit Number</b>	<b>Description of Document</b>
10.15(17)	<a href="#">Lease Agreement, dated July 23, 2014, by and between the Registrant and BMR-Medical Center Drive, LLC.</a>
10.16(18)	<a href="#">Sales Agreement, dated October 7, 2020 by and between the Registrant and Cowen and Company, LLC.</a>
10.17(19)	<a href="#">First Amendment to Lease, dated March 24, 2016, by and between the Registrant and BMR-Medical Center Drive LLC.</a>
10.18*(20)	<a href="#">Collaboration and License Agreement, dated January 2, 2020, by and between the Registrant and Apollomics (Hong Kong) Limited.</a>
10.19+	<a href="#">GlycoMimetics, Inc. Amended and Restated Inducement Plan dated as of January 21, 2022.</a>
10.20+(21)	<a href="#">Form of Stock Option Grant Notice and Stock Option Agreement under the GlycoMimetics, Inc. Inducement Plan.</a>
23.1	<a href="#">Consent of Ernst &amp; Young LLP, independent registered public accounting firm.</a>
24.1	<a href="#">Power of Attorney (contained on signature page hereto).</a>
31.1	<a href="#">Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as adopted pursuant to section 302 of the Sarbanes-Oxley Act of 2002.</a>
31.2	<a href="#">Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as adopted pursuant to section 302 of the Sarbanes-Oxley Act of 2002.</a>
32.1 <sup>^</sup>	<a href="#">Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rules 13a-14(b) and 15d-14(b) promulgated under the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350, as adopted pursuant to section 906 of The Sarbanes-Oxley Act of 2002.</a>
101.INS	XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document)
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)
<sup>^</sup>	These certifications are being furnished solely to accompany this Annual Report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and are not to be incorporated by reference into any filing of the registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.
+	Indicates management contract or compensatory plan.
*	Certain portions of this exhibit (indicated by asterisks) have been omitted because they are not material and would likely cause competitive harm to the registrant if publicly disclosed.
(1)	Previously filed as Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-36177), filed with the Commission on January 15, 2014, and incorporated by reference herein.
(2)	Previously filed as Exhibit 3.2 to the Registrant's Current Report on Form 8-K (File No. 001-36177), filed with the Commission on January 15, 2014, and incorporated by reference herein.

- (3) Previously filed as Exhibit 4.2 to Amendment No. 2 to the Registrant's Registration Statement on Form S-1 (File No. 333-191567), filed with the Commission on October 31, 2013, and incorporated by reference herein.
- (4) Previously filed as Exhibit 4.2 to the Registrant's Annual Report on Form 10-K (File No. 001-36177), filed with the Commission on February 28, 2020, and incorporated by reference herein.
- (5) Previously filed as Exhibit 10.8 to the Registrant's Registration Statement on Form S-1 (File No. 333-191567), filed with the Commission on October 4, 2013, and incorporated by reference herein.
- (6) Previously filed as Exhibit 10.9 to the Registrant's Registration Statement on Form S-1 (File No. 333-191567), filed with the Commission on October 4, 2013, and incorporated by reference herein.
- (7) Previously filed as Exhibit 10.10 to the Registrant's Registration Statement on Form S-1 (File No. 333-191567), filed with the Commission on October 4, 2013, and incorporated by reference herein.
- (8) Previously filed as Exhibit 10.11 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (File No. 333-191567), filed with the Commission on October 28, 2013, and incorporated by reference herein.
- (9) Previously filed as Exhibit 10.12 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (File No. 333-191567), filed with the Commission on October 28, 2013, and incorporated by reference herein.
- (10) Previously filed as Exhibit 10.13 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (File No. 333-191567), filed with the Commission on October 28, 2013, and incorporated by reference herein.
- (11) Previously filed as Exhibit 10.14 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (File No. 333-191567), filed with the Commission on October 28, 2013, and incorporated by reference herein.
- (12) Previously filed as Exhibit 10.15 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (File No. 333-191567), filed with the Commission on October 28, 2013, and incorporated by reference herein.
- (13) Previously filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-36177), filed with the Commission on November 2, 2021, and incorporated by reference herein.
- (14) Previously filed as Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-36177), filed with the Commission on August 1, 2019, and incorporated by reference herein.
- (15) Previously filed as Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-36177), filed with the Commission on August 1, 2019, and incorporated by reference herein.
- (16) Previously filed as Exhibit 10.6 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-36177), filed with the Commission on August 1, 2019, and incorporated by reference herein.
- (17) Previously filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-36177), filed with the Commission on July 28, 2014, and incorporated by reference herein.
- (18) Previously filed as Exhibit 1.1 to the Registrant's Current Report on Form 8-K (File No. 001-36177), filed with the Commission on October 7, 2020, and incorporated by reference herein.
- (19) Previously filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-36177), filed with the Commission on March 29, 2016, and incorporated by reference herein.
- (20) Previously filed as Exhibit 10.20 to the Registrant's Annual Report on Form 10-K (File No. 001-36177), filed with the Commission on February 28, 2020, and incorporated by reference herein.
- (21) Previously filed as Exhibit 10.22 to the Registrant's Annual Report on Form 10-K (File No. 001-36177), filed with the Commission on February 28, 2020, and incorporated by reference herein.

**ITEM 16. FORM 10-K SUMMARY**

Not applicable.

**SIGNATURES**

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

**GLYCOMIMETICS, INC.**

By: /s/ Harout Semerjian

Harout Semerjian  
*President and Chief Executive Officer*

March 3, 2022

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Harout Semerjian and Brian M. Hahn, jointly and severally, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign this Annual Report on Form 10-K of GlycoMimetics, Inc., and any or all amendments thereto, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises hereby ratifying and confirming all that said attorneys-in-fact and agents, or his, her or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Harout Semerjian</u> Harout Semerjian	President, Chief Executive Officer and Director <i>(Principal Executive Officer)</i>	March 3, 2022
<u>/s/ Brian M. Hahn</u> Brian M. Hahn	Chief Financial Officer <i>(Principal Financial Officer and Principal Accounting Officer)</i>	March 3, 2022
<u>/s/ Patricia S. Andrews</u> Patricia S. Andrews	Director	March 3, 2022
<u>/s/ Mark A. Goldberg, M.D.</u> Mark A. Goldberg M.D.	Director	March 3, 2022
<u>/s/ Scott T. Jackson</u> Scott T. Jackson	Director	March 3, 2022
<u>/s/ Daniel M. Junius</u> Daniel M. Junius	Director	March 3, 2022
<u>/s/ Rachel K. King</u> Rachel K. King	Director	March 3, 2022
<u>/s/ Scott Koenig, M.D., Ph.D.</u> Scott Koenig, M.D., Ph.D.	Director	March 3, 2022
<u>/s/ Timothy Pearson</u> Timothy Pearson	Director	March 3, 2022

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## **Report of Independent Registered Public Accounting Firm**

To the Shareholders and the Board of Directors of GlycoMimetics, Inc.

### **Opinion on the Financial Statements**

We have audited the accompanying balance sheets of GlycoMimetics, Inc. (the Company) as of December 31, 2021 and 2020, the related statements of operations and comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2021, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021, in conformity with U.S. generally accepted accounting principles.

### **The Company's Ability to Continue as a Going Concern**

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has suffered recurring losses from operations and has stated that substantial doubt exists about the Company's ability to continue as a going concern without obtaining additional funding or entering into another form of non-equity or debt arrangement. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

### **Basis for Opinion**

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

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

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

### **Critical Audit Matter**

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

#### ***Accrued Clinical Trial Expenses***

*Description of the Matter*

As discussed in Note 3 to the financial statements, the Company records costs for clinical trial activities based upon estimates of costs incurred through the balance sheet date that have yet to be invoiced by the contract research organizations, investigative sites, and other consultants. The Company's accrued expenses of \$8.7 million at December 31, 2021 include accrued clinical trial expenses, and the Company's research and development costs and

expenses of \$47.5 million for the year ended December 31, 2021 include 2021 clinical trial expenses.

Auditing the Company's accruals for clinical trials was challenging due to the multiple sources of information used to evaluate the Company's estimated accruals. In addition, in certain circumstances, the determination of the work that has been completed and measurement of progress during the reporting period required judgment because the timing and pattern of vendor invoicing may not correspond to the level of services provided and there may be delays in receiving clinical information from investigative sites and other consultants.

*How We Addressed  
the Matter in Our  
Audit*

To evaluate the accrual for clinical expenses, our audit procedures included, among others, reading certain contracts with contract research organizations and clinical study sites to evaluate financial and certain other contractual terms, testing the completeness and accuracy of the underlying data used in the estimates, and evaluating the significant assumptions. For example, we evaluated patient enrollment, patient cycles incurred, clinical site activations, estimated project duration, and other pass-through costs, that are used by management to estimate the recorded accruals. We assessed the reasonableness of the significant assumptions. For example, we corroborated the progress of clinical trials with the Company's clinical team and inspected information from third parties related to active patient sites and currently enrolled patients. We also examined subsequent invoices from the service providers and cash disbursements to the service providers, to the extent such invoices were received, or payments were made prior to the date that the financial statements were issued.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2011.

Baltimore, Maryland  
March 3, 2022

**GLYCOMIMETICS, INC.****Balance Sheets**

	<b>December 31,</b>	
	<b>2021</b>	<b>2020</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 90,254,890	\$ 137,035,017
Prepaid expenses and other current assets	533,804	1,238,328
Total current assets	90,788,694	138,273,345
Property and equipment, net	368,842	620,673
Prepaid research and development expenses	1,560,607	1,560,607
Deposits	52,320	52,320
Operating lease right-of-use asset	1,576,185	2,325,224
Total assets	<u>\$ 94,346,648</u>	<u>\$ 142,832,169</u>
<b>Liabilities &amp; stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 2,107,615	\$ 2,089,939
Accrued expenses	8,715,368	9,439,881
Lease liabilities	1,001,407	898,549
Total current liabilities	11,824,390	12,428,369
Noncurrent accrued expenses	—	264,329
Lease liabilities, net of current portion	918,607	1,920,015
Total liabilities	12,742,997	14,612,713
Stockholders' equity:		
Preferred stock; \$0.001 par value; 5,000,000 shares authorized, no shares issued and outstanding at December 31, 2021 and December 31, 2020	—	—
Common stock; \$0.001 par value; 100,000,000 shares authorized; 52,313,894 shares issued and outstanding at December 31, 2021; 49,017,622 shares issued and outstanding at December 31, 2020	52,314	49,018
Additional paid-in capital	454,448,327	437,639,991
Accumulated deficit	(372,896,990)	(309,469,553)
Total stockholders' equity	81,603,651	128,219,456
Total liabilities and stockholders' equity	<u>\$ 94,346,648</u>	<u>\$ 142,832,169</u>

See accompanying notes.

**GLYCOMIMETICS, INC.**  
**Statements of Operations and Comprehensive Loss**

	<u>Year Ended December 31,</u>		
	<u>2021</u>	<u>2020</u>	<u>2019</u>
Revenue from collaboration and license agreements	\$ 1,159,767	\$ 10,162,935	\$ —
Costs and expenses:			
Research and development expense	47,491,567	44,929,198	47,029,264
General and administrative expense	17,115,405	16,743,127	14,360,038
Total costs and expenses	<u>64,606,972</u>	<u>61,672,325</u>	<u>61,389,302</u>
Loss from operations	(63,447,205)	(51,509,390)	(61,389,302)
Interest income	19,768	482,487	3,497,391
Net loss and comprehensive loss	<u>\$ (63,427,437)</u>	<u>\$ (51,026,903)</u>	<u>\$ (57,891,911)</u>
Basic and diluted net loss per common share	\$ (1.23)	\$ (1.12)	\$ (1.34)
Basic and diluted weighted-average number of common shares outstanding	51,453,204	45,721,139	43,254,782

*See accompanying notes.*

**GLYCOMIMETICS, INC.**  
**Statements of Stockholders' Equity**

	<u>Common Stock</u>		<u>Additional Paid-In Capital</u>	<u>Accumulated Deficit</u>	<u>Total Stockholders' Equity</u>
	<u>Shares</u>	<u>Amount</u>			
<b>Balance at December 31, 2018</b>	43,160,751	\$ 43,159	\$ 405,972,075	\$ (200,550,739)	\$ 205,464,495
Exercise of options and vesting of restricted stock units	306,182	306	412,607	—	412,913
Stock-based compensation	—	—	6,215,090	—	6,215,090
Net loss	—	—	—	(57,891,911)	(57,891,911)
<b>Balance at December 31, 2019</b>	43,466,933	43,465	412,599,772	(258,442,650)	154,200,587
Issuance of common stock, net of issuance costs	5,161,502	5,163	17,819,554	—	17,824,717
Exercise of options and vesting of restricted stock units	389,187	390	318,907	—	319,297
Stock-based compensation	—	—	6,901,758	—	6,901,758
Net loss	—	—	—	(51,026,903)	(51,026,903)
<b>Balance at December 31, 2020</b>	49,017,622	49,018	437,639,991	\$ (309,469,553)	\$ 128,219,456
Issuance of common stock, net of issuance costs	3,092,603	3,092	10,696,225	—	10,699,317
Exercise of options and vesting of restricted stock units	203,669	204	24,825	—	25,029
Stock-based compensation	—	—	6,087,286	—	6,087,286
Net loss	—	—	—	(63,427,437)	(63,427,437)
<b>Balance at December 31, 2021</b>	<u>52,313,894</u>	<u>\$ 52,314</u>	<u>\$ 454,448,327</u>	<u>\$ (372,896,990)</u>	<u>\$ 81,603,651</u>

See accompanying notes.

**GLYCOMIMETICS, INC.****Statements of Cash Flows**

	Year Ended December 31,		
	2021	2020	2019
<b>Operating activities</b>			
Net loss	\$ (63,427,437)	\$ (51,026,903)	\$ (57,891,911)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	264,600	270,754	279,234
Loss on disposal of assets	2,174	—	—
Non-cash lease expense	749,039	680,845	620,068
Stock-based compensation	6,087,286	6,901,758	6,215,090
Changes in assets and liabilities:			
Prepaid expenses and other current assets	704,524	3,087,994	(2,059,260)
Accounts payable	17,676	654,279	(1,227,919)
Accrued expenses	(988,842)	993,420	2,709,986
Lease liabilities	(898,550)	(804,078)	(629,427)
Net cash used in operating activities	(57,489,530)	(39,241,931)	(51,984,139)
<b>Investing activities</b>			
Purchases of property and equipment	(14,943)	(68,507)	(144,928)
Net cash used in investing activities	(14,943)	(68,507)	(144,928)
<b>Financing activities</b>			
Proceeds from issuance of common stock, net of issuance costs	10,699,317	17,824,717	—
Proceeds from exercise of stock options	25,029	319,297	412,913
Net cash provided by financing activities	10,724,346	18,144,014	412,913
Net change in cash and cash equivalents	(46,780,127)	(21,166,424)	(51,716,154)
Cash and cash equivalents, beginning of period	137,035,017	158,201,441	209,917,595
Cash and cash equivalents, end of period	\$ 90,254,890	\$ 137,035,017	\$ 158,201,441

See accompanying notes.

## GLYCOMIMETICS, INC.

### Notes to Financial Statements

#### 1. Description of the Business

GlycoMimetics, Inc. (the Company), a Delaware corporation headquartered in Rockville, Maryland, was incorporated in 2003. The Company is a clinical stage biotechnology company focused on the discovery and development of novel glycomimetic drugs to address unmet medical needs resulting from diseases in which carbohydrate biology plays a key role. Glycomimetics are molecules that mimic the structure of carbohydrates involved in important biological processes. Using its expertise in carbohydrate chemistry and knowledge of carbohydrate biology, the Company is developing a pipeline of proprietary glycomimetics that inhibit disease-related functions of carbohydrates, such as the roles they play in inflammation, cancer and infection.

#### 2. Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern within one year after the date that the financial statements are issued. During 2021, the Company incurred a net loss of \$63.4 million and had net cash flows used in operating activities of \$57.5 million. At December 31, 2021, the Company had \$90.3 million in cash and cash equivalents and had no committed source of additional funding from either debt or equity financings. Management believes that given the Company's current cash position and forecasted negative cash flows from operating activities over the next twelve months, including the completion of its planned Phase 3 clinical trial of uproleselan, there is substantial doubt about its ability to continue as a going concern after the date that is one year from the date that these financial statements are issued, without obtaining additional financing or entering into another form of non-equity or debt arrangement.

The Company's ability to fund its operations is dependent upon management's plans, which include raising additional capital in the near term primarily through a combination of equity and debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements and in the longer term, from revenue related to product sales, to the extent its product candidates receive marketing approval and can be commercialized. There can be no assurances that new financings or other transactions will be available to us on commercially acceptable terms, or at all. Also, any collaborations, strategic alliances and marketing, distribution or licensing arrangements may require the Company to give up some or all of its rights to a product or technology, which in some cases may be at less than the full potential value of such rights. If the Company is unable to obtain additional capital, the Company will assess its capital resources and may be required to delay, reduce the scope of or eliminate some or all of our operations, which may have a material adverse effect on our business, financial condition, results of operations and ability to operate as a going concern.

The financial statements do not include any adjustments that might be necessary if the Company is not able to continue as a going concern.

#### 3. Summary of Significant Accounting Policies

##### *Basis of Accounting*

The accompanying financial statements were prepared based on the accrual method of accounting in accordance with U.S. generally accepted accounting principles (GAAP).

