UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-K

(Mark One)

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

For the fiscal year ended December 31, 2024

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

For the Transition Period from to

Commission File Number: 001-39555

GREENWICH LIFESCIENCES, INC.
(Exact name of registrant as specified in its charter)

Delaware	**20-5473709**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
3992 Bluebonnet Dr., Building 14, Stafford, Texas 77477	**77477**
(Address of principal executive offices)	(Zip Code)

(832) 819-3232
(Registrant's telephone number, including area code)
Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value	GLSI	The NASDAQ Capital Market LLC

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

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

Indicate by check 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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

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

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☒ Smaller reporting company ☒ Emerging growth company ☒

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

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

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates based on a closing sale price of $17.26 per share, which was the last sale price of the common stock as of June 28, 2024, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $101 million.

As of April 11, 2025, 13,273,539 shares of the registrant's common stock, $0.001 par value per share, were issued and outstanding.

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Forward-Looking Statements

This Annual Report on Form 10-K contains forward-looking statements which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These statements may be identified by such forward-looking terminology as "may," "should," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "potential," "continue" or the negative of these terms or other comparable terminology. Our forward-looking statements are based on a series of expectations, assumptions, estimates and projections about our company, are not guarantees of future results or performance and involve substantial risks and uncertainty. We may not actually achieve the plans, intentions or expectations disclosed in these forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in these forward-looking statements. Our business and our forward-looking statements involve substantial known and unknown risks and uncertainties, including the risks and uncertainties inherent in our statements regarding:

- our projected financial position and estimated cash burn rate;
- our estimates regarding expenses, future revenues and capital requirements;
- our ability to continue as a going concern;
- our need to raise substantial additional capital to fund our operations;
- the success, cost and timing of our clinical trials;
- our dependence on third parties in the conduct of our clinical trial;
- our ability to obtain the necessary regulatory approvals to market and commercialize our product candidate;
- the ultimate impact of the current coronavirus pandemic, or any other health epidemic, on our business, our clinical trials, our research programs, healthcare systems or the global economy as a whole;
- the potential that results of preclinical and clinical trials indicate our current product candidate or any future product candidates we may seek to develop are unsafe or ineffective;
- the results of market research conducted by us or others;
- our ability to obtain and maintain intellectual property protection for our current product candidate;
- our ability to protect our intellectual property rights and the potential for us to incur substantial costs from lawsuits to enforce or protect our intellectual property rights;
- the possibility that a third party may claim we or our third-party licensors have infringed, misappropriated or otherwise violated their intellectual property rights and that we may incur substantial costs and be required to devote substantial time defending against claims against us;
- our reliance on third-party suppliers and manufacturers;
- the success of competing therapies and products that are or become available;
- our ability to expand our organization to accommodate potential growth and our ability to retain and attract key personnel;
- the potential for us to incur substantial costs resulting from product liability lawsuits against us and the potential for these product liability lawsuits to cause us to limit our commercialization of our product candidate;
- market acceptance of our product candidate, the size and growth of the potential markets for our current product candidate and any future product candidates we may seek to develop, and our ability to serve those markets; and
- the successful development of our commercialization capabilities, including sales and marketing capabilities.

All of our forward-looking statements are as of the date of this Annual Report on Form 10-K only. In each case, actual results may differ materially from such forward-looking information. We can give no assurance that such expectations or forward-looking statements will prove to be correct. An occurrence of, or any material adverse change in, one or more of the risk factors or risks and uncertainties referred to in this Annual Report on Form 10-K or included in our other public disclosures or our other periodic reports or other documents or filings filed with or furnished to the U.S. Securities and Exchange Commission (the "SEC") could materially and adversely affect our business, prospects, financial condition and results of operations. Except as required by law, we do not undertake or plan to update or revise any such forward-looking statements to reflect actual results, changes in plans, assumptions, estimates or projections or other circumstances affecting such forward-looking statements occurring after the date of this Annual Report on Form 10-K, even if such results, changes or circumstances make it clear that any forward-looking information will not be realized. Any public statements or disclosures by us following this Annual Report on Form 10-K that modify or impact any of the forward-looking statements contained in this Annual Report on Form 10-K will be deemed to modify or supersede such statements in this Annual Report on Form 10-K.

This Annual Report on Form 10-K may include market data and certain industry data and forecasts, which we may obtain from internal company surveys, market research, consultant surveys, publicly available information, reports of governmental agencies and industry publications, articles and surveys. Industry surveys, publications, consultant surveys and forecasts generally state that the information contained therein has been obtained from sources believed to be reliable, but the accuracy and completeness of such information is not guaranteed. While we believe that such studies, clinical trials and publications are reliable, we have not independently verified market and industry data from third-party sources.

Risk Factor Summary

Our business is subject to significant risks and uncertainties that make an investment in us speculative and risky. Below we summarize what we believe are the principal risk factors but these risks are not the only ones we face, and you should carefully review and consider the full discussion of our risk factors in the section titled "Risk Factors", together with the other information in this Annual Report on Form 10-K. If any of the following risks actually occurs (or if any of those listed elsewhere in this Annual Report on Form 10-K occur), our business, reputation, financial condition, results of operations, revenue, and future prospects could be seriously harmed. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that adversely affect our business.

Risks Relating to Our Business

We have incurred substantial losses since our inception and anticipate that we will continue to incur substantial and increasing losses for the foreseeable future.

We need significant additional financing to fund our operations and complete the development and, if approved, the commercialization of our product candidate. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.

Clinical-stage biopharmaceutical companies with product candidates in clinical development face a wide range of challenging activities which may entail substantial risk.

We may find it difficult to enroll patients in our clinical trials given the limited number of patients who have the diseases for which our product candidate is being studied which could delay or prevent the start of clinical trials for our product candidate.

The results of preclinical studies or earlier clinical trials are not necessarily predictive of future results. Our existing product candidate in clinical trials, and any other product candidates that may advance into clinical trials, may not have favorable results in later clinical trials or receive regulatory approval.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome.

Our current and future product candidates, the methods used to deliver them or their dosage levels may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following any regulatory approval.

Our product development program may not uncover all possible adverse events that patients who take our product candidate may experience. The number of patients exposed to our product candidate and the average exposure time in the clinical development program may be inadequate to detect rare adverse events or chance findings that may only be detected once the product is administered to more patients and for greater periods of time.

Our future success is dependent on the regulatory approval of our product candidate.

We have limited to no manufacturing, sales, marketing or distribution capability and must rely upon third parties for such.

We are subject to a multitude of manufacturing risks, any of which could substantially increase our costs and limit supply of our product candidate.

In the clinical trials using GP2, GM-CSF is also administered and its availability is dependent upon a third-party manufacturer, which may or may not reliably provide GM-CSF, thus jeopardizing the completion of the trials.

We rely on third parties to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, or if we lose any of our CROs or other key third-party vendors, we may not be able to obtain regulatory approval for or commercialize our current or future product candidates on a timely basis, if at all.

We are dependent on technologies we license, and if we lose the right to license such technologies or we fail to license new technologies in the future, our ability to develop new products would be harmed, and if we fail to meet our obligations under our license agreements, we may lose the ability to develop our product candidate.

Our commercial success depends upon attaining significant market acceptance of our current product candidate and future product candidates, if approved, among physicians, patients, healthcare payors and cancer treatment centers.

Even if we are able to commercialize our current product candidate or any future product candidates, the products may not receive coverage and adequate reimbursement from third-party payors in the U.S. and in other countries in which we seek to commercialize our products, which could harm our business.

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

The price of our common stock may fluctuate substantially.

Because certain of our stockholders control a significant number of shares of our common stock, they may have effective control over actions requiring stockholder approval.