##### *Segment Information*

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business in one segment, which is the identification and development of glycomimetic compounds.

##### *Use of Estimates*

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Although actual results could differ from those estimates, management does not believe that such differences would be material.

### **Cash and Cash Equivalents**

Cash and cash equivalents consist of investment in money market funds with commercial banks and financial institutions. The Company considers all investments in highly liquid financial instruments with an original maturity of three months or less at the date of purchase to be cash equivalents. Cash equivalents are stated at amortized cost, plus accrued interest, which approximates fair value.

### **Fair Value Measurements**

The Company's financial instruments include cash and cash equivalents. The fair values of the financial instruments approximated their carrying values at December 31, 2021 and 2020, due to their short-term maturities. The Company accounts for recurring and nonrecurring fair value measurements in accordance with ASC 820, *Fair Value Measurements*. ASC 820 defines fair value, establishes a fair value hierarchy for assets and liabilities measured at fair value, and requires expanded disclosures about fair value measurements. The ASC hierarchy ranks the quality of reliability of inputs, or assumptions, used in the determination of fair value, and requires assets and liabilities carried at fair value to be classified and disclosed in one of the following three categories:

- Level 1—Fair value is determined by using unadjusted quoted prices that are available in active markets for identical assets and liabilities.
- Level 2—Fair value is determined by using inputs, other than Level 1 quoted prices, that are directly and indirectly observable. Inputs can include quoted prices for similar assets and liabilities in active markets or quoted prices for identical assets and liabilities in inactive markets. Related inputs can also include those used in valuation or other pricing models that can be corroborated by observable market data.
- Level 3—Fair value is determined by inputs that are unobservable and not corroborated by market data. Use of these inputs involves significant and subjective judgments to be made by a reporting entity. In instances where the determination of the fair value measurement is based on inputs from different levels of fair value hierarchy, the fair value measurement will fall within the lowest level input that is significant to the fair value measurement in its entirety.

The Company periodically evaluates financial assets and liabilities subject to fair value measurements to determine the appropriate level at which to classify them each reporting period. This determination requires the Company to make subjective judgments as to the significance of inputs used in determining fair value and where such inputs lie within the ASC 820 hierarchy.

The Company had no assets or liabilities that were measured using quoted prices for similar assets and liabilities or significant unobservable inputs (Level 2 and Level 3 assets and liabilities, respectively) either on a recurring or non-recurring basis as of December 31, 2021 and 2020. The carrying value of cash held in money market funds of approximately \$88.3 million and \$135.0 million as of December 31, 2021 and 2020, respectively, is included in cash and cash equivalents and approximates market values based on quoted market prices (Level 1 inputs). The Company did not transfer any assets measured at fair value on a recurring basis between levels during the years ended December 31, 2021 and 2020.

### **Concentration of Credit Risk**

Credit risk represents the risk that the Company would incur a loss if counterparties failed to perform pursuant to the terms of their agreements. Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and cash equivalents. Cash and cash equivalents consist of investment in money market funds with major financial institutions in the United States. These deposits and funds may be redeemed upon demand and, therefore, bear minimal risk. The Company does not anticipate any losses on such balances.

### **Property and Equipment**

Property and equipment are recorded at cost and depreciated on a straight-line basis over estimated useful lives ranging from three to seven years. Upon retirement or disposition of assets, the costs and related accumulated depreciation are removed from the accounts and any resulting gain or loss is included in the results of operations. Expenditures for repairs and maintenance are charged to operations as incurred; major replacements that extend the

useful life are capitalized. Depreciation and amortization are computed using the straight-line method over the following estimated useful lives:

	<u>ESTIMATED USEFUL LIVES</u>
Furniture and fixtures	7 years
Laboratory equipment	5 years
Office equipment	5 years
Computer equipment	5 years
Leasehold improvements	Shorter of lease term or useful life

### **Impairment of Long-Lived Assets**

The Company periodically assesses the recoverability of the carrying value of its long-lived assets in accordance with the provisions of ASC 360, *Property, Plant, and Equipment*. ASC 360 requires that long-lived assets and certain identifiable intangible assets be reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of the long-lived asset is measured by a comparison of the carrying amount of the asset to future undiscounted net cash flows expected to be generated by the asset. If the carrying value exceeds the sum of undiscounted cash flows, the Company then determines the fair value of the underlying asset. Any impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the estimated fair value of the assets. Assets to be disposed of are reported at the lower of the carrying amount or fair value, less costs to sell. As of December 31, 2021 and 2020, the Company determined that there were no impaired assets and it had no assets held for sale.

### **Revenue Recognition**

The Company applies Accounting Standards Codification, or ASC, Topic 606, *Revenue from Contracts with Customers* (Topic 606), to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services in an amount that reflects the consideration which the entity expects to receive in exchange for those goods and services. To determine revenue recognition for arrangements that an entity determines are within the scope of Topic 606, the entity performs the following five steps: (i) identify the contract(s) with the customer(s); (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods and services it transfers to the customer. At contract inception, the Company assesses the goods or services promised within each contract that falls under the scope of Topic 606, determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

The Company enters into licensing agreements which are within the scope of Topic 606, under which it licenses certain of its drug candidates' rights to third parties. The terms of these arrangements typically include payment of one or more of the following: non-refundable, up-front license fees; development, regulatory and commercial milestone payments; and royalties on net sales of the licensed product, if and when earned. See Note 11 for additional information regarding the Company's license agreements.

In determining the appropriate amount of revenue to be recognized as it fulfills its obligation under each of its agreements, the Company performs the five steps under Topic 606 described above. As part of the accounting for these arrangements, the Company must develop assumptions that require judgment to determine the stand-alone selling price, which may include forecasted revenues, development timelines, reimbursement of personnel costs, discount rates and probabilities of technical and regulatory success.

*Licensing of Intellectual Property:* If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenue from non-refundable, up-front fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to

assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. The Company evaluates the measure of progress each reporting period, and, if necessary, adjusts the measure of performance and related revenue recognition.

*Milestone Payments:* At the inception of each arrangement that includes development milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal will not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such development milestones and any related constraint and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect license, collaboration and other revenues and earnings in their period of adjustment.

*Royalties:* For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and for which the license is deemed to be the predominant item to which royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any royalty revenue from its license agreements.

*Manufacturing and Supply:* The obligations under the Company's agreements may include clinical and commercial manufacturing products to be provided by the Company to the counterparty. The services are generally determined to be distinct from the other promises or performance obligations identified in the arrangement. The Company recognizes the transaction price allocated to these services as revenue at a point in time when transfer of control of the related products to the customer occurs.

#### **Research and Development Costs**

Except for payments made in advance of services, research and development costs are expensed as incurred. For payments made in advance, the Company recognizes research and development expense as the services are rendered. Research and development costs primarily consist of salaries and related expenses for personnel, laboratory supplies and raw materials, sponsored research, depreciation of laboratory facilities and leasehold improvements, and utilities costs related to research space. Other research and development expenses include fees paid to consultants and outside service providers including clinical research organizations and clinical manufacturing organizations.

#### **Accruals for Clinical Trial Expenses**

Clinical trial costs primarily consist of expenses incurred under agreements with contract research organizations (CROs), investigative sites, laboratory testing expenses, data management and consultants that conduct the Company's clinical trials. Clinical trial expenses are a significant component of research and development expenses, and the Company outsources a significant portion of these clinical trial activities to third parties. The accrual for site and patient costs includes inputs such as estimates of patient enrollment, patient cycles incurred, clinical site activations, estimated project duration and other pass-through costs. These inputs are required to be estimated due to a lag in receiving the actual clinical information from third parties. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected on the balance sheets as a prepaid asset or accrued expenses. These third-party agreements are generally cancellable, and related costs are recorded as research and development expenses as incurred. Except for payments made in advance of services, clinical trial costs are expensed as incurred. Non-refundable advance clinical payments for goods or services that will be used or rendered for future research and development activities are recorded as a prepaid asset and recognized as expense as the related goods are delivered or the related services are performed. When evaluating the adequacy of the accrued expenses, management assessments include: (i) an evaluation by the project manager of the work that has been completed during the period; (ii) measurement of progress prepared internally and/or provided by the third-party service provider; (iii) analyses of data that justify the progress; and (iv) the Company's judgment. Significant judgments and estimates may be made in determining the accrued balances at the end of any reporting period. Actual results could differ from the estimates made.

The Company's historical clinical accrual estimates have not been materially different from the actual costs. Clinical trial accruals that are due longer than one year are classified as noncurrent accrued expenses.

#### **Stock-Based Compensation**

Stock-based payments are accounted for in accordance with the provisions of ASC 718, *Compensation—Stock Compensation*. The fair value of stock-based payments is estimated, on the date of grant, using the Black-Scholes-Merton model. The resulting fair value is recognized ratably over the requisite service period, which is generally the vesting period of the option. The Company has elected to account for forfeitures as they occur.

The Company has elected to use the Black-Scholes-Merton option pricing model to value any options granted. The Company will reconsider use of the Black-Scholes-Merton model if additional information becomes available in the future that indicates another model would be more appropriate or if grants issued in future periods have characteristics that prevent their value from being reasonably estimated using this model.

A discussion of management's methodology for developing some of the assumptions used in the valuation model follows:

*Expected Dividend Yield*—The Company has never declared or paid dividends and has no plans to do so in the foreseeable future.

*Expected Volatility*—Volatility is a measure of the amount by which a financial variable such as share price has fluctuated (historical volatility) or is expected to fluctuate (expected volatility) during a period. Effective January 1, 2020, the Company bases the expected volatility on the historical volatility of the Company's publicly traded common stock. Prior to January 1, 2020, the Company utilized the historical volatilities of a peer group (e.g., several public entities of similar size, complexity, and stage of development), along with the Company's historical volatility since its initial public offering, to determine its expected volatility.

*Risk-Free Interest Rate*—This is the U.S. Treasury rate for the week of each option grant during the year, having a term that most closely resembles the expected life of the option.

*Expected Term*—This is a period of time that the options granted are expected to remain unexercised. Options granted have a maximum term of 10 years. The Company estimates the expected life of the option term to be 6.25 years. The Company uses a simplified method to calculate the average expected term.

#### **Income Taxes**

The Company accounts for income taxes using the asset and liability method in accordance with ASC 740, *Income Taxes*. Deferred income taxes are recognized for the tax consequences in future years of differences between the tax bases of assets and liabilities and the financial reporting amounts at each year-end based on enacted tax laws and statutory tax rates applicable to the periods in which the differences are expected to affect taxable income. A valuation allowance is established when necessary to reduce deferred tax assets to the amount expected to be realized.

The Company accounts for uncertain tax positions pursuant to ASC 740. Financial statement recognition of a tax position taken or expected to be taken in a tax return is determined based on a more-likely-than-not threshold of that tax position being sustained. If the tax position meets this threshold, the benefit to be recognized is measured as the tax benefit having the highest likelihood of being realized upon ultimate settlement with the taxing authority. The Company recognizes interest accrued related to unrecognized tax benefits and penalties in the provision for income taxes.

#### **Comprehensive Loss**

Comprehensive loss comprises net loss and other changes in equity that are excluded from net loss. For the years ended December 31, 2021, 2020 and 2019, the Company's net loss was equal to comprehensive loss and, accordingly, no additional disclosure is presented.

#### **Adopted Accounting Standards**

In December 2019, the FASB issued ASU 2019-12. ASU 2019-12 removes certain exceptions for recognizing deferred taxes for investments, performing intra-period allocation and calculating income taxes in interim periods. The ASU also adds guidance to reduce complexity in certain areas, including deferred taxes for goodwill and allocating taxes for members of a consolidated group. ASU 2019-12 was effective for all entities for fiscal years beginning after

December 15, 2020. As of January 1, 2021, the Company adopted the standard, which did not have a material impact on the Company's financial statements.

#### **Accounting Standards Not Yet Adopted**

With the exception of the new standard discussed above, there have been no new accounting pronouncements that have significance, or potential significance, to the Company's financial statements.

#### **4. Net Loss Per Share of Common Stock**

Basic net loss per common share is determined by dividing net loss by the weighted-average number of common shares outstanding during the period, without consideration of common stock equivalents. Diluted net loss per share is computed by dividing net loss by the weighted-average number of common stock equivalents outstanding for the period. The treasury stock method is used to determine the dilutive effect of the Company's stock options and restricted stock units (RSUs).

The following potentially dilutive securities outstanding have been excluded from the computation of diluted weighted-average common shares outstanding, as they would be anti-dilutive:

	2021	2020	2019
Stock options and restricted stock units	7,908,122	6,143,594	5,106,493

#### **5. Prepaid Expenses and Other Current Assets**

The following is a summary of the Company's prepaid expenses and other current assets at December 31:

	2021	2020
Prepaid research and development expenses	\$ 273,396	\$ 965,504
Other prepaid expenses	259,061	270,675
Other receivables	1,347	2,149
Prepaid expenses and other current assets	<u>\$ 533,804</u>	<u>\$ 1,238,328</u>

#### **6. Property and Equipment**

Property and equipment, net consisted of the following at December 31:

	2021	2020
Furniture and fixtures	\$ 345,712	\$ 345,712
Laboratory equipment	1,406,346	1,446,596
Office equipment	17,762	16,755
Computer equipment	305,784	327,776
Leasehold improvements	616,133	616,133
Property and equipment	2,691,737	2,752,972
Less accumulated depreciation	<u>(2,322,895)</u>	<u>(2,132,299)</u>
Property and equipment, net	<u>\$ 368,842</u>	<u>\$ 620,673</u>

Depreciation of property and equipment totaled \$264,600, \$270,754 and \$279,234 for the years ended December 31, 2021, 2020 and 2019, respectively.

## 7. Accrued Expenses

The following is a summary of the Company's accrued expenses at December 31:

	2021	2020
Accrued research and development expenses	\$ 5,824,365	\$ 5,114,420
Accrued bonuses	2,152,302	3,341,184
Accrued consulting and other professional fees	299,607	194,760
Accrued employee benefits	348,752	569,048
Other accrued expenses	90,342	220,469
Accrued expenses	<u>\$ 8,715,368</u>	<u>\$ 9,439,881</u>

## 8. Operating Leases

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the circumstances present. The Company determines a lease exists if the contract conveys the right to control an identified asset for a period of time in exchange for consideration. Control is considered to exist when the lessee has the right to obtain substantially all of the economic benefits from the use of an identified asset as well as direct the right to use of that asset. Leases with a term greater than one year are recognized on the balance sheet as right-of-use assets, lease liabilities and, if applicable, long-term lease liabilities. The Company has elected not to recognize on the balance sheet leases with terms of one year or less on the lease commencement date. If a contract is considered to be a lease, the Company recognizes a lease liability based on the present value of the future lease payments over the expected lease term, with an offsetting entry to recognize a right-of-use asset. The Company has also elected to use the practical expedient and account for each lease component and related non-lease component as one single component. The lease component results in a right-of-use asset being recorded on the balance sheet and amortized as lease expense on a straight-line basis.

The interest rate implicit in lease contracts is typically not readily determinable. As such, the Company utilizes the appropriate incremental borrowing rate, which is the rate incurred to borrow on a collateralized basis over a term similar to the term of the lease for which the rate is estimated. Certain adjustments to the right-of-use asset may be required for items such as initial direct costs paid or incentives received.

The Company leases office and research space in Rockville, Maryland under an operating lease with a term from June 15, 2015 through October 31, 2023 (the Lease) that is subject to annual rent increases. The Company has the right to sublease or assign all or a portion of the premises, subject to the conditions set forth in the Lease. The Lease may be terminated early by either the landlord or the Company in certain circumstances. In connection with the Lease, the Company received rent abatement as a lease incentive in the initial year of the Lease.

In March 2016, the Company amended the Lease (the Lease Amendment) to lease additional space as of June 1, 2016. In May 2016, the Company also paid a security deposit of \$52,320 to be held until the expiration or termination of the Company's obligations under the Lease. The term of the Lease Amendment for the additional space continues through October 31, 2023, the same date as for the premises originally leased under the Lease, subject to the Company's renewal option set forth in the Lease.

The Company identified and applied the following significant assumptions in recognizing the right-of-use asset and corresponding liability for the Lease and Lease Amendment:

- Lease term – The lease term includes both the noncancelable period and, when applicable, cancelable option periods where failure to exercise such option would result in an economic penalty. The Company's renewal option to extend is not reasonably certain of being exercised as of December 31, 2021.
- Incremental borrowing rate – As the Company's lease does not provide an implicit rate, the Company used an incremental borrowing rate (IBR), which is the rate incurred to borrow on a collateralized basis over a term similar to the term of the lease for which the rate is estimated. The Company determined the IBR to be 8% based on an estimated rate that considered the Company's credit risk in the United States for a collateralized borrowing and lease term similar to the Lease.

As of December 31, 2021 the weighted-average remaining lease term was 1.8 years. There were no additional operating leases entered into during the year ended December 31, 2021.