PART I

ITEM 1. BUSINESS

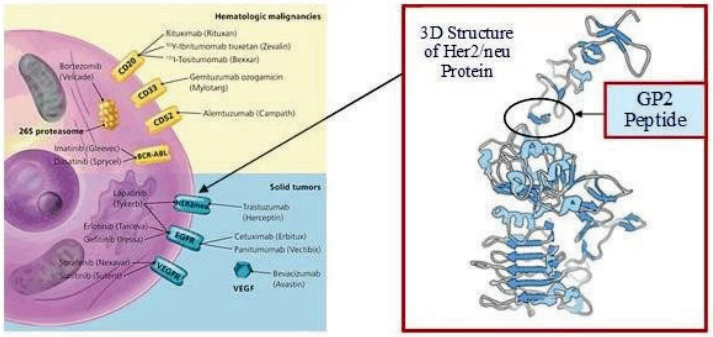
BUSINESS

Overview

We are a clinical-stage biopharmaceutical company focused on our Phase III clinical trial, Flamingo-01, which is evaluating GLSI-100, an immunotherapy to prevent breast cancer recurrences. GP2 is a 9 amino acid transmembrane peptide of the HER2/neu protein, a cell surface receptor protein that is expressed in a variety of common cancers, including expression in 75% of breast cancers at low (1+), intermediate (2+), and high (3+ or over-expressor) levels. The combination of GP2 + GM-CSF is called GLSI-100. We are currently expanding Flamingo-01 into Europe with plans to open up to 150 sites globally. Flamingo-01 is designed to evaluate the safety and efficacy of GLSI-100 in HER2/*neu* positive patients with residual disease or high-risk pathologic complete response at surgery and who have completed both neoadjuvant and postoperative adjuvant trastuzumab based treatment.

Our Product Candidate

GP2 is a HER2/*neu* transmembrane peptide that elicits a targeted immune response against HER2/*neu*-expressing cancers. Below is an image of a cell surface showing therapeutically relevant cell surface proteins in cancer. Breast cancers and other solid tumors with elevated expression of HER2/*neu* protein are highly aggressive with an increased disease recurrence and a worse prognosis.



GM-CSF Immunoadjuvant

Recombinant human granulocyte macrophage colony-stimulating factor or GM-CSF (sargramostim, Leukine®) has been shown to enhance monocyte and neutrophil cytotoxicity against melanoma tumor cells and to enhance activity-dependent cellular cytotoxicity of monocytes and neutrophils against targets coated with the anti-ganglioside antibodies. GP2 will be delivered in combination with GM-CSF to induce GP2 peptide specific immunity. GP2 treatment is administered via an intradermal injection by mixing GP2 peptide and GM-CSF at the time of administration.

GM-CSF is available in lyophilized form exclusively from one manufacturer. We will continue to be dependent on the manufacturer for our supply of GM-CSF in our ongoing GP2 clinical trials and upon potential commercialization of GP2. Although GM-CSF is only approved for sale in the U.S. by the FDA and is available in other countries on a named patient basis through a specialized company that focuses on making products approved in the U.S. available globally, GM-CSF may be registered for sale in other countries by the manufacturer in the future.

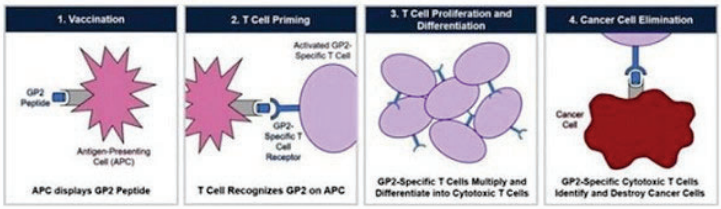
Cancer Immunotherapy

Cancer immunotherapy is a new method of cancer treatment among more established treatment options such as surgery, chemotherapy, targeted therapy, and radiation therapy. This method seeks to stimulate an individual's immune system to selectively attack cancer cells while not affecting normal cells or to deliver certain immune system components in order to inhibit the spread of cancer. Thus, cancer immunotherapy is an important and rapidly emerging field, which has led to new clinical research studies and garnered the attention of biotechnology and pharmaceutical companies, regulatory agencies, payors and hospital systems, cancer patients and their families, and the general public at large.

Cancer immunotherapy harnesses the body's natural immune system response to fight and/or prevent tumor growth. An essential characteristic of the immune system, which is a network of tissues, cells, and signaling molecules that work to protect the body, is its ability to differentiate foreign threats, including cancerous growths, from normal cells. Despite the fact that tumor cells originate from normal cells, tumor cells can be recognized as foreign threats because of their ability to elicit the production of tumor antigens. These antigens may be released in the interstitial tissues, and eventually in the bloodstream or may remain on the surface of cognate cancer cells. The HER2/*neu* protein is one of the most widely expressed tumor antigens in multiple malignances.

Several cell types play an important role in the development and maintenance of immune responses against cancer. The most important cell types with regard to immune response are antigen-presenting cells ("APCs") and lymphocytes. APCs include various subtypes, such as dendritic cells, monocytes and macrophages. Once a patient is exposed to a tumor antigen (either by the presence of cancer itself or through active immunization through a vaccine type immunotherapeutic), the tumor antigen gets recognized by the APC and becomes "processed" through digestion into smaller fragments within the APC. Subsequently, the APC "communicates" with a specific type of lymphocyte called a T-cell. Inactive T-cells search for tumor antigens by transiently binding to antigens presented by major histocompatibility complexes ("MHCs") on the APCs. There is great variability in the expression of different subtypes of MHCs in the human population. The MHC system expresses human leukocyte antigens ("HLAs") and these HLA subtypes determine the vigor and duration of any given T-cell response to a cancer among different patients.

As shown below, following GP2 immunotherapy, CD8+ cytotoxic T lymphocytes recognize and destroy HER2/*neu*-expressing cancer cells. GP2 is administered in combination with an FDA-approved immunoadjuvant GM-CSF, which stimulates the proliferation of antigen presenting cells. Preclinical studies have shown that T cells sensitized against the GP2 peptide demonstrate significant recognition of HER2/*neu*-expressing tumors. Both ovarian and breast cancer-specific CTLs recognize GP2, which is widely expressed in HER2/*neu*-expressing tumors and is capable of inducing tumor-specific CTL populations in vitro.

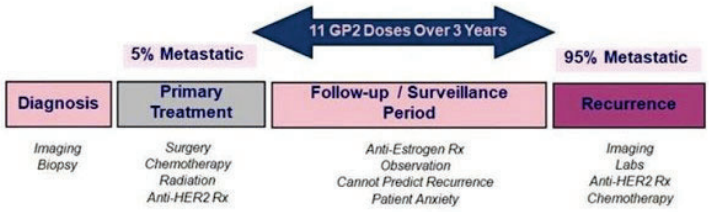


Breast Cancer Treatment Approach — Adjuvant & Neoadjuvant Treatments

As shown below, in the adjuvant setting, a HER2/*neu* 3+ patient typically receives Herceptin in the first year following breast cancer surgery, with the hope that their breast cancer will not recur, and with the odds of recurrence slowly decreasing over the first 5 years following surgery. Herceptin has been shown to reduce recurrence rates by approximately 50%, from 25% to 12%, in the adjuvant setting. In the neoadjuvant setting, a HER2/*neu* 3+ patient receives treatment before surgery and based on the results of a biopsy at surgery, will receive Herceptin or Kadcyla, a more potent form of Herceptin, following surgery. Kadcyla has been shown to reduce recurrence rates by 50%, from 22% to 11%, in the neoadjuvant setting. Accordingly, we believe that GP2 may be effective in safely addressing the 50% of recurring patients who do not respond to either Herceptin or Kadcyla.

GP2 is administered in combination with the immunoadjuvant GM-CSF in years 2-4, following the first year of treatment with Herceptin, in a series of 11 intradermal injections comprising 6 primary injections over 6 months (1 injection per month) followed by 5 booster injections every 6 months thereafter.

The adverse events observed to date have been well-tolerated with no SAEs reported in the Phase IIb clinical trial considered related to GLSI-100 treatment. Therefore, GLSI-100 is well-positioned to serve this population at this stage of treatment. We believe that clinicians and patients are seeking a de-escalation and a return to normal life free of toxic treatments, especially if the chance of recurrence is reduced substantially. GLSI-100 may significantly reduce the incidence of recurrence/metastatic disease and need for additional therapy. Lastly, we believe that GP2 may be the treatment that will synergistically overlap with or follow trastuzumab based treatments, such as Herceptin, Kadcyla, Enhertu or any of the other Herceptin derivatives or antibody drug conjugates being developed.



GP2 Clinical Data & Phase III Clinical Trial (Flamingo-01)

In the Phase IIb and 3 Phase I clinical trials where 146 patients received GP2 immunotherapy, there were no serious adverse events observed related to the immunotherapy or any other GP2 combination treatments.