The components of lease expense and related cash flows were as follows:

	Year Ended December 31,		
	2021	2020	2019
Operating lease cost	\$ 927,957	\$ 927,957	\$ 927,957
Variable lease cost	490,871	593,973	465,028
Total operating lease cost	<u>\$ 1,418,828</u>	<u>\$ 1,521,930</u>	<u>\$ 1,392,985</u>

Cash paid for amounts included in the measurement of lease liabilities:

Operating cash outflows for operating leases	\$ 1,077,469	\$ 1,051,190	\$ 941,089
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Maturities of lease liability due under these lease agreements as of December 31, 2021 were as follows:

	<b>Operating Lease Obligation</b>
2022	\$ 1,104,356
2023	940,840
Thereafter	—
Total	2,045,196
Present value adjustment	(125,182)
Present value of lease payments	<u>\$ 1,920,014</u>

## 9. Stockholders' Equity

### Common Stock

#### At-The-Market Equity Offerings

On September 28, 2017, the Company entered into an at-the-market sales agreement (the 2017 Sales Agreement) with Cowen and Company, LLC (Cowen) to sell up to \$100.0 million of the Company's common stock registered under a shelf registration statement filed with the U.S. Securities and Exchange Commission in September 2017. During the year ended December 31, 2020, the Company issued and sold 4,136,742 shares of common stock under the 2017 Sales Agreement at a weighted average price per share of \$3.52, for aggregate net proceeds of \$14.1 million, after deducting commissions and offering expenses. There were no shares sold under the 2017 Sales Agreement during the year ended December 31, 2019. The shelf registration statement, under which the shares that could be sold under the 2017 Sales Agreement were registered, expired on October 6, 2020.

On October 7, 2020, the Company filed a prospectus supplement to a shelf registration statement that it filed in May 2019 and entered into a new at-the-market sales agreement (the 2020 Sales Agreement) with Cowen. Under the 2020 Sales Agreement, the Company may sell up to \$100.0 million of the Company's common stock registered under the shelf registration statement that was filed in May 2019. The 2020 Sales Agreement replaced the 2017 Sales Agreement between the Company and Cowen, and the \$100.0 million that may be sold under the 2020 Sales Agreement excludes any amounts that were sold under the 2017 Sales Agreement. During the year ended December 31, 2020, the Company issued and sold 1,024,760 shares of common stock under the 2020 Sales Agreement at a weighted average price per share of \$3.74, for aggregate net proceeds of \$3.7 million, after deducting commissions and offering expenses.

During the year ended December 31, 2021, the Company issued and sold an additional 3,092,603 shares of common stock under the 2020 Sales Agreement at a weighted average price per share of \$3.57, for aggregate net proceeds of \$10.7 million, after deducting commissions and offering expenses. As of December 31, 2021, approximately \$85.1 million remained available to be sold under the terms of the 2020 Sales Agreement. Subsequent to December 31, 2021 and through the date these financial statements were issued, there have been no additional sales under the 2020 Sales Agreement.

#### 2003 Stock Incentive Plan

The 2003 Stock Incentive Plan (the 2003 Plan) provided for the grant of incentives and nonqualified stock options and restricted stock awards. The exercise price for incentive stock options must be at least equal to the fair value of the

common stock on the grant date. Unless otherwise stated in a stock option agreement, 25% of the shares subject to an option grant will vest upon the first anniversary of the vesting start date and thereafter at the rate of one forty-eighth of the option shares per month as of the first day of each month after the first anniversary. Upon termination of employment by reasons other than death, cause, or disability, any vested options shall terminate 60 days after the termination date. Stock options terminate 10 years from the date of grant. The 2003 Plan expired on May 21, 2013.

A summary of the Company's stock option activity under the 2003 Plan for the year ended December 31, 2021 is as follows:

	OUTSTANDING OPTIONS	WEIGHTED- AVERAGE EXERCISE PRICE	WEIGHTED- AVERAGE REMAINING CONTRACTUAL TERM (YEARS)	AGGREGATE INTRINSIC VALUE (IN THOUSANDS)
Outstanding as of December 31, 2020	97,250	\$ 1.96	1.3	
Options exercised	(3,785)	1.12		
Options forfeited	—	—		
Outstanding, Vested and Exercisable as of December 31, 2021	93,465	2.00	0.3	\$ —

During 2021, 2020 and 2019 the Company issued 3,785, 285,087 and 284,743 shares of common stock, respectively, in conjunction with exercises of stock options granted under the 2003 Plan. The Company received cash proceeds from the exercise of these stock options of \$4,239, \$319,297 and \$318,912 during 2021, 2020 and 2019, respectively. Total intrinsic value of the options exercised during the years ended December 31, 2021, 2020 and 2019 was \$8,668, \$921,168 and \$924,688, respectively.

As of December 31, 2021, the options under the 2003 Plan were fully expensed and all options outstanding under the 2003 Plan were fully vested. There were no options granted under the 2003 Plan in 2021, 2020 and 2019.

### **2013 Equity Incentive Plan**

The Company's board of directors adopted, and its stockholders approved, its 2013 Equity Incentive Plan (the 2013 Plan) effective on January 9, 2014. The 2013 Plan provides for the grant of incentive stock options within the meaning of Section 422 of the Internal Revenue Code (the Code), to the Company's employees and its parent and subsidiary corporations' employees, and for the grant of nonstatutory stock options, restricted stock awards, restricted stock unit awards, stock appreciation rights, performance stock awards and other forms of stock compensation to its employees, including officers, consultants and directors. The 2013 Plan also provides for the grant of performance cash awards to the Company's employees, consultants and directors. Unless otherwise stated in a stock option agreement, 25% of the shares subject to an option grant will typically vest upon the first anniversary of the vesting start date and thereafter at the rate of one forty-eighth of the option shares per month as of the first day of each month after the first anniversary. Upon termination of employment by reasons other than death, cause, or disability, any vested options shall terminate 90 days after the termination date, unless otherwise set forth in a stock option agreement. Stock options generally terminate 10 years from the date of grant.

#### *Authorized Shares*

The maximum number of shares of common stock that may be issued under the 2013 Plan was 1,000,000 shares, plus any shares subject to stock options or similar awards granted under the 2003 Plan that expire or terminate without having been exercised in full or are forfeited to or repurchased by the Company. The number of shares of common stock reserved for issuance under the 2013 Plan will automatically increase on January 1 of each year, beginning on January 1, 2015 and ending on January 1, 2023, by 3% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares as may be determined by the Company's board of directors. The maximum number of shares that may be issued pursuant to exercise of incentive stock options under the 2013 Plan is 20,000,000.

Shares issued under the 2013 Plan may be authorized but unissued or reacquired shares of common stock. Shares subject to stock awards granted under the 2013 Plan that expire or terminate without being exercised in full, or that are paid out in cash rather than in shares, will not reduce the number of shares available for issuance under the 2013 Plan. Additionally, shares issued pursuant to stock awards under the 2013 Plan that the Company repurchases or that are

forfeited, as well as shares reacquired by the Company as consideration for the exercise or purchase price of a stock award or to satisfy tax withholding obligations related to a stock award, will become available for future grant under the 2013 Plan.

*Stock Options*

A summary of the Company's stock option activity under the 2013 Plan for the year ended December 31, 2021 is as follows:

	OUTSTANDING OPTIONS	WEIGHTED- AVERAGE EXERCISE PRICE	WEIGHTED- AVERAGE REMAINING CONTRACTUAL TERM (YEARS)	AGGREGATE INTRINSIC VALUE (IN THOUSANDS)
Outstanding as of December 31, 2020	5,753,211	\$ 8.93	6.6	
Options granted	898,100	3.70		
Options exercised	—	—		
Options forfeited	(995,854)	7.89		
Outstanding as of December 31, 2021	<u>5,655,457</u>	8.30	6.0	\$ —
Vested or expected to vest as of December 31, 2021	<u>5,655,457</u>	8.30	6.0	—
Exercisable as of December 31, 2021	<u>4,118,394</u>	9.43	5.1	—

As of December 31, 2021, there was \$4,936,519 of total unrecognized compensation expense related to unvested options that will be recognized over a weighted-average period of approximately 2.0 years. The total fair value of options that vested in the years ended December 31, 2021, 2020 and 2019 was \$5,936,641, \$7,347,548 and \$6,159,610, respectively. There were no options exercised under the 2013 Plan during the years ended December 31, 2021 or 2020. During the year ended December 31, 2019, the Company received cash of \$94,001 and issued 16,606 shares of common stock in conjunction with exercises of stock options granted under the 2013 Plan. The intrinsic value of the options exercised for the year ended December 31, 2019 was \$97,429.

*Restricted Stock Units (RSUs)*

A restricted stock unit (RSU) is a stock award that entitles the holder to receive shares of the Company's common stock as the award vests. The fair value of each RSU is based on the closing price of the Company's common stock on the date of grant. In January 2021, the Company awarded RSUs under the 2013 Plan to all of its employees. The RSUs granted vest over four years in equal installments on each anniversary of the grant date. In September 2019, the Company granted an aggregate of 332,106 RSUs with service conditions to the Company's non-executive employees. The RSUs granted in September 2019 vested over a two-year period, with one-third vesting on the first anniversary of the date of grant and the remaining two-thirds vesting on the second anniversary of the date of grant, provided that the employee remained employed with the Company at the applicable vesting date. Compensation expense is recognized on a straight-line basis. As of December 31, 2021, there was \$943,458 of total unrecognized compensation expense associated with these RSU grants that will be recognized over a weighted-average period of approximately 3.0 years.

The following is a summary of RSU activity for the 2013 Plan for the year ended December 31, 2021:

	Number of Shares Underlying RSUs	Weighted-Average Grant Date Fair Value
Unvested at December 31, 2020	192,533	\$ 4.53
Granted	444,613	3.72
Forfeited	(101,754)	3.84
Vested	(189,792)	4.53
Unvested at December 31, 2021	<u>345,600</u>	3.70

*Inducement Plan*

In January 2020, the Company's board of directors adopted the GlycoMimetics, Inc. Inducement Plan (the Inducement Plan). The Inducement Plan provides for the grant of nonstatutory stock options, restricted stock awards, restricted stock unit awards, stock appreciation rights and other forms of stock awards to individuals not previously an

employee or director of the Company as an inducement for such individuals to join the Company. Unless otherwise stated in an applicable stock option agreement, one-fourth of the shares subject to an option grant under the Inducement Plan will typically vest upon the first anniversary of the vesting start date, with the balance of the shares vesting in a series of thirty-six successive equal monthly installments as of the first day of each month measured from the first anniversary of the vesting start date, subject to the new employee's continued service with the Company through the applicable vesting dates. Upon termination of employment by reasons other than death, cause or disability, any vested options will terminate 90 days after the termination date, unless otherwise set forth in a stock option agreement. Stock options generally terminate 10 years from the date of grant. There were 500,000 shares of common stock reserved under the Inducement Plan at its adoption date. In August 2021, the Company's board of directors adopted an amendment to the Inducement Plan to increase the number of shares reserved to 2,000,000 shares, and in January 2022 the Company's board of directors adopted an amendment to the Inducement Plan to further increase the number of shares reserved to 3,000,000 shares.

A summary of the Company's stock option activity under the Inducement Plan for the year ended December 31, 2021 is as follows:

	OUTSTANDING OPTIONS	WEIGHTED- AVERAGE EXERCISE PRICE	WEIGHTED- AVERAGE REMAINING CONTRACTUAL TERM (YEARS)	AGGREGATE INTRINSIC VALUE (IN THOUSANDS)
Outstanding as of December 31, 2020	100,600	\$ 3.09	9.5	
Options granted	1,747,600	2.02		
Options exercised	(10,092)	2.06		
Options forfeited	(24,508)	2.06		
Outstanding as of December 31, 2021	<u>1,813,600</u>	2.08	9.6	\$ —
Vested or expected to vest as of December 31, 2021	<u>1,264,400</u>	2.10	9.6	—
Exercisable as of December 31, 2021	<u>22,879</u>	3.58	8.6	—

As of December 31, 2021, there was \$1,672,270 of total unrecognized compensation expense related to unvested options under the Inducement Plan that will be recognized over a weighted-average period of approximately 3.6 years. In August 2021, the Company granted stock options to purchase an aggregate of 1,647,600 shares to its new Chief Executive Officer under the Inducement Plan. This consisted of (a) an option to purchase 1,098,400 shares, subject to vesting as to 25% of the underlying shares on August 3, 2022 and as to the remaining underlying shares in equal monthly installments over 36 months thereafter, subject to the officer's continued service through each such vesting date, and (b) an option to purchase 549,200 shares that is subject to performance vesting conditions and will vest upon achievement of milestones as follows: (i) one-half of the shares will vest upon FDA approval of uproleselan in patients with relapsed/refractory acute myeloid leukemia and (ii) one-half of the shares will vest upon the first commercial sale of uproleselan in the United States or abroad. The maximum fair value of \$798,053 associated with the performance-based option is excluded from the unrecognized compensation expense under the Inducement Plan as the completion of the performance milestones are not probable as of December 31, 2021. The Company will reevaluate at the end of each reporting period the probability that the performance conditions will be achieved and record any compensation cost at that time.

The total fair value of options that vested in the year ended December 31, 2021 was \$73,334. During the year ended December 31, 2021, the Company received cash of \$20,790 and issued 10,092 shares of common stock in conjunction with exercises of stock options granted under the Inducement Plan. The intrinsic value of the options exercised for the year ended December 31, 2021 was \$1,944. There were no options vested or exercised under the Inducement Plan during the year ended December 31, 2020.

The weighted-average fair value of the options granted under all equity incentive plans during the years ended December 31, 2021, 2020 and 2019 was \$1.85, \$3.17 and \$7.17 per share, respectively, applying the Black-Scholes-Merton option pricing model utilizing the following weighted-average assumptions:

	2021	2020	2019
Expected term	6.25 years	6.25 years	6.25 years
Expected volatility	84.19%	84.40%	71.15%
Risk-free interest rate	0.78%	1.41%	2.54%
Expected dividend yield	0%	0%	0%

Total stock-based compensation expense associated with stock options and RSUs was classified as follows on the statement of operations for the years ended December 31:

	2021	2020	2019
Research and development expense	\$ 2,214,848	\$ 2,946,952	\$ 2,402,242
General and administrative expense	3,872,438	3,954,806	3,812,848
Total stock-based compensation expense	\$ 6,087,286	\$ 6,901,758	\$ 6,215,090

## 10. Income Taxes

The components of the gross deferred tax asset and related valuation allowance at December 31 were as follows:

	2021	2020
Deferred income tax assets:		
Net operating loss carryforward	\$ 79,788,146	\$ 63,830,866
Capitalized start-up costs	920,516	1,114,309
Patent amortization	73,480	88,949
Research and orphan drug credits	47,976,370	42,008,797
Stock-based compensation	7,102,947	6,778,569
Operating lease liabilities	528,340	775,598
Accrued bonus	592,260	919,410
Other	209,580	283,751
Gross deferred income tax assets	137,191,639	115,800,249
Valuation allowance	(136,613,829)	(115,016,323)
Net deferred income tax assets	577,810	783,926
Deferred income tax liabilities:		
Operating lease right-of-use assets	(433,727)	(639,843)
Property and equipment	(144,083)	(144,083)
Gross deferred income tax liabilities	(577,810)	(783,926)
Net deferred income tax asset/(liability)	\$ —	\$ —

Based on the Company's operating history and management's expectation regarding future profitability, management believes the Company's deferred tax assets will not be realizable under ASC 740, *Income Taxes*. Accordingly, a full valuation allowance has been established as of December 31, 2021 and 2020.

As of December 31, 2021, the Company had \$290.0 million of U.S. Federal and state net operating losses, \$10.3 million of research and development tax credits and \$37.7 million of orphan drug tax credits available to carry forward. A portion of the net operating loss carryforwards will begin to expire in 2026, the research and development tax credits in 2023 and the orphan drug tax credit in 2033. Under current federal income tax laws, federal net operating losses incurred in 2018 and in future years may be carried forward, indefinitely, but the deductibility of such federal net operating losses is limited.

The Company's tax attributes, including net operating losses and credits, are subject to any ownership changes as defined under Internal Revenue Code Sections 382 and 383. A change in ownership could affect the Company's ability

to utilize its net operating losses and credits. As of December 31, 2021, the Company does not believe that an ownership change has occurred. Any future ownership changes may cause a limitation on the Company's ability to utilize existing tax attributes.

The Company files income tax returns in the U.S. federal jurisdiction and in the State of Maryland. The Company's federal income tax returns for tax years 2003 and after remain subject to examination by the U.S. Internal Revenue Service due to tax attributes available to be carried forward to open or future tax years. The Company's Maryland income tax returns for the tax years 2006 and thereafter remain subject to examination by the Comptroller of Maryland. In addition, all of the net operating losses, research and development tax credit and orphan drug credit carryforwards that may be used in future years are still subject to adjustment.

The Company did not have unrecognized tax benefits as of December 31, 2021 and 2020, and does not anticipate this to change significantly over the next 12 months. The Company will recognize interest and penalties accrued on any unrecognized tax benefits as a component of income tax expense. Reconciliations between the statutory federal income tax rate and the effective income tax rate of income tax expense is as follows as of December 31:

	2021	2020	2019
U.S. Federal statutory tax rate	21.0 %	21.0 %	21.0 %
State taxes	5.9	5.7	5.7
Research credit	0.9	0.7	0.8
Orphan drug credit	6.6	9.8	8.8
Other	(0.3)	0.4	(0.1)
Change in valuation allowance	(34.1)	(37.6)	(36.2)
Provision for income taxes	— %	— %	— %

## 11. Research and License Agreements

### *Apollomics*

In January 2020, the Company entered into a collaboration and license agreement (the Agreement) with Apollomics (Hong Kong), Limited (Apollomics) for the development, manufacture and commercialization of products derived from two of the Company's compounds, GMI-1271 and GMI-1687 (the Products) for therapeutic and prophylactic uses (the Field) in China, Taiwan, Hong Kong and Macau (the Territory). Under the terms of the Agreement, the Company granted Apollomics:

- an exclusive license, with the right to sublicense, to develop, manufacture and have manufactured, distribute, market, promote, sell, have sold, offer for sale, import, label, package and otherwise the Products in the Field in the Territory; and
- a non-exclusive license to conduct preclinical research with respect to Products in the Field outside of the Territory for the purposes of developing such Products for use in the Territory.

In June 2020, the Company and Apollomics entered into a clinical supply agreement pursuant to which the Company will manufacture and supply the Products at agreed upon prices. Apollomics has the option to begin manufacture of the Products after appropriate material transfer requirements are met. During the year ended December 30, 2021, the Company recognized \$1.1 million as revenue from the sale of clinical supplies to Apollomics.

The Company evaluated the Agreement under the provisions of ASC 606 and identified two performance obligations under this revenue arrangement: the (i) delivery of functional licenses and (ii) manufacture and supply of the Products. The initial transaction price consists of a \$9.0 million non-refundable up-front payment which was allocated to the delivered functional licenses and recognized in full as revenue in the first quarter of 2020 given that the performance obligation was satisfied upon inception. The Agreement contains various forms of variable consideration, including (i) up to \$75.0 million in development milestones based on achievement of certain clinical and regulatory events, (ii) up to \$105.0 million of sales-based commercial milestones based on achievement of certain annual net sales targets, (iii) sales-based royalties at specified percentages of net sales ranging from the high single digits to 15%, and (iv) manufacture and supply of clinical and commercial Products. The Company has fully constrained the development milestone consideration using the most likely amount method and will recognize that revenue when it is probable that recognition

of revenue related to the milestone will not result in a significant reversal in amounts recognized in future periods, and as such have been excluded from the transaction price. In September 2020, the Company received a non-refundable \$1.0 million development milestone payment upon acceptance by Chinese regulatory authorities of a Phase 3 bridging study design to support registration in China. The Company recognized this \$1.0 million payment as revenue in the quarter ended September 30, 2020. The Company did not recognize any milestone revenue under the Agreement for the year ended December 31, 2021.

The Company will recognize revenue related to the sales-based commercial and royalty milestones and royalties at the later of (i) when the related sales occur or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied), as they were determined to relate predominantly to the licenses granted to Apollomics and, therefore, have been excluded from the transaction price. Lastly, the Company has determined that the consideration for the manufacturing and supply is all variable and is fully constrained. Variable consideration allocated to manufacturing and supply will be recognized at a point in time when the Product is delivered and when the title to the Product is transferred to the customer pursuant to the agreement. The Company reassesses the transaction price in each reporting period and upon the occurrence of a change in circumstances or final resolution of any particular event.

## **12. Employee Benefit Plan**

The Company has a defined contribution plan under the Internal Revenue Code Section 401(k). This plan covers substantially all employees who meet minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. For the years ended December 31, 2021, 2020 and 2019, the Company matched 50% up to the first 6% of employee contributions. All matching contributions have been paid by the Company. The Company's matching contributions vest in full immediately. The total Company matching contributions were approximately \$270,000, \$252,000 and \$219,000 for the years ended December 31, 2021, 2020 and 2019, respectively.

## **13. Risks and Uncertainties**

### **COVID-19**

In March 2020, the World Health Organization declared the novel coronavirus disease 2019, or COVID-19, outbreak a pandemic. In order to mitigate the spread of COVID-19, governments have imposed unprecedented restrictions on business operations, travel and gatherings, resulting in a global economic downturn and other adverse economic and societal impacts. The COVID-19 pandemic has also overwhelmed or otherwise led to changes in the operations of many healthcare facilities.

The impact of the COVID-19 pandemic on the Company's business and financial performance is uncertain and depends on various factors, including the duration of the pandemic, government restrictions and other actions, including relief measures and mass vaccination efforts, implemented to address the impact of the pandemic, and resulting impacts on the financial markets and overall economy. The imposition of "lockdown," "social distancing" and "shelter in place" directives by state and federal governments in the United States as well as governments in other regions of the world in response to the COVID-19 pandemic, including in locations in which its Phase 3 clinical trial of uproleselan is being conducted, resulted in slowed clinical site initiation, patient recruitment and enrollment rates early in the pandemic. Enrollment rates have returned to forecasted levels since the lockdowns. However, COVID-19 infection rates continue to fluctuate, particularly with the emergence of variants, which could negatively affect completion of the trial. The Company is unable to determine the extent of the impact of the pandemic on its operations and financial condition going forward. These developments are highly uncertain and unpredictable, and may materially adversely affect the Company's financial position and results of operations. The Company continues to closely monitor the COVID-19 situation and any potential impact to its planned activities.

## CONSULTING AGREEMENT

THIS CONSULTING AGREEMENT (the “*Agreement*”) by and between GlycoMimetics, Inc. (“*Client*”) and Rachel K. King, an individual (“*Consultant*”) is effective as of August 31, 2021 (the “*Effective Date*”).

## RECITALS

WHEREAS the parties desire for the Client to engage Consultant to perform the services described herein and for Consultant to provide such services on the terms and conditions described herein; and

WHEREAS, the parties desire to use Consultant’s independent skill and expertise pursuant to this Agreement as an independent contractor;

NOW THEREFORE, in consideration of the promises and mutual agreements contained herein, the parties hereto, intending to be legally bound, agree as follows:

**1. Engagement of Services.** Consultant agrees to provide consulting services to include, among other things, strategic business advice, assistance with executive transitions and other services upon request of the Chief Executive Officer (“*Executive*”) of the Client. Consultant agrees to exercise the highest degree of professionalism and utilize her expertise and creative talents in performing these services. Consultant agrees to make herself available to perform such consulting services throughout the Consulting Period, up to 20 hours per week throughout the Consulting Period, and to be reasonably available to meet with the Client at its offices or otherwise.

**2. Compensation.** In consideration for the services rendered pursuant to this Agreement and for the assignment of certain of Consultant’s right, title and interest pursuant hereto, Client will pay Consultant a consulting fee of \$23,304.17 per month for services rendered during the Consulting Period to be paid by the 15<sup>th</sup> calendar day of each applicable month during the Consulting Period.

**3. Ownership of Work Product.** Consultant hereby irrevocably assigns, grants and conveys to Client all right, title and interest now existing or that may exist in the future in and to any document, development, work product, know-how, design, processes, invention, technique, trade secret, or idea, and all intellectual property rights related thereto, that is created by Consultant, to which Consultant contributes, or which relates to Consultant’s services provided pursuant to this Agreement (the “*Work Product*”), including all copyrights, trademarks and other intellectual property rights (including but not limited to patent rights) relating thereto. Consultant agrees that any and all Work Product shall be and remain the property of Client. Consultant will immediately disclose to the Client all Work Product. Consultant agrees to execute, at Client’s request and expense, all documents and other instruments necessary or desirable to confirm such assignment. In the event that Consultant does not, for any reason, execute such documents within a reasonable time of Client’s request, Consultant hereby irrevocably appoints Client as Consultant’s attorney-in-fact for the purpose of executing such documents on Consultant’s behalf, which appointment is coupled with an interest. Consultant

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shall not attempt to register any works created by Consultant pursuant to this Agreement at the U.S. Copyright Office, the U.S. Patent & Trademark Office, or any foreign copyright, patent, or trademark registry. Consultant retains no rights in the Work Product and agrees not to challenge Client's ownership of the rights embodied in the Work Product. Consultant further agrees to assist Client in every proper way to enforce Client's rights relating to the Work Product in any and all countries, including, but not limited to, executing, verifying and delivering such documents and performing such other acts (including appearing as a witness) as Client may reasonably request for use in obtaining, perfecting, evidencing, sustaining and enforcing Client's rights relating to the Work Product.

**4. Artist's, Moral, and Other Rights.** If Consultant has any rights, including without limitation "artist's rights" or "moral rights," in the Work Product which cannot be assigned (the "**Non-Assignable Rights**"), Consultant agrees to waive enforcement worldwide of such rights against Client. In the event that Consultant has any such rights that cannot be assigned or waived Consultant hereby grants to Client a royalty-free, paid-up, exclusive, worldwide, irrevocable, perpetual license under the Non-Assignable Rights to (i) use, make, sell, offer to sell, have made, and further sublicense the Work Product, and (ii) reproduce, distribute, create derivative works of, publicly perform and publicly display the Work Product in any medium or format, whether now known or later developed.

**5. Representations and Warranties.** Consultant represents and warrants that: (a) Consultant has the full right and authority to enter into this Agreement and perform her obligations hereunder; (b) Consultant has the right and unrestricted ability to assign the Work Product to Client as set forth in Sections 4 and 5 (including without limitation the right to assign any Work Product created by Consultant's employees or contractors); (c) the Work Product has not heretofore been published in its entirety; and (d) the Work Product will not infringe upon any copyright, patent, trademark, right of publicity or privacy, or any other proprietary right of any person, whether contractual, statutory or common law. Consultant agrees to indemnify Client from any and all damages, costs, claims, expenses or other liability (including reasonable attorneys' fees) arising from or relating to the breach or alleged breach by Consultant of the representations and warranties set forth in this Section 5.

**6. Independent Contractor Relationship.** Consultant is an independent contractor and not an employee of the Client. Nothing in this Agreement is intended to, or should be construed to, create a partnership, agency, joint venture or employment relationship. The manner and means by which Consultant chooses to complete the consulting services are in Consultant's sole discretion and control. In completing the consulting services, Consultant agrees to provide her own equipment, tools and other materials at her own expense. Consultant is not authorized to represent that she is an agent, employee, or legal representative of the Client, but may disclose that she is a member of the Board of Directors, independent of this Agreement. Consultant is not authorized to make any representation, contract, or commitment on behalf of Client or incur any liabilities or obligations of any kind in the name of or on behalf of the Client. Consultant shall be free at all times to arrange the time and manner of performance of the consulting services. Consultant is not required to maintain any schedule of duties or assignments. Consultant is also not required to provide reports to the Client. In addition to all other obligations contained herein, Consultant agrees: (a) to proceed with diligence and promptness and hereby warrants that such services shall be performed in accordance with the

highest professional standards in the field to the satisfaction of the Client; and (b) to comply, at Consultant's own expense, with the provisions of all state, local, and federal laws, regulations, ordinances, requirements and codes which are applicable to the performance of the services hereunder.

**7. Consultant's Responsibilities.** As an independent contractor, the mode, manner, method and means used by Consultant in the performance of services shall be of Consultant's selection and under the sole control and direction of Consultant. Consultant shall be responsible for all risks incurred in the operation of Consultant's business and shall enjoy all the benefits thereof. Any persons employed by or subcontracting with Consultant to perform any part of Consultant's obligations hereunder shall be under the sole control and direction of Consultant and Consultant shall be solely responsible for all liabilities and expenses thereof. The Client shall have no right or authority with respect to the selection, control, direction, or compensation of such persons.

**8. Tax Treatment.** Consultant and the Client agree that the Client will treat Consultant as an independent contractor for purposes of all tax laws (local, state and federal) and file forms consistent with that status. Consultant agrees, as an independent contractor, that neither she nor her employees are entitled to unemployment benefits in the event this Agreement terminates, or workers' compensation benefits in the event that Consultant, or any employee of Consultant, is injured in any manner while performing obligations under this Agreement. Consultant will be solely responsible to pay any and all local, state, and/or federal income, social security and unemployment taxes for Consultant and her employees. The Client will not withhold any taxes or prepare W-2 Forms for Consultant, but will provide Consultant with a Form 1099, if required by law. Consultant is solely responsible for, and will timely file, all tax returns and payments required to be filed with, or made to, any federal, state or local tax authority with respect to the performance of services and receipt of fees under this Agreement. Consultant is solely responsible for, and must maintain adequate records of, expenses incurred in the course of performing services under this Agreement, except as provided herein. No part of Consultant's compensation will be subject to withholding by Client for the payment of any social security, federal, state or any other employee payroll taxes. Client will regularly report amounts paid to Consultant with the appropriate taxing authorities, as required by law.

**9. No Employee Benefits.** Consultant acknowledges and agrees that neither she nor anyone acting on her behalf shall receive any employee benefits of any kind from the Client as a result of this Agreement. Consultant (and Consultant's agents, employees, and subcontractors) is excluded from participating in any fringe benefit plans or programs as a result of the performance of services under this Agreement, without regard to Consultant's independent contractor status. In addition, Consultant (on behalf of herself and on behalf of Consultant's agents, employees, and contractors) waives any and all rights, if any, to participation in any of the Client's fringe benefit plans or programs including, but not limited to, health, sickness, accident or dental coverage, life insurance, disability benefits, severance, accidental death and dismemberment coverage, unemployment insurance coverage, workers' compensation coverage, and pension or 401(k) benefit(s) provided by the Client to its employees. Notwithstanding the foregoing, this Agreement does not amend or abrogate in any manner any benefit continuation or conversion rights provided by the provision of a benefit plan or by law arising out of Consultant's previous employment relationship with Client.

**10. Expenses and Liabilities.** Consultant agrees that as an independent contractor, she is solely responsible for all expenses (and profits/losses) she incurs in connection with the performance of services. Consultant understands that she will not be reimbursed for any supplies, equipment, or operating costs, nor will these costs of doing business be defrayed in any way by the Client. In addition, the Client does not guarantee to Consultant that fees derived from Consultant's business will exceed Consultant's costs.

**11. Non-Exclusivity.** The Client reserves the right to engage other consultants to perform services, without giving Consultant a right of first refusal or any other exclusive rights. Consultant reserves the right to perform services for other persons, provided that the performance of such services do not conflict or interfere with services provided pursuant to or obligations under this Agreement.

**12. No Conflict of Interest.** During the term of this Agreement, unless written permission is given by the Executive, Consultant will not accept work, enter into a contract, or provide services to any third party that provides products or services which compete with the products or services provided by the Client nor may Consultant enter into any agreement or perform any services which would conflict or interfere with the services provided pursuant to or the obligations under this Agreement. Consultant warrants that there is no other contract or duty on her part that prevents or impedes Consultant's performance under this Agreement. Consultant agrees to indemnify Client from any and all loss or liability incurred by reason of the alleged breach by Consultant of any services agreement with any third party.

**13. No Solicitation.** During the Consulting Period, and for a period of one (1) year thereafter, Consultant will not, directly or indirectly (whether for compensation or without compensation) (i) recruit, solicit or induce, or attempt to induce, any employee, consultant, or contractor of the Client to terminate their employment, contractual or other relationship with the Client; or (ii) solicit the business of any client or customer of Client other than as expressly directed to by the Client.

**14. Confidential Information.** Consultant agrees to hold Client's Confidential Information (as defined below) in strict confidence and not to disclose such Confidential Information to any third parties. Consultant also agrees not to use any of Client's Confidential Information for any purpose other than performance of Consultant's services hereunder. "**Confidential Information**" as used in this Agreement shall mean all information disclosed by Client to Consultant, or otherwise, regarding Client or its business obtained by Consultant pursuant to services provided under this Agreement that is not generally known in the Client's trade or industry and shall include, without limitation, (a) concepts and ideas relating to the development and distribution of content in any medium or to the current, future and proposed products or services of Client or its subsidiaries or affiliates; (b) trade secrets, drawings, inventions, know-how, software programs, and software source documents; (c) information regarding plans for research, development, new service offerings or products, marketing and selling, business plans, business forecasts, budgets and unpublished financial statements, licenses and distribution arrangements, prices and costs, suppliers and customers; and (d) any information regarding the skills and compensation of employees, contractors or other agents of the Client or its subsidiaries or affiliates. Confidential Information also includes proprietary or confidential information of any third party who may disclose such information to Client or Consultant in the

course of Client's business. Consultant's obligations set forth in this Section shall not apply with respect to any portion of the Confidential Information that Consultant can document by competent proof that such portion: (i) is in the public domain through no fault of Consultant; (ii) has been rightfully independently communicated to Consultant free of any obligation of confidence; or (iii) was developed by Consultant independently of and without reference to any information communicated to Consultant by Client. In addition, Consultant may disclose Client's Confidential Information in response to a valid order by a court or other governmental body, as otherwise required by law. All Confidential Information furnished to Consultant by Client is the sole and exclusive property of Client or its suppliers or customers. Upon request by Client, Consultant agrees to promptly deliver to Client the original and any copies of such Confidential Information. Notwithstanding the foregoing or anything to the contrary in this Agreement or any other agreement between Client and Consultant, nothing in this Agreement shall limit Consultant's right to discuss Consultant's engagement with the Client or report possible violations of law or regulation with the Equal Employment Opportunity Commission, United States Department of Labor, the National Labor Relations Board, the Securities and Exchange Commission, or other federal government agency or similar state or local agency or to discuss the terms and conditions of Consultant's engagement with others to the extent expressly permitted by applicable provisions of law or regulation, including but not limited to "whistleblower" statutes or other similar provisions that protect such disclosure. Further, notwithstanding the foregoing, pursuant to 18 U.S.C. Section 1833(b), Consultant shall not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of a trade secret that: (1) is made in confidence to a Federal, State, or local government official, either directly or indirectly, or to an attorney, and solely for the purpose of reporting or investigating a suspected violation of law; or (2) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal.