Clinical Trial Description	Status
GP2 Phase III Clinical Trial – Flamingo-01 ● A Randomized, Multicenter, Placebo-controlled, Phase 3 Study to Evaluate the Efficacy and Safety of HER2/*neu* Peptide GLSI-100 (GP2 + GM-CSF) in HER2/*neu* Positive Subjects with Residual Disease or High-Risk PCR after both Neoadjuvant and Postoperative Trastuzumab-based Therapy	Enrolling in US and Europe
GP2 Phase IIb Clinical Trial ● Prospective, Randomized, Single-Blinded, Multi-Center Phase II Trial of the HER2/*neu* Peptide GP2 + GM-CSF Vaccine versus GM-CSF Alone in HLA-A*02+ Node-Positive and High-Risk Node-Negative Breast Cancer Patients to Prevent Recurrence ● 89 patients treated with GP2 + GM-CSF, 91 placebo patients treated with GM-CSF	Trial Completed
GP2 Phase I Clinical Trial — Combination with AE37 ● Phase I Safety Trial of the GP2 + GM-CSF Vaccine in Combination with the Helper Peptide AE37 + GM-CSF Vaccine ● 22 patients treated with GP2 + AE37 + GM-CSF	Trial Completed
GP2 Phase I Clinical Trial — Combination with Trastuzumab ● Phase Ib Trial of Combination Immunotherapy with HER2/*neu* Peptide GP2 + GM-CSF Vaccine and Trastuzumab in Breast Cancer Patients ● 17 patients treated with GP2 + GM-CSF + trastuzumab	Trial Completed
First GP2 Phase I Clinical Trial ● Phase Ib Trial of HER2/*neu* Peptide (GP2) Vaccine in Breast Cancer Patients ● 18 patients treated with GP2 + GM-CSF	Trial Completed

Phase I Clinical Trials

First GP2 Phase I Clinical Trial

As shown in the table above, the first GP2 Phase I clinical trial was conducted at Walter Reed Army Medical Center. The clinical trial was conducted in patients over the age of 18 years with a diagnosis of HER2/*neu* 1-3+, node negative breast cancer who had undergone primary surgical and medical therapies and who were without evidence of disease at the time of enrollment into the clinical trial. Patients were HLA typed and HLA-A*02 patients were skin tested for recall antigens. HLA-A*02 patients found to be immunologically intact received the vaccine. There were no grade 3-5 toxicities observed among the 18 patients that received a total of 108 doses of GP2 + GM-CSF. Among all patients that participated in the clinical trial, the maximum observed local toxicity that occurred was grade 1 in 38.9% and grade 2 in 61.1% of the patients. The maximum systemic toxicity observed during the clinical trial was grade 0 in 5.6%, grade 1 in 61.1%, and grade 2 in 33.3% of the patients. The most common local reactions included erythema and induration (100% of patients), pruritis (25%), and inflammation (23%). The most common systemic reactions were grade 1 fatigue (40%) and grade 1 arthralgia/myalgia (15%). There were no recurrences and no deaths reported among the patients that participated in the clinical trial. Additional data analysis reported by the investigators, included topics such as pre-existing immunity, effects of dosing, and epitope spreading.

GP2 Phase I Clinical Trial — Combination with Trastuzumab

Preclinical research previously demonstrated that a synergy may exist between trastuzumab and GP2 peptide-stimulated CTLs ex vivo. Pretreatment of breast cancer cells with trastuzumab followed by incubation with GP2 peptide-induced CTLs resulted in enhanced cytotoxicity in 3 tumor cell lines compared to treatment with trastuzumab or GP2-specific CTLs alone. These results suggest that concurrent GP2 vaccination during trastuzumab therapy may be a possible combination immunotherapy.

As shown in the table above, a Phase I trial evaluating the combination therapy of GP2 + GM-CSF administered simultaneously with trastuzumab was conducted. The combination therapy was found to be well tolerated when given concurrently in 17 clinically disease-free, HER2/*neu* over-expressing breast cancer patients.

GP2 Phase I Clinical Trial — Combination with AE37

As shown in the table above, a Phase I trial evaluating the combination therapy of GP2 + GM-CSF administered simultaneously with HER2/*neu* peptide AE37 in 22 clinically disease-free, HER2/*neu* breast cancer and ovarian cancer patients was conducted. While 28 patients enrolled, 22 were treated and 14 patients completed the 6 vaccination series. Final results suggest that the combination of GP2 and AE37 peptides is well tolerated at each of the tested dosing levels. Additionally, we believe that the combination is capable of stimulating strong peptide-specific in vivo immune responses.

During the primary vaccination series, an AE37/GP2+GM-CSF dual peptide vaccine resulted in robust T-cell proliferation. However, significant immune responses became more variable at 6 and 12 months post vaccination suggesting the need for boosters in some individuals.

Phase II Clinical Trial

GP2 Phase IIb Clinical Trial Overview

Phase II Clinical Trial Study Report: We are preparing a comprehensive study report of the Phase II trial for the FDA prior to the filing of a BLA. This report will include the patients with breast cancer recurrences, the last known date of patients who did not recur (censoring data), the adverse events, immune responses, and other final study report analyses. This report will serve to complement the Phase III data and to provide a drug product dossier that can also be submitted to regulatory agencies in other countries for marketing