## **15. Term and Termination.**

**15.1 Term.** The term of this Agreement and the "**Consulting Period**" is for twelve (12) months from the Effective Date set forth above; *provided, however*, that the Consulting Period may be renewed and extended by the mutual written agreement of Consultant and an authorized officer of Client.

**15.2 Effect of Termination.** Upon any termination or expiration of this Agreement, Consultant (i) shall immediately discontinue all use of Client's Confidential Information delivered under this Agreement; (ii) shall delete any such Client Confidential Information from Consultant's computer storage or any other media, including, but not limited to, online and off-line libraries; and (iii) shall return to Client, or, at Client's option, destroy, all copies of such Confidential Information then in Consultant's possession.

**15.3 Survival.** The rights and obligations contained in Sections 3-6, 8-9, 13-14, 15.3 and 16-24 will survive any termination or expiration of this Agreement.

**16. Indemnification.** Consultant shall indemnify and hold harmless the Client and its officers, directors, agents, owners, and employees, for any claims brought or liabilities imposed against the Client by Consultant or any of her employees or by any other party (including private parties, governmental bodies and courts), including claims related to worker's compensation,

wage and hour laws, employment taxes, and benefits, and whether relating to Consultant's status as an independent contractor, the status of her personnel, or any other matters involving the acts or omissions of Consultant and her personnel. Indemnification shall be for any and all losses and damages, including costs and attorneys' fees.

**17. Insurance.** Consultant will obtain for herself and her personnel before providing services, at her own expense, General Liability (GL) insurance coverage for consulting services performed under this Agreement and (if available under state law) worker's compensation coverage.

**18. Successors and Assigns.** Consultant may not subcontract or otherwise delegate her obligations under this Agreement without Client's prior written consent. Client may assign this Agreement. Subject to the foregoing, this Agreement will be for the benefit of Client's successors and assigns and will be binding on Consultant's subcontractors or delegates.

**19. Notices.** Any notice required or permitted by this Agreement shall be in writing and shall be delivered as follows with notice deemed given as indicated: (i) by overnight courier upon written verification of receipt; or (ii) by telecopy or facsimile transmission upon acknowledgment of receipt of electronic transmission. Notice shall be sent to the addresses set forth below or such other address as either party may specify in writing.

**20. Governing Law.** This Agreement shall be governed in all respects by the laws of the State of Maryland, as such laws are applied to agreements entered into and to be performed entirely within Maryland between Maryland residents. Any suit involving this Agreement shall be brought in a court sitting in Maryland. The parties agree that venue shall be proper in such courts, and that such courts will have personal jurisdiction over them.

**21. Severability.** Should any provisions of this Agreement be held by a court of law to be illegal, invalid or unenforceable, the legality, validity and enforceability of the remaining provisions of this Agreement shall not be affected or impaired thereby.

**22. Waiver.** The waiver by Client of a breach of any provision of this Agreement by Consultant shall not operate or be construed as a waiver of any other or subsequent breach by Consultant.

**23. Injunctive Relief for Breach.** Consultant's obligations under this Agreement are of a unique character that gives them particular value; breach of any of such obligations will result in irreparable and continuing damage to Client for which there will be no adequate remedy at law; and, in the event of such breach, Client will be entitled to injunctive relief and/or a decree for specific performance, and such other and further relief as may be proper (including monetary damages if appropriate and attorney's fees).

**24. Entire Agreement.** This Agreement constitutes the entire understanding of the parties relating to the subject matter and supersedes any previous oral or written communications, representations, understanding, or agreement between the parties concerning such subject matter. This Agreement shall not be changed, modified, supplemented or amended except by express written agreement signed by Consultant and the Client. The parties have entered into separate agreements related to Consultant's previous employment relationship with

GlycoMimetics, Inc. These separate agreements govern the previous employment relationship between Consultant and GlycoMimetics, Inc., have or may have provisions that survive termination of Consultant's relationship with Client under this Agreement, may be amended or superseded without regard to this Agreement, and are enforceable according to their terms without regard to the enforcement provision of this Agreement.

**[The remainder of this page is intentionally blank. Signature page follows.]**

IN WITNESS WHEREOF, the parties have executed this Agreement effective as of the date first written above.

**“CLIENT”**

**GLYCOMIMETICS, INC.**

By: /s/ Brian Hahn

Name (print): Brian Hahn

Title: Chief Financial Officer and  
Senior Vice President

Telephone: (301) 417-4254

Fax: (240) 599-7656

**“CONSULTANT”**

**RACHEL K. KING**

/s/ Rachel K. King

Name (print): Rachel King

Address: 8009 Spring Road  
Cabin John, MD 20818

Tel: (202) 256-6991

Fax: N/A

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**GLYCOMIMETICS, INC.****AMENDED AND RESTATED  
NON-EMPLOYEE DIRECTOR COMPENSATION POLICY**

Each member of the Board of Directors (the “**Board**”) who is not also serving as an employee of GlycoMimetics, Inc. (the “**Company**”) or any of its subsidiaries (each such member, an “**Eligible Director**”) will receive the compensation described in this Amended and Restated Non-Employee Director Compensation Policy for his or her Board service. This policy may be amended at any time in the sole discretion of the Board or the Compensation Committee of the Board.

**Annual Cash Compensation**

The annual cash compensation amount set forth below is payable in equal quarterly installments, payable in arrears on the last day of each fiscal quarter in which the service occurred. If an Eligible Director joins the Board or a committee of the Board at a time other than effective as of the first day of a fiscal quarter, each annual retainer set forth below will be pro-rated based on days served in the applicable fiscal year, with the pro-rated amount paid for the first fiscal quarter in which the Eligible Director provides the service, and regular full quarterly payments thereafter. All annual cash fees are vested upon payment.

1. Annual Board Service Retainer:
  - a. All Eligible Directors: \$40,000
  - b. Chair of the Board Service Retainer (in addition to Eligible Director Service Retainer): \$30,000
2. Annual Committee (Non-Chair) Member Service Retainer:
  - a. Member of the Audit Committee: \$9,000
  - b. Member of the Compensation Committee: \$6,000
  - c. Member of the Nominating and Corporate Governance Committee: \$4,500
3. Annual Committee Chair Service Retainer:
  - a. Chair of the Audit Committee: \$18,000
  - b. Chair of the Compensation Committee: \$12,000
  - c. Chair of the Nominating and Corporate Governance Committee: \$9,000

**Equity Compensation**

The equity compensation set forth below will be granted under the GlycoMimetics, Inc. 2013 Equity Incentive Plan (the “**Plan**”). Any stock options granted under this policy will be nonstatutory stock options, with an exercise price per share equal to 100% of the Fair Market Value (as defined in the Plan) of the underlying Common Stock on the date of grant, and a term of ten years from the date of grant (subject to earlier termination in connection with a termination of service as provided in the Plan).

1. Initial Grant: On the date of an Eligible Director’s initial election to the Board (or if such date is not a market trading day, the first market trading day thereafter), the Eligible Director will be automatically, and without further action by the Board or Compensation Committee of the Board, granted a stock option for 42,000 shares of Common Stock. The shares subject to each stock option
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will vest in three equal installments on the first, second and third anniversary of the date of grant, subject to the Eligible Director's Continuous Service (as defined in the Plan) at each vesting date.

2. Annual Grant: On the date of each annual stockholder meeting of the Company, each Eligible Director who continues to serve as a non-employee member of the Board will be automatically, and without further action by the Board or Compensation Committee of the Board, granted a stock option for 21,000 shares of Common Stock (or an equivalent award of equity in such form as the Board or Compensation Committee of the Board shall determine). The shares subject to each stock option or other equity award granted hereunder will vest in full on the first anniversary of the applicable annual stockholder meeting, subject to the Eligible Director's Continuous Service (as defined in the Plan) as of such vesting date.

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**GLYCOMIMETICS, INC.**  
**AMENDED AND RESTATED**  
**INDUCEMENT PLAN**

**1. GENERAL.**

(a) **Eligible Stock Award Recipients.** The only persons eligible to receive grants of Stock Awards under this Plan are individuals who satisfy the standards for inducement grants under Nasdaq Marketplace Rule 5635(c)(4) and the related guidance under Nasdaq IM 5635-1 – that is, generally, a person not previously an employee or director of the Company, or following a bona fide period of non-employment, as an inducement material to the individual’s entering into employment with the Company. Such eligible individuals are referred to in this Plan as “**Eligible Employees**”. These grants will be approved by either the Compensation Committee or a majority of the Company’s “**Independent Directors**” (as such term is defined by Nasdaq for purposes of Nasdaq Marketplace Rule 5635(c)(4)). We refer to Nasdaq Marketplace Rule 5635(c)(4) and the related guidance under Nasdaq IM 5635-1 as the “**Inducement Award Rules**”.

(b) **Available Stock Awards.** The Plan provides for the grant of the following Stock Awards: (i) Nonstatutory Stock Options, (ii) Stock Appreciation Rights (iii) Restricted Stock Awards, (iv) Restricted Stock Unit Awards, and (v) Other Stock Awards. As provided in Section 2(a), Stock Awards may be granted only by either the Compensation Committee or a majority of the Independent Directors as required by the Inducement Award Rules. Incentive Stock Options may not be granted under this Plan.

(c) **General Purpose.** The Company, by means of the Plan, seeks to secure and retain the services of one or more Eligible Employees, to provide incentives for such persons to exert maximum efforts for the success of the Company and any Affiliate, and to provide a means by which such persons may be given an opportunity to benefit from increases in value of the Common Stock through the granting of Stock Awards.

**2. ADMINISTRATION.**

(a) **Administration.** The Compensation Committee shall administer the Plan. Stock Awards may only be granted by either: (i) the Compensation Committee as composed solely of Independent Directors, (ii) another Committee composed solely of Independent Directors and constituting a majority of the Company’s Independent Directors, or (iii) at the Board level by a majority of the Company’s Independent Directors, with non-Independent Directors abstaining. Subject to the foregoing Stock Award approval requirements and the other constraints of the Inducement Award Rules, the Compensation Committee may delegate some of its powers of administration of the Plan to another Committee, as provided in Section 2(c) (and references in this Plan to the Compensation Committee will thereafter be to the applicable Committee).

(b) **Powers of Compensation Committee.** The Compensation Committee will have the power, subject to, and within the limitations of, the express provisions of the Plan and the Inducement Award Rules, including:

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**(i)** To determine: (A) which Eligible Employees will be granted Stock Awards; (B) when and how each Stock Award will be granted; (C) what type of Stock Award will be granted; (D) the provisions of each Stock Award (which need not be identical), including when a person will be permitted to exercise or otherwise receive cash or Common Stock under the Stock Award; (E) the number of shares of Common Stock subject to, or the cash value of, a Stock Award; and (F) the Fair Market Value applicable to a Stock Award; provided, however, that Stock Awards may only be granted by either (1) the Compensation Committee as composed solely of Independent Directors, (2) another Committee composed solely of Independent Directors constituting a majority of the Company's Independent Directors, or (3) at the Board level by a majority of the Company's Independent Directors, with non-Independent Directors abstaining.

**(ii)** To construe and interpret the Plan and Stock Awards granted under it, and to establish, amend and revoke rules and regulations for administration of the Plan and Stock Awards. The Compensation Committee, in the exercise of these powers, may correct any defect, omission or inconsistency in the Plan or in any Stock Award Agreement, in a manner and to the extent it will deem necessary or expedient to make the Plan or Stock Award fully effective.

**(iii)** To settle all controversies regarding the Plan and Stock Awards granted under it.

**(iv)** To accelerate, in whole or in part, the time at which a Stock Award may be exercised or vest (or at which cash or shares of Common Stock may be issued).

**(v)** To suspend or terminate the Plan at any time. Except as otherwise provided in the Plan or a Stock Award Agreement, suspension or termination of the Plan will not materially impair a Participant's rights under his or her then-outstanding Stock Award without his or her written consent except as provided in Section 2(b)(viii) below.

**(vi)** To amend the Plan in any respect the Compensation Committee deems necessary or advisable consistent with the Inducement Award Rules, including, without limitation, by adopting amendments relating to certain nonqualified deferred compensation under Section 409A of the Code and/or to make the Plan or Stock Awards granted under the Plan exempt from or compliant with the requirements for nonqualified deferred compensation under Section 409A of the Code, subject to the limitations, if any, of applicable law, and subject to any stockholder approval required under the Inducement Award Rules in connection with such amendment of the Plan. Except as otherwise provided in the Plan or a Stock Award Agreement, no amendment of the Plan will materially impair a Participant's rights under an outstanding Stock Award without the Participant's written consent.

**(vii)** To approve forms of Stock Award Agreements for use under the Plan.

**(viii)** To amend the terms of any one or more Stock Awards, including, but not limited to, amendments to provide terms more favorable to the Participant than previously provided in the Stock Award Agreement, subject to any specified limits in the Plan that are not subject to Compensation Committee discretion, and subject to any stockholder approval required under the Inducement Award Rules in connection with such amendment of a Stock Award;

provided however, that a Participant's rights under any Stock Award will not be impaired by any such amendment unless (A) the Company requests the consent of the affected Participant, and (B) such Participant consents in writing. Notwithstanding the foregoing, (1) a Participant's rights will not be deemed to have been impaired by any such amendment if the Compensation Committee, in its sole discretion, determines that the amendment, taken as a whole, does not materially impair the Participant's rights, and (2) subject to the limitations of applicable law, if any, the Compensation Committee may amend the terms of any one or more Stock Awards without the affected Participant's consent (A) to clarify the manner of exemption from, or to bring the Stock Award into compliance with, Section 409A of the Code or (B) to comply with other applicable laws or listing requirements, including the Inducement Award Rules.

(ix) Generally, to exercise such powers and to perform such acts as the Compensation Committee deems necessary or expedient to promote the best interests of the Company and that are not in conflict with the provisions of the Plan or Stock Awards.

(x) To adopt such procedures and sub-plans as are necessary or appropriate to permit participation in the Plan by Eligible Employees who are foreign nationals or employed outside the United States (provided that Compensation Committee approval will not be necessary for immaterial modifications to the Plan or any Stock Award Agreement that are required for compliance with the laws of the relevant foreign jurisdiction).

**(c) Delegation to Committee.**

(i) **General.** Subject to the Stock Award approval requirements set forth in Section 2(a), the Compensation Committee may delegate some or all of the administration of the Plan to a Committee but only to the extent that such delegation is consistent with the Inducement Award Rules. If administration is delegated to a Committee, the Committee will have, in connection with the administration of the Plan, the powers theretofore possessed by the Compensation Committee that have been delegated to the Committee, including the power to delegate to a subcommittee any of the administrative powers the Committee is authorized to exercise, subject, however, to such resolutions, not inconsistent with the provisions of the Plan, as may be adopted from time to time by the Compensation Committee. The Compensation Committee may retain the authority to concurrently administer the Plan with the Committee and may, at any time, re-vest in the Compensation Committee some or all of the powers previously delegated.

(d) **Effect of Compensation Committee's Decision.** All determinations, interpretations and constructions made by the Compensation Committee in good faith will not be subject to review by any person and will be final, binding and conclusive on all persons.

(e) **Cancellation and Re-Grant of Stock Awards.** Neither the Compensation Committee nor any Committee will have the authority to: (i) reduce the exercise price or strike price of any outstanding Options or SARs under the Plan, or (ii) cancel any outstanding Options or SARs that have an exercise price or strike price greater than the current Fair Market Value in exchange for cash or other Stock Awards under the Plan, unless the stockholders of the Company have approved such an action within twelve months prior to such an event.

### 3. SHARES SUBJECT TO THE PLAN.

(a) **Share Reserve.** Subject to Section 9(a) relating to Capitalization Adjustments, the aggregate number of shares of Common Stock that may be issued pursuant to Stock Awards from and after the Effective Date will not exceed 3,000,000 shares (the “**Share Reserve**”). For clarity, the Share Reserve is a limitation on the number of shares of Common Stock that may be issued under the Plan. Accordingly, this Section 3(a) does not limit the granting of Stock Awards except as provided in Section 7(a). Shares may be issued in connection with a merger or acquisition as permitted by NASDAQ Listing Rule 5635(c) or, if applicable, NYSE Listed Company Manual Section 303A.08, AMEX Company Guide Section 711 or other applicable rule, and such issuance will not reduce the number of shares available for issuance under the Plan.

(b) **Reversion of Shares to the Share Reserve.** If a Stock Award or any portion thereof (i) expires or otherwise terminates without all of the shares covered by such Stock Award having been issued or (ii) is settled in cash (*i.e.*, the Participant receives cash rather than stock), such expiration, termination or settlement will not reduce (or otherwise offset) the number of shares of Common Stock that may be available for issuance under the Plan. If any shares of Common Stock issued pursuant to a Stock Award are forfeited back to or repurchased by the Company because of the failure to meet a contingency or condition required to vest such shares in the Participant, then the shares that are forfeited or repurchased will revert to and again become available for issuance under the Plan. Any shares reacquired by the Company in satisfaction of tax withholding obligations on a Stock Award or as consideration for the exercise or purchase price of a Stock Award will again become available for issuance under the Plan.

(c) **Source of Shares.** The stock issuable under the Plan will be shares of authorized but unissued or reacquired Common Stock, including shares repurchased by the Company on the open market or otherwise.

### 4. ELIGIBILITY.

Stock Awards may be granted to Eligible Employees; *provided, however*, that Stock Awards may not be granted to Eligible Employees who are providing Continuous Service only to any “parent” of the Company, as such term is defined in Rule 405 of the Securities Act, unless (i) the stock underlying such Stock Awards is treated as “service recipient stock” under Section 409A of the Code (for example, because the Stock Awards are granted pursuant to a corporate transaction such as a spin off transaction), (ii) the Company, in consultation with its legal counsel, has determined that such Stock Awards are otherwise exempt from Section 409A of the Code, or (iii) the Company, in consultation with its legal counsel, has determined that such Stock Awards comply with the distribution requirements of Section 409A of the Code.

### 5. PROVISIONS RELATING TO OPTIONS AND STOCK APPRECIATION RIGHTS.

Each Option or SAR will be in such form and will contain such terms and conditions as the Compensation Committee deems appropriate. The provisions of separate Options or SARs need not be identical; *provided, however*, that each Stock Award Agreement will conform to

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(through incorporation of provisions hereof by reference in the applicable Stock Award Agreement or otherwise) the substance of each of the following provisions:

**(a) Term.** No Option or SAR will be exercisable after the expiration of ten years from the date of its grant or such shorter period specified in the Stock Award Agreement.

**(b) Exercise Price.** The exercise or strike price of each Option or SAR will be not less than 100% of the Fair Market Value of the Common Stock subject to the Option or SAR on the date the Stock Award is granted. Each SAR will be denominated in shares of Common Stock equivalents.

**(c) Purchase Price for Options.** The purchase price of Common Stock acquired pursuant to the exercise of an Option may be paid, to the extent permitted by applicable law and as determined by the Compensation Committee in its sole discretion, by any combination of the methods of payment set forth below. The Compensation Committee will have the authority to grant Options that do not permit all of the following methods of payment (or that otherwise restrict the ability to use certain methods) and to grant Options that require the consent of the Company to use a particular method of payment. The permitted methods of payment are as follows:

**(i)** by cash, check, bank draft or money order payable to the Company;

**(ii)** pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board that, prior to the issuance of the stock subject to the Option, results in either the receipt of cash (or check) by the Company or the receipt of irrevocable instructions to pay the aggregate exercise price to the Company from the sales proceeds;

**(iii)** by delivery to the Company (either by actual delivery or attestation) of shares of Common Stock;

**(iv)** by a “net exercise” arrangement pursuant to which the Company will reduce the number of shares of Common Stock issuable upon exercise by the largest whole number of shares with a Fair Market Value that does not exceed the aggregate exercise price; *provided, however*, that the Company will accept a cash or other payment from the Participant to the extent of any remaining balance of the aggregate exercise price not satisfied by such reduction in the number of whole shares to be issued. Shares of Common Stock will no longer be subject to an Option and will not be exercisable thereafter to the extent that (A) shares issuable upon exercise are reduced to pay the exercise price pursuant to the “net exercise,” (B) shares are delivered to the Participant as a result of such exercise, and (C) shares are withheld to satisfy tax withholding obligations; or

**(v)** in any other form of legal consideration that may be acceptable to the Compensation Committee and specified in the applicable Stock Award Agreement.

**(d) Exercise and Payment of a SAR.** To exercise any outstanding SAR, the Participant must provide written notice of exercise to the Company in compliance with the provisions of the Stock Appreciation Right Agreement evidencing such SAR. The appreciation

distribution payable on the exercise of a SAR will be not greater than an amount equal to the excess of (A) the aggregate Fair Market Value (on the date of the exercise of the SAR) of a number of shares of Common Stock equal to the number of Common Stock equivalents in which the Participant is vested under such SAR, and with respect to which the Participant is exercising the SAR on such date, over (B) the aggregate strike price of the number of Common Stock equivalents with respect to which the Participant is exercising the SAR on such date. The appreciation distribution may be paid in Common Stock, in cash, in any combination of the two or in any other form of consideration, as determined by the Compensation Committee and contained in the Stock Award Agreement evidencing such SAR.

**(e) Transferability of Options and SARs.** The Compensation Committee may, in its sole discretion, impose such limitations on the transferability of Options and SARs as the Compensation Committee will determine. In the absence of such a determination by the Compensation Committee to the contrary, the following restrictions on the transferability of Options and SARs will apply:

**(i) Restrictions on Transfer.** An Option or SAR will not be transferable except by will or by the laws of descent and distribution (or pursuant to subsections (ii) and (iii) below), and will be exercisable during the lifetime of the Participant only by the Participant. The Compensation Committee may permit transfer of the Option or SAR in a manner that is not prohibited by applicable tax and securities laws. Except as explicitly provided herein, neither an Option nor a SAR may be transferred for consideration.

**(ii) Domestic Relations Orders.** Subject to the approval of the Compensation Committee or a duly authorized Officer, an Option or SAR may be transferred pursuant to the terms of a domestic relations order, official marital settlement agreement or other divorce or separation instrument.

**(iii) Beneficiary Designation.** Subject to the approval of the Compensation Committee or a duly authorized Officer, a Participant may, by delivering written notice to the Company, in a form approved by the Company (or the designated broker), designate a third party who, on the death of the Participant, will thereafter be entitled to exercise the Option or SAR and receive the Common Stock or other consideration resulting from such exercise. In the absence of such a designation, the executor or administrator of the Participant's estate will be entitled to exercise the Option or SAR and receive the Common Stock or other consideration resulting from such exercise. However, the Company may prohibit designation of a beneficiary at any time, including due to any conclusion by the Company that such designation would be inconsistent with the provisions of applicable laws.

**(f) Vesting Generally.** The total number of shares of Common Stock subject to an Option or SAR may vest and become exercisable in periodic installments that may or may not be equal. The Option or SAR may be subject to such other terms and conditions on the time or times when it may or may not be exercised (which may be based on the satisfaction of performance goals or other criteria) as the Compensation Committee may deem appropriate. The vesting provisions of individual Options or SARs may vary. The provisions of this Section 5(f) are subject to any Option or SAR provisions governing the minimum number of shares of Common Stock as to which an Option or SAR may be exercised.

**(g) Termination of Continuous Service.** Except as otherwise provided in the applicable Stock Award Agreement or other agreement between the Participant and the Company, if a Participant's Continuous Service terminates (other than for Cause and other than upon the Participant's death or Disability), the Participant may exercise his or her Option or SAR (to the extent that the Participant was entitled to exercise such Stock Award as of the date of termination of Continuous Service) within the period of time ending on the earlier of (i) the date three months following the termination of the Participant's Continuous Service (or such longer or shorter period specified in the applicable Stock Award Agreement), and (ii) the expiration of the term of the Option or SAR as set forth in the Stock Award Agreement. If, after termination of Continuous Service, the Participant does not exercise his or her Option or SAR (as applicable) within the applicable time frame, the Option or SAR will terminate.

**(h) Extension of Termination Date.** If the exercise of an Option or SAR following the termination of the Participant's Continuous Service (other than for Cause and other than upon the Participant's death or Disability) would be prohibited at any time solely because the issuance of shares of Common Stock would violate the registration requirements under the Securities Act, then the Option or SAR will terminate on the earlier of (i) the expiration of a total period of time (that need not be consecutive) equal to the applicable post termination exercise period after the termination of the Participant's Continuous Service during which the exercise of the Option or SAR would not be in violation of such registration requirements, and (ii) the expiration of the term of the Option or SAR as set forth in the applicable Stock Award Agreement. In addition, unless otherwise provided in a Participant's Stock Award Agreement, if the sale of any Common Stock received on exercise of an Option or SAR following the termination of the Participant's Continuous Service (other than for Cause) would violate the Company's insider trading policy, then the Option or SAR will terminate on the earlier of (i) the expiration of a period of months (that need not be consecutive) equal to the applicable post-termination exercise period after the termination of the Participant's Continuous Service during which the sale of the Common Stock received upon exercise of the Option or SAR would not be in violation of the Company's insider trading policy, or (ii) the expiration of the term of the Option or SAR as set forth in the applicable Stock Award Agreement.

**(i) Disability of Participant.** Except as otherwise provided in the applicable Stock Award Agreement or other agreement between the Participant and the Company, if a Participant's Continuous Service terminates as a result of the Participant's Disability, the Participant may exercise his or her Option or SAR (to the extent that the Participant was entitled to exercise such Option or SAR as of the date of termination of Continuous Service), but only within such period of time ending on the earlier of (i) the date 12 months following such termination of Continuous Service (or such longer or shorter period specified in the Stock Award Agreement), and (ii) the expiration of the term of the Option or SAR as set forth in the Stock Award Agreement. If, after termination of Continuous Service, the Participant does not exercise his or her Option or SAR within the applicable time frame, the Option or SAR (as applicable) will terminate.

**(j) Death of Participant.** Except as otherwise provided in the applicable Stock Award Agreement or other agreement between the Participant and the Company, if (i) a Participant's Continuous Service terminates as a result of the Participant's death, or (ii) the Participant dies within the period (if any) specified in the Stock Award Agreement for

exercisability after the termination of the Participant's Continuous Service for a reason other than death, then the Option or SAR may be exercised (to the extent the Participant was entitled to exercise such Option or SAR as of the date of death) by the Participant's estate, by a person who acquired the right to exercise the Option or SAR by bequest or inheritance or by a person designated to exercise the Option or SAR upon the Participant's death, but only within the period ending on the earlier of (i) the date 18 months following the date of death (or such longer or shorter period specified in the Stock Award Agreement), and (ii) the expiration of the term of such Option or SAR as set forth in the Stock Award Agreement. If, after the Participant's death, the Option or SAR is not exercised within the applicable time frame, the Option or SAR will terminate.

**(k) Termination for Cause.** Except as explicitly provided otherwise in a Participant's Stock Award Agreement or other individual written agreement between the Company or any Affiliate and the Participant, if a Participant's Continuous Service is terminated for Cause, the Option or SAR will terminate immediately upon such Participant's termination of Continuous Service, and the Participant will be prohibited from exercising his or her Option or SAR from and after the date of such termination of Continuous Service.

**(l) Non-Exempt Employees.** If an Option or SAR is granted to an Eligible Employee who is a non-exempt employee for purposes of the Fair Labor Standards Act of 1938, as amended, the Option or SAR will not be first exercisable for any shares of Common Stock until at least six (6) months following the date of grant of the Option or SAR (although the Stock Award may vest prior to such date). Consistent with the provisions of the Worker Economic Opportunity Act, (i) if such non-exempt Employee dies or suffers a Disability, (ii) upon a Corporate Transaction in which such Option or SAR is not assumed, continued, or substituted, (iii) upon a Change in Control, or (iv) upon the Participant's retirement (as such term may be defined in the Participant's Stock Award Agreement in another agreement between the Participant and the Company, or, if no such definition, in accordance with the Company's then current employment policies and guidelines), the vested portion of any Options and SARs may be exercised earlier than six months following the date of grant. The foregoing provision is intended to operate so that any income derived by a non-exempt employee in connection with the exercise or vesting of an Option or SAR will be exempt from his or her regular rate of pay. To the extent permitted and/or required for compliance with the Worker Economic Opportunity Act to ensure that any income derived by a non-exempt employee in connection with the exercise, vesting or issuance of any shares under any other Stock Award will be exempt from the employee's regular rate of pay, the provisions of this Section 5(l) will apply to all Stock Awards and are hereby incorporated by reference into such Stock Award Agreements.

## **6. PROVISIONS OF STOCK AWARDS OTHER THAN OPTIONS AND SARs.**

**(a) Restricted Stock Awards.** Each Restricted Stock Award Agreement will be in such form and will contain such terms and conditions as the Compensation Committee will deem appropriate. To the extent consistent with the Company's bylaws, at the Compensation Committee's election, shares of Common Stock may be (x) held in book entry form subject to the Company's instructions until any restrictions relating to the Restricted Stock Award lapse; or (y) evidenced by a certificate, which certificate will be held in such form and manner as determined by the Compensation Committee. The terms and conditions of Restricted Stock

Award Agreements may change from time to time, and the terms and conditions of separate Restricted Stock Award Agreements need not be identical. Each Restricted Stock Award Agreement will conform to (through incorporation of the provisions hereof by reference in the agreement or otherwise) the substance of each of the following provisions:

**(i) Consideration.** A Restricted Stock Award may be awarded in consideration for (A) cash, check, bank draft or money order payable to the Company, (B) past services to the Company or an Affiliate, or (C) any other form of legal consideration (including future services) that may be acceptable to the Compensation Committee, in its sole discretion, and permissible under applicable law.

**(ii) Vesting.** Shares of Common Stock awarded under the Restricted Stock Award Agreement may be subject to forfeiture to the Company in accordance with a vesting schedule to be determined by the Compensation Committee.

**(iii) Termination of Participant's Continuous Service.** If a Participant's Continuous Service terminates, the Company may receive through a forfeiture condition or a repurchase right any or all of the shares of Common Stock held by the Participant as of the date of termination of Continuous Service under the terms of the Restricted Stock Award Agreement.

**(iv) Transferability.** Rights to acquire shares of Common Stock under the Restricted Stock Award Agreement will be transferable by the Participant only upon such terms and conditions as are set forth in the Restricted Stock Award Agreement, as the Compensation Committee will determine in its sole discretion, so long as Common Stock awarded under the Restricted Stock Award Agreement remains subject to the terms of the Restricted Stock Award Agreement.

**(v) Dividends.** A Restricted Stock Award Agreement may provide that any dividends paid on Restricted Stock will be subject to the same vesting and forfeiture restrictions as apply to the shares subject to the Restricted Stock Award to which they relate.

**(b) Restricted Stock Unit Awards.** Each Restricted Stock Unit Award Agreement will be in such form and will contain such terms and conditions as the Compensation Committee will deem appropriate. The terms and conditions of Restricted Stock Unit Award Agreements may change from time to time, and the terms and conditions of separate Restricted Stock Unit Award Agreements need not be identical. Each Restricted Stock Unit Award Agreement will conform to (through incorporation of the provisions hereof by reference in the Agreement or otherwise) the substance of each of the following provisions:

**(i) Consideration.** At the time of grant of a Restricted Stock Unit Award, the Compensation Committee will determine the consideration, if any, to be paid by the Participant upon delivery of each share of Common Stock subject to the Restricted Stock Unit Award. The consideration to be paid (if any) by the Participant for each share of Common Stock subject to a Restricted Stock Unit Award may be paid in any form of legal consideration that may be acceptable to the Compensation Committee, in its sole discretion, and permissible under applicable law.

**(ii) Vesting.** At the time of the grant of a Restricted Stock Unit Award, the Compensation Committee may impose such restrictions on or conditions to the vesting of the Restricted Stock Unit Award as it, in its sole discretion, deems appropriate.

**(iii) Payment.** A Restricted Stock Unit Award may be settled by the delivery of shares of Common Stock, their cash equivalent, any combination thereof or in any other form of consideration, as determined by the Compensation Committee and contained in the Restricted Stock Unit Award Agreement.

**(iv) Additional Restrictions.** At the time of the grant of a Restricted Stock Unit Award, the Compensation Committee, as it deems appropriate, may impose such restrictions or conditions that delay the delivery of the shares of Common Stock (or their cash equivalent) subject to a Restricted Stock Unit Award to a time after the vesting of such Restricted Stock Unit Award.

**(v) Dividend Equivalents.** Dividend equivalents may be credited in respect of shares of Common Stock covered by a Restricted Stock Unit Award, as determined by the Compensation Committee and contained in the Restricted Stock Unit Award Agreement. At the sole discretion of the Compensation Committee, such dividend equivalents may be converted into additional shares of Common Stock covered by the Restricted Stock Unit Award in such manner as determined by the Compensation Committee. Any additional shares covered by the Restricted Stock Unit Award credited by reason of such dividend equivalents will be subject to all of the same terms and conditions of the underlying Restricted Stock Unit Award Agreement to which they relate.

**(vi) Termination of Participant's Continuous Service.** Except as otherwise provided in the applicable Restricted Stock Unit Award Agreement, such portion of the Restricted Stock Unit Award that has not vested will be forfeited upon the Participant's termination of Continuous Service.

**(c) Other Stock Awards.** Other forms of Stock Awards valued in whole or in part by reference to, or otherwise based on, Common Stock, including the appreciation in value thereof (e.g., options or stock rights with an exercise price or strike price less than 100% of the Fair Market Value of the Common Stock at the time of grant) may be granted either alone or in addition to Stock Awards provided for under Section 5 and the preceding provisions of this Section 6. Subject to the provisions of the Plan, the Compensation Committee will have sole and complete authority to determine the persons to whom and the time or times at which such Other Stock Awards will be granted, the number of shares of Common Stock (or the cash equivalent thereof) to be granted pursuant to such Other Stock Awards and all other terms and conditions of such Other Stock Awards.

## **7. COVENANTS OF THE COMPANY.**

**(a) Availability of Shares.** The Company will keep available at all times the number of shares of Common Stock reasonably required to satisfy then-outstanding Stock Awards.

**(b) Securities Law Compliance.** The Company will seek to obtain from each regulatory commission or agency having jurisdiction over the Plan such authority as may be required to grant Stock Awards and to issue and sell shares of Common Stock upon exercise of the Stock Awards; *provided, however*, that this undertaking will not require the Company to register under the Securities Act the Plan, any Stock Award or any Common Stock issued or issuable pursuant to any such Stock Award. If, after reasonable efforts and at a reasonable cost, the Company is unable to obtain from any such regulatory commission or agency the authority that counsel for the Company deems necessary for the lawful issuance and sale of Common Stock under the Plan, the Company will be relieved from any liability for failure to issue and sell Common Stock upon exercise of such Stock Awards unless and until such authority is obtained. A Participant will not be eligible for the grant of a Stock Award or the subsequent issuance of cash or Common Stock pursuant to the Stock Award if such grant or issuance would be in violation of any applicable securities law.

**(c) No Obligation to Notify or Minimize Taxes.** The Company will have no duty or obligation to any Participant to advise such holder as to the time or manner of exercising such Stock Award. Furthermore, the Company will have no duty or obligation to warn or otherwise advise such holder of a pending termination or expiration of a Stock Award or a possible period in which the Stock Award may not be exercised. The Company has no duty or obligation to minimize the tax consequences of a Stock Award to the holder of such Stock Award.

## **8. MISCELLANEOUS.**

**(a) Use of Proceeds from Sales of Common Stock.** Proceeds from the sale of shares of Common Stock pursuant to Stock Awards will constitute general funds of the Company.

**(b) Corporate Action Constituting Grant of Stock Awards.** Corporate action constituting a grant by the Company of a Stock Award to any Participant will be deemed completed as of the date of such corporate action, unless otherwise determined by the Compensation Committee, regardless of when the instrument, certificate, or letter evidencing the Stock Award is communicated to, or actually received or accepted by, the Participant. In the event that the corporate records (e.g., Compensation Committee consents, resolutions or minutes) documenting the corporate action constituting the grant contain terms (e.g., exercise price, vesting schedule or number of shares) that are inconsistent with those in the Stock Award Agreement or related grant documents as a result of a clerical error in the papering of the Stock Award Agreement or related grant documents, the corporate records will control and the Participant will have no legally binding right to the incorrect term in the Stock Award Agreement or related grant documents.

**(c) Stockholder Rights.** No Participant will be deemed to be the holder of, or to have any of the rights of a holder with respect to, any shares of Common Stock subject to a Stock Award unless and until (i) such Participant has satisfied all requirements for exercise of, or the issuance of shares under, the Stock Award pursuant to its terms, and (ii) the issuance of the Common Stock subject to such Stock Award has been entered into the books and records of the Company.

**(d) No Employment or Other Service Rights.** Nothing in the Plan, any Stock Award Agreement or any other instrument executed thereunder or in connection with any Stock Award granted pursuant thereto will confer upon any Participant any right to continue to serve the Company or an Affiliate in the capacity in effect at the time the Stock Award was granted or will affect the right of the Company or an Affiliate to terminate (i) the employment of an Employee with or without notice and with or without cause, (ii) the service of a Consultant pursuant to the terms of such Consultant's agreement with the Company or an Affiliate, or (iii) the service of a Director pursuant to the bylaws of the Company or an Affiliate, and any applicable provisions of the corporate law of the state in which the Company or the Affiliate is incorporated, as the case may be.

**(e) Change in Time Commitment.** In the event a Participant's regular level of time commitment in the performance of his or her services for the Company and any Affiliates is reduced (for example, and without limitation, if the Participant is an Employee of the Company and the Employee has a change in status from a full-time Employee to a part-time Employee or takes an extended leave of absence) after the date of grant of any Stock Award to the Participant, the Compensation Committee has the right in its sole discretion to (x) make a corresponding reduction in the number of shares or cash amount subject to any portion of such Stock Award that is scheduled to vest or become payable after the date of such change in time commitment, and (y) in lieu of or in combination with such a reduction, extend the vesting or payment schedule applicable to such Stock Award. In the event of any such reduction, the Participant will have no right with respect to any portion of the Stock Award that is so reduced.

**(f) Investment Assurances.** The Company may require a Participant, as a condition of exercising or acquiring Common Stock under any Stock Award, (i) to give written assurances satisfactory to the Company as to the Participant's knowledge and experience in financial and business matters and/or to employ a purchaser representative reasonably satisfactory to the Company who is knowledgeable and experienced in financial and business matters and that he or she is capable of evaluating, alone or together with the purchaser representative, the merits and risks of exercising the Stock Award; and (ii) to give written assurances satisfactory to the Company stating that the Participant is acquiring Common Stock subject to the Stock Award for the Participant's own account and not with any present intention of selling or otherwise distributing the Common Stock. The foregoing requirements, and any assurances given pursuant to such requirements, will be inoperative if (A) the issuance of the shares upon the exercise or acquisition of Common Stock under the Stock Award has been registered under a then currently effective registration statement under the Securities Act, or (B) as to any particular requirement, a determination is made by counsel for the Company that such requirement need not be met in the circumstances under the then applicable securities laws. The Company may, upon advice of counsel to the Company, place legends on stock certificates issued under the Plan as such counsel deems necessary or appropriate in order to comply with applicable securities laws, including, but not limited to, legends restricting the transfer of the Common Stock.

**(g) Withholding Obligations.** Unless prohibited by the terms of a Stock Award Agreement, the Company may, in its sole discretion, satisfy any federal, state or local tax withholding obligation relating to a Stock Award by any of the following means or by a combination of such means: (i) causing the Participant to tender a cash payment; (ii) withholding shares of Common Stock from the shares of Common Stock issued or otherwise

issuable to the Participant in connection with the Stock Award; *provided, however*, that no shares of Common Stock are withheld with a value exceeding the minimum amount of tax required to be withheld by law (or such lesser amount as may be necessary to avoid classification of the Stock Award as a liability for financial accounting purposes); (iii) withholding cash from a Stock Award settled in cash; (iv) withholding payment from any amounts otherwise payable to the Participant; or (v) by such other method as may be set forth in the Stock Award Agreement.

**(h) Electronic Delivery.** Any reference herein to a “written” agreement or document will include any agreement or document delivered electronically, filed publicly at [www.sec.gov](http://www.sec.gov) (or any successor website thereto) or posted on the Company’s intranet (or other shared electronic medium controlled by the Company to which the Participant has access).

**(i) Deferrals.** To the extent permitted by applicable law, the Compensation Committee, in its sole discretion, may determine that the delivery of Common Stock or the payment of cash, upon the exercise, vesting or settlement of all or a portion of any Stock Award may be deferred and may establish programs and procedures for deferral elections to be made by Participants. Deferrals by Participants will be made in accordance with Section 409A of the Code. Consistent with Section 409A of the Code, the Compensation Committee may provide for distributions while a Participant is still an employee or otherwise providing services to the Company. The Compensation Committee is authorized to make deferrals of Stock Awards and determine when, and in what annual percentages, Participants may receive payments, including lump sum payments, following the Participant’s termination of Continuous Service, and implement such other terms and conditions consistent with the provisions of the Plan and in accordance with applicable law.

**(j) Compliance with Section 409A.** Unless otherwise expressly provided for in a Stock Award Agreement, the Plan and Stock Award Agreements will be interpreted to the greatest extent possible in a manner that makes the Plan and the Stock Awards granted hereunder exempt from Section 409A of the Code, and, to the extent not so exempt, in compliance with Section 409A of the Code. If the Compensation Committee determines that any Stock Award granted hereunder is not exempt from and is therefore subject to Section 409A of the Code, the Stock Award Agreement evidencing such Stock Award will incorporate the terms and conditions necessary to avoid the consequences specified in Section 409A(a)(1) of the Code, and to the extent a Stock Award Agreement is silent on terms necessary for compliance, such terms are hereby incorporated by reference into the Stock Award Agreement. Notwithstanding anything to the contrary in this Plan (and unless the Stock Award Agreement specifically provides otherwise), if the shares of Common Stock are publicly traded, and if a Participant holding a Stock Award that constitutes “deferred compensation” under Section 409A of the Code is a “specified employee” for purposes of Section 409A of the Code, no distribution or payment of any amount that is due because of a “separation from service” (as defined in Section 409A of the Code without regard to alternative definitions thereunder) will be issued or paid before the date that is six months following the date of such Participant’s “separation from service” or, if earlier, the date of the Participant’s death, unless such distribution or payment can be made in a manner that complies with Section 409A of the Code, and any amounts so deferred will be paid in a lump sum on the day after such six month period elapses, with the balance paid thereafter on the original schedule.

**(k) Clawback/Recovery.** All Stock Awards granted under the Plan will be subject to recoupment in accordance with any clawback policy that the Company is required to adopt pursuant to the listing standards of any national securities exchange or association on which the Company's securities are listed or as is otherwise required by the Dodd-Frank Wall Street Reform and Consumer Protection Act or other applicable law. In addition, the Compensation Committee may impose such other clawback, recovery or recoupment provisions in a Stock Award Agreement as the Compensation Committee determines necessary or appropriate, including but not limited to a reacquisition right in respect of previously acquired shares of Common Stock or other cash or property upon the occurrence of Cause. No recovery of compensation under such a clawback policy will be an event giving rise to a right to resign for "good reason" or "constructive termination" (or similar term) under any agreement with the Company.

## **9. ADJUSTMENTS UPON CHANGES IN COMMON STOCK; OTHER CORPORATE EVENTS.**

**(a) Capitalization Adjustments.** In the event of a Capitalization Adjustment, the Compensation Committee will appropriately and proportionately adjust: (i) the class(es) and maximum number of securities subject to the Plan pursuant to Section 3(a) and (ii) the class(es) and number of securities and price per share of stock subject to outstanding Stock Awards. The Compensation Committee will make such adjustments, and its determination will be final, binding and conclusive.

**(b) Dissolution or Liquidation.** Except as otherwise provided in the Stock Award Agreement, in the event of a dissolution or liquidation of the Company, all outstanding Stock Awards (other than Stock Awards consisting of vested and outstanding shares of Common Stock not subject to a forfeiture condition or the Company's right of repurchase) will terminate immediately prior to the completion of such dissolution or liquidation, and the shares of Common Stock subject to the Company's repurchase rights or subject to a forfeiture condition may be repurchased or reacquired by the Company notwithstanding the fact that the holder of such Stock Award is providing Continuous Service; *provided, however*, that the Compensation Committee may, in its sole discretion, cause some or all Stock Awards to become fully vested, exercisable and/or no longer subject to repurchase or forfeiture (to the extent such Stock Awards have not previously expired or terminated) before the dissolution or liquidation is completed but contingent on its completion.

**(c) Corporate Transaction.** The following provisions will apply to Stock Awards in the event of a Corporate Transaction unless otherwise provided in the instrument evidencing the Stock Award or any other written agreement between the Company or any Affiliate and the Participant or unless otherwise expressly provided by the Compensation Committee at the time of grant of a Stock Award. In the event of a Corporate Transaction, then, notwithstanding any other provision of the Plan, the Compensation Committee will take one or more of the following actions with respect to Stock Awards, contingent upon the closing or completion of the Corporate Transaction:

**(i)** arrange for the surviving corporation or acquiring corporation (or the surviving or acquiring corporation's parent company) to assume or continue the Stock Award or to substitute a similar stock award for the Stock Award (including, but not limited to, an award to

acquire the same consideration paid to the stockholders of the Company pursuant to the Corporate Transaction);

(ii) arrange for the assignment of any reacquisition or repurchase rights held by the Company in respect of Common Stock issued pursuant to the Stock Award to the surviving corporation or acquiring corporation (or the surviving or acquiring corporation's parent company);

(iii) accelerate the vesting, in whole or in part, of the Stock Award (and, if applicable, the time at which the Stock Award may be exercised) to a date prior to the effective time of such Corporate Transaction as the Compensation Committee will determine (or, if the Compensation Committee will not determine such a date, to the date that is five days prior to the effective date of the Corporate Transaction), with such Stock Award terminating if not exercised (if applicable) at or prior to the effective time of the Corporate Transaction;

(iv) arrange for the lapse, in whole or in part, of any reacquisition or repurchase rights held by the Company with respect to the Stock Award;

(v) cancel or arrange for the cancellation of the Stock Award, to the extent not vested or not exercised prior to the effective time of the Corporate Transaction, in exchange for such cash consideration, if any, as the Compensation Committee, in its sole discretion, may consider appropriate; and

(vi) make a payment, in such form as may be determined by the Compensation Committee equal to the excess, if any, of (A) the value of the property the Participant would have received upon the exercise of the Stock Award immediately prior to the effective time of the Corporate Transaction, over (B) any exercise price payable by such holder in connection with such exercise.

The Compensation Committee need not take the same action or actions with respect to all Stock Awards or portions thereof or with respect to all Participants. The Compensation Committee may take different actions with respect to the vested and unvested portions of a Stock Award.

(d) **Change in Control.** A Stock Award may be subject to additional acceleration of vesting and exercisability upon or after a Change in Control as may be provided in the Stock Award Agreement for such Stock Award or as may be provided in any other written agreement between the Company or any Affiliate and the Participant, but in the absence of such provision, no such acceleration will occur.

#### **10. PLAN TERM; EARLIER TERMINATION OR SUSPENSION OF THE PLAN.**

The Compensation Committee may suspend or terminate the Plan at any time. No Stock Awards may be granted under the Plan while the Plan is suspended or after it is terminated.

#### **11. EFFECTIVE DATE OF PLAN.**

The Plan will become effective on the Effective Date.

**12. CHOICE OF LAW.**

The law of the State of Delaware will govern all questions concerning the construction, validity and interpretation of the Plan, without regard to that state's conflict of laws rules.

**13. DEFINITIONS.** As used in the Plan, the following definitions will apply to the capitalized terms indicated below:

(a) "**Affiliate**" means, at the time of determination, any "parent" or "subsidiary" of the Company as such terms are defined in Rule 405 of the Securities Act. The Compensation Committee will have the authority to determine the time or times at which "parent" or "subsidiary" status is determined within the foregoing definition.

(b) "**Award**" means a Stock Award.

(c) "**Award Agreement**" means a Stock Award Agreement.

(d) "**Board**" means the Board of Directors of the Company.

(e) "**Capital Stock**" means each and every class of common stock of the Company, regardless of the number of votes per share.

(f) "**Capitalization Adjustment**" means any change that is made in, or other events that occur with respect to, the Common Stock subject to the Plan or subject to any Stock Award after the Effective Date without the receipt of consideration by the Company through merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large nonrecurring cash dividend, stock split, reverse stock split, liquidating dividend, combination of shares, exchange of shares, change in corporate structure or any similar equity restructuring transaction, as that term is used in Statement of Financial Accounting Standards Board Accounting Standards Codification Topic 718 (or any successor thereto). Notwithstanding the foregoing, the conversion of any convertible securities of the Company will not be treated as a Capitalization Adjustment.

(g) "**Cause**" will have the meaning ascribed to such term in any written agreement between the Participant and the Company defining such term and, in the absence of such agreement, such term means, with respect to a Participant, the occurrence of any of the following events: (i) such Participant's conviction of any felony or any crime involving fraud; (ii) such Participant's participation (whether by affirmative act or omission) in a fraud or felonious act against the Company and/or its Affiliates; (iii) conduct by such Participant which, based upon a good faith and reasonable factual investigation by the Company (or, if such Participant is an Officer, by the Board or Compensation Committee), demonstrates such Participant's unfitness to serve; (iv) such Participant's violation of any statutory or fiduciary duty, or duty of loyalty owed to the Company and/or its Affiliates and which has a material adverse effect on the Company and/or its Affiliates; (v) such Participant's violation of state or federal law in connection with such Participant's performance of such Participant's job which has a material adverse effect on the Company and/or its Affiliates; (vi) breach of any material term of any contract between such Participant and the Company and/or its Affiliates; and (vii) such Participant's violation of any

material Company policy. Notwithstanding the foregoing, such Participant's death or Disability shall not constitute Cause as set forth herein. The determination that a termination of the Participant's Continuous Service is either for Cause or without Cause will be made by the Board or Compensation Committee, as applicable, in its sole and exclusive judgment and discretion. Any determination by the Company that the Continuous Service of a Participant was terminated with or without Cause for the purposes of outstanding Stock Awards held by such Participant will have no effect upon any determination of the rights or obligations of the Company or such Participant for any other purpose.

**(h)** **"Change in Control"** means the occurrence, in a single transaction or in a series of related transactions, of any one or more of the following events:

**(i)** any Exchange Act Person becomes the Owner, directly or indirectly, of securities of the Company representing more than 50% of the combined voting power of the Company's then outstanding securities other than by virtue of a merger, consolidation or similar transaction. Notwithstanding the foregoing, a Change in Control will not be deemed to occur (A) on account of the acquisition of securities of the Company directly from the Company, (B) on account of the acquisition of securities of the Company by an investor, any affiliate thereof or any other Exchange Act Person that acquires the Company's securities in a transaction or series of related transactions the primary purpose of which is to obtain financing for the Company through the issuance of equity securities, (C) on account of the acquisition of securities of the Company by any individual who is, on the Effective Date, either an executive officer or a Director (either, a **"Registration Investor"**) and/or any entity in which a Registration Investor has a direct or indirect interest (whether in the form of voting rights or participation in profits or capital contributions) of more than 50% (collectively, the **"Registration Entities"**) or on account of the Registration Entities continuing to hold shares that come to represent more than 50% of the combined voting power of the Company's then outstanding securities as a result of the conversion of any class of the Company's securities into another class of the Company's securities having a different number of votes per share pursuant to the conversion provisions set forth in the Company's Amended and Restated Certificate of Incorporation; or (D) solely because the level of Ownership held by any Exchange Act Person (the **"Subject Person"**) exceeds the designated percentage threshold of the outstanding voting securities as a result of a repurchase or other acquisition of voting securities by the Company reducing the number of shares outstanding, provided that if a Change in Control would occur (but for the operation of this sentence) as a result of the acquisition of voting securities by the Company, and after such share acquisition, the Subject Person becomes the Owner of any additional voting securities that, assuming the repurchase or other acquisition had not occurred, increases the percentage of the then outstanding voting securities Owned by the Subject Person over the designated percentage threshold, then a Change in Control will be deemed to occur;

**(ii)** there is consummated a merger, consolidation or similar transaction involving (directly or indirectly) the Company and, immediately after the consummation of such merger, consolidation or similar transaction, the stockholders of the Company immediately prior thereto do not Own, directly or indirectly, either (A) outstanding voting securities representing more than 50% of the combined outstanding voting power of the surviving Entity in such merger, consolidation or similar transaction or (B) more than 50% of the combined outstanding voting power of the parent of the surviving Entity in such merger, consolidation or similar

transaction, in each case in substantially the same proportions as their Ownership of the outstanding voting securities of the Company immediately prior to such transaction; *provided, however*, that a merger, consolidation or similar transaction will not constitute a Change in Control under this prong of the definition if the outstanding voting securities representing more than 50% of the combined voting power of the surviving Entity or its parent are owned by the Registration Entities;

(iii) there is consummated a sale, lease, exclusive license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries, other than a sale, lease, license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries to an Entity, more than fifty percent (50%) of the combined voting power of the voting securities of which are Owned by stockholders of the Company in substantially the same proportions as their Ownership of the outstanding voting securities of the Company immediately prior to such sale, lease, license or other disposition; *provided, however*, that a sale, lease, exclusive license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries will not constitute a Change in Control under this prong of the definition if the outstanding voting securities representing more than 50% of the combined voting power of the acquiring Entity or its parent are owned by the Registration Entities; or

(iv) individuals who, on the date the Plan is adopted by the Compensation Committee, are members of the Board (the “**Incumbent Board**”) cease for any reason to constitute at least a majority of the members of the Board; *provided, however*, that if the appointment or election (or nomination for election) of any new Board member was approved or recommended by a majority vote of the members of the Incumbent Board then still in office, such new member will, for purposes of this Plan, be considered as a member of the Incumbent Board.

Notwithstanding the foregoing definition or any other provision of this Plan, the term Change in Control will not include a sale of assets, merger or other transaction effected exclusively for the purpose of changing the domicile of the Company and the definition of Change in Control (or any analogous term) in an individual written agreement between the Company or any Affiliate and the Participant will supersede the foregoing definition with respect to Stock Awards subject to such agreement; *provided, however*, that if no definition of Change in Control or any analogous term is set forth in such an individual written agreement, the foregoing definition will apply.

(i) “**Code**” means the Internal Revenue Code of 1986, as amended, including any applicable regulations and guidance thereunder.

(j) “**Committee**” means a committee of one or more Directors to whom authority has been delegated by the Compensation Committee in accordance with Section 2(c). Authority to grant Awards may only be delegated to a Committee comprised of a majority of the Company’s Independent Directors.

(k) “**Common Stock**” means, as of the Effective Date, the common stock of the Company, having 1 vote per share.

(l) “**Company**” means GlycoMimetics, Inc., a Delaware corporation.

(m) “**Compensation Committee**” means the Compensation Committee of the Board as composed solely of Independent Directors.

(n) “**Consultant**” means any person, including an advisor, who is (i) engaged by the Company or an Affiliate to render consulting or advisory services and is compensated for such services, or (ii) serving as a member of the board of directors of an Affiliate and is compensated for such services. However, service solely as a Director, or payment of a fee for such service, will not cause a Director to be considered a “Consultant” for purposes of the Plan. Notwithstanding the foregoing, a person is treated as a Consultant under this Plan only if a Form S-8 Registration Statement under the Securities Act is available to register either the offer or the sale of the Company’s securities to such person.

(o) “**Continuous Service**” means that the Participant’s service with the Company or an Affiliate, whether as an Employee, Director or Consultant, is not interrupted or terminated. A change in the capacity in which the Participant renders service to the Company or an Affiliate as an Employee, Consultant or Director or a change in the entity for which the Participant renders such service, provided that there is no interruption or termination of the Participant’s service with the Company or an Affiliate, will not terminate a Participant’s Continuous Service ; *provided, however*, that if the Entity for which a Participant is rendering services ceases to qualify as an Affiliate, as determined by the Compensation Committee, in its sole discretion, such Participant’s Continuous Service will be considered to have terminated on the date such Entity ceases to qualify as an Affiliate.

To the extent permitted by law, the Compensation Committee or the chief executive officer of the Company, in that party’s sole discretion, may determine whether Continuous Service will be considered interrupted in the case of (i) any leave of absence approved by the Compensation Committee or chief executive officer, including sick leave, military leave or any other personal leave, or (ii) transfers between the Company, an Affiliate, or their successors. Notwithstanding the foregoing, a leave of absence will be treated as Continuous Service for purposes of vesting in a Stock Award only to such extent as may be provided in the Company’s leave of absence policy, in the written terms of any leave of absence agreement or policy applicable to the Participant, or as otherwise required by law.

(p) “**Corporate Transaction**” means the consummation, in a single transaction or in a series of related transactions, of any one or more of the following events:

(i) a sale or other disposition of all or substantially all, as determined by the Compensation Committee, in its sole discretion, of the consolidated assets of the Company and its Subsidiaries;

(ii) a sale or other disposition of at least 90% of the outstanding securities of the Company;

(iii) a merger, consolidation or similar transaction following which the Company is not the surviving corporation; or

(iv) a merger, consolidation or similar transaction following which the Company is the surviving corporation but the shares of Common Stock outstanding immediately preceding the merger, consolidation or similar transaction are converted or exchanged by virtue of the merger, consolidation or similar transaction into other property, whether in the form of securities, cash or otherwise.

(q) “**Director**” means a member of the Board.

(r) “**Disability**” means, with respect to a Participant, the inability of such Participant to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment that can be expected to result in death or that has lasted or can be expected to last for a continuous period of not less than 12 months, as provided in Sections 22(e)(3) and 409A(a)(2)(c)(i) of the Code, and will be determined by the Compensation Committee on the basis of such medical evidence as the Compensation Committee deems warranted under the circumstances.

(s) “**Effective Date**” means January 22, 2020, the date the Compensation Committee approved the Plan.

(t) “**Eligible Employee**” has the meaning set forth in Section 1(a).

(u) “**Employee**” means any person employed by the Company or an Affiliate. However, service solely as a Director, or payment of a fee for such services, will not cause a Director to be considered an “Employee” for purposes of the Plan.

(v) “**Entity**” means a corporation, partnership, limited liability company or other entity.

(w) “**Exchange Act**” means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

(x) “**Exchange Act Person**” means any natural person, Entity or “group” (within the meaning of Section 13(d) or 14(d) of the Exchange Act), except that “Exchange Act Person” will not include (i) the Company or any Subsidiary of the Company, (ii) any employee benefit plan of the Company or any Subsidiary of the Company or any trustee or other fiduciary holding securities under an employee benefit plan of the Company or any Subsidiary of the Company, (iii) an underwriter temporarily holding securities pursuant to a registered public offering of such securities, (iv) an Entity Owned, directly or indirectly, by the stockholders of the Company in substantially the same proportions as their Ownership of stock of the Company; or (v) any natural person, Entity or “group” (within the meaning of Section 13(d) or 14(d) of the Exchange Act) that, as of the Effective Date, is the Owner, directly or indirectly, of securities of the Company representing more than 50% of the combined voting power of the Company’s then outstanding securities.

(y) “**Fair Market Value**” means, as of any date, the value of the Common Stock determined as follows:

(i) If the Common Stock is listed on any established stock exchange or traded on any established market, the Fair Market Value of a share of Common Stock will be, unless otherwise determined by the Compensation Committee, **the closing sales price** for such stock as quoted on such exchange or market (or the exchange or market with the greatest volume of trading in the Common Stock) **on the date of determination**, as reported in a source the Compensation Committee deems reliable.

(ii) Unless otherwise provided by the Compensation Committee, if there is no closing sales price for the Common Stock on the date of determination, then the Fair Market Value will be the closing selling price on the last preceding date for which such quotation exists.

(iii) In the absence of such markets for the Common Stock, the Fair Market Value will be determined by the Compensation Committee in good faith and in a manner that complies with Sections 409A of the Code.

(z) “**Incentive Stock Option**” means an option that is intended to be, and qualifies as, an “incentive stock option” within the meaning of Section 422 of the Code.

(aa) “**Independent Director**” has the meaning set forth in Section 1(a).

(bb) “**Inducement Award Rules**” has the meaning set forth in Section 1(a).

(cc) “**Non-Employee Director**” means a Director who either (i) is not a current employee or officer of the Company or an Affiliate, does not receive compensation, either directly or indirectly, from the Company or an Affiliate for services rendered as a consultant or in any capacity other than as a Director (except for an amount as to which disclosure would not be required under Item 404(a) of Regulation S-K promulgated pursuant to the Securities Act (“**Regulation S-K**”)), does not possess an interest in any other transaction for which disclosure would be required under Item 404(a) of Regulation S-K, and is not engaged in a business relationship for which disclosure would be required pursuant to Item 404(b) of Regulation S-K; or (ii) is otherwise considered a “non-employee director” for purposes of Rule 16b-3.

(dd) “**Nonstatutory Stock Option**” means any option granted pursuant to Section 5 of the Plan that does not qualify as an Incentive Stock Option.

(ee) “**Officer**” means a person who is an officer of the Company within the meaning of Section 16 of the Exchange Act.

(ff) “**Option**” means a Nonstatutory Stock Option to purchase shares of Common Stock granted pursuant to the Plan.

(gg) “**Option Agreement**” means a written agreement between the Company and an Optionholder evidencing the terms and conditions of an Option grant. Each Option Agreement will be subject to the terms and conditions of the Plan.

(hh) “**Optionholder**” means a person to whom an Option is granted pursuant to the Plan or, if applicable, such other person who holds an outstanding Option.

(ii) “**Other Stock Award**” means an award based in whole or in part by reference to the Common Stock which is granted pursuant to the terms and conditions of Section 6(c).

(jj) “**Other Stock Award Agreement**” means a written agreement between the Company and a holder of an Other Stock Award evidencing the terms and conditions of an Other Stock Award grant. Each Other Stock Award Agreement will be subject to the terms and conditions of the Plan.

(kk) “**Own,**” “**Owned,**” “**Owner,**” “**Ownership**” means a person or Entity will be deemed to “Own,” to have “Owned,” to be the “Owner” of, or to have acquired “Ownership” of securities if such person or Entity, directly or indirectly, through any contract, arrangement, understanding, relationship or otherwise, has or shares voting power, which includes the power to vote or to direct the voting, with respect to such securities.

(ll) “**Participant**” means a person to whom a Stock Award is granted pursuant to the Plan or, if applicable, such other person who holds an outstanding Stock Award.

(mm) “**Plan**” means this GlycoMimetics, Inc. Inducement Plan.

(nn) “**Restricted Stock Award**” means an award of shares of Common Stock which is granted pursuant to the terms and conditions of Section 6(a).

(oo) “**Restricted Stock Award Agreement**” means a written agreement between the Company and a holder of a Restricted Stock Award evidencing the terms and conditions of a Restricted Stock Award grant. Each Restricted Stock Award Agreement will be subject to the terms and conditions of the Plan.

(pp) “**Restricted Stock Unit Award**” means a right to receive shares of Common Stock which is granted pursuant to the terms and conditions of Section 6(b).

(qq) “**Restricted Stock Unit Award Agreement**” means a written agreement between the Company and a holder of a Restricted Stock Unit Award evidencing the terms and conditions of a Restricted Stock Unit Award grant. Each Restricted Stock Unit Award Agreement will be subject to the terms and conditions of the Plan.

(rr) “**Rule 16b-3**” means Rule 16b-3 promulgated under the Exchange Act or any successor to Rule 16b-3, as in effect from time to time.

(ss) “**Securities Act**” means the Securities Act of 1933, as amended.

(tt) “**Stock Appreciation Right**” or “**SAR**” means a right to receive the appreciation on Common Stock that is granted pursuant to the terms and conditions of Section 5.

(uu) “**Stock Appreciation Right Agreement**” means a written agreement between the Company and a holder of a Stock Appreciation Right evidencing the terms and conditions of a Stock Appreciation Right grant. Each Stock Appreciation Right Agreement will be subject to the terms and conditions of the Plan.

(vv) “**Stock Award**” means any right to receive Common Stock granted under the Plan, including a Nonstatutory Stock Option, a Restricted Stock Award, a Restricted Stock Unit Award, a Stock Appreciation Right or any Other Stock Award.

(ww) “**Stock Award Agreement**” means a written agreement between the Company and a Participant evidencing the terms and conditions of a Stock Award grant. Each Stock Award Agreement will be subject to the terms and conditions of the Plan.

(xx) “**Subsidiary**” means, with respect to the Company, (i) any corporation of which more than 50% of the outstanding capital stock having ordinary voting power to elect a majority of the board of directors of such corporation (irrespective of whether, at the time, stock of any other class or classes of such corporation will have or might have voting power by reason of the happening of any contingency) is at the time, directly or indirectly, Owned by the Company, and (ii) any partnership, limited liability company or other entity in which the Company has a direct or indirect interest (whether in the form of voting or participation in profits or capital contribution) of more than 50%.

**Consent of Independent Registered Public Accounting Firm**

We consent to the incorporation by reference in the following Registration Statements:

- (1) Registration Statement (Form S-8 No. 333-193317) pertaining to the 2003 Stock Incentive Plan, as amended, 2013 Equity Incentive Plan and 2013 Employee Stock Purchase Plan of GlycoMimetics, Inc.,
- (2) Registration Statement (Form S-8 No. 333-206166) pertaining to the 2013 Equity Incentive Plan and 2013 Employee Stock Purchase Plan of GlycoMimetics, Inc.,
- (3) Registration Statement (Form S-8 No. 333-209814) pertaining to the 2013 Equity Incentive Plan and 2013 Employee Stock Purchase Plan of GlycoMimetics, Inc.,
- (4) Registration Statement (Form S-8 No. 333-216366) pertaining to the 2013 Equity Incentive Plan and 2013 Employee Stock Purchase Plan of GlycoMimetics, Inc.,
- (5) Registration Statement (Form S-8 No. 333-223462) pertaining to the 2013 Equity Incentive Plan and 2013 Employee Stock Purchase Plan of GlycoMimetics, Inc.,
- (6) Registration Statement (Form S-8 No. 333-230117) pertaining to the 2013 Equity Incentive Plan and 2013 Employee Stock Purchase Plan of GlycoMimetics, Inc.,
- (7) Registration Statement (Form S-3 No. 333-231577) of GlycoMimetics, Inc.,
- (8) Registration Statement (Form S-8 No. 333-236754) pertaining to the 2013 Equity Incentive Plan, 2013 Employee Stock Purchase Plan, and Inducement Plan of GlycoMimetics, Inc.; and
- (9) Registration Statement (Form S-8 No. 333-253788) pertaining to the 2013 Equity Incentive Plan and 2013 Employee Stock Purchase Plan of GlycoMimetics, Inc.

of our report dated March 3, 2022, with respect to the financial statements of GlycoMimetics, Inc. included in this Annual Report (Form 10-K) of GlycoMimetics, Inc. for the year ended December 31, 2021.

/s/ Ernst & Young LLP

Baltimore, Maryland  
March 3, 2022

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**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER  
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Harout Semerjian, certify that:

1. I have reviewed this annual report on Form 10-K of GlycoMimetics, Inc. (the “registrant”);
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant’s other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and 15d-15(e) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
  - (c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and
5. The registrant’s other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: March 3, 2022

/s/ Harout Semerjian  
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Harout Semerjian  
President & Chief Executive Officer  
(principal executive officer)

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**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER  
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Brian M. Hahn, certify that:

1. I have reviewed this annual report on Form 10-K of GlycoMimetics, Inc. (the “registrant”);
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant’s other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
  - (c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and
5. The registrant’s other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: March 3, 2022

/s/ Brian M. Hahn

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Brian M. Hahn  
Chief Financial Officer and Senior Vice President  
(principal financial officer)

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**CERTIFICATIONS OF  
PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER  
PURSUANT TO 18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Harout Semerjian, Chief Executive Officer of GlycoMimetics, Inc. (the "Company"), and Brian M. Hahn, Chief Financial Officer and Senior Vice President of the Company, each hereby certifies that, to the best of his or her knowledge:

1. The Company's Annual Report on Form 10-K for the year ended December 31, 2021 (the "Annual Report"), to which this Certification is attached as Exhibit 32.1, fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act, and
2. The information contained in the Annual Report fairly presents, in all material respects, the financial condition of the Company as of the end of the period covered by the Annual Report and results of operations of the Company for the periods covered by the Annual Report.

**In Witness Whereof**, the undersigned have set their hands hereto as of the 3<sup>rd</sup> day of March 2022.

/s/ Harout Semerjian

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Harout Semerjian  
President & Chief Executive Officer

/s/ Brian M. Hahn

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Brian M. Hahn  
Chief Financial Officer and Senior Vice President

\* This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of GlycoMimetics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

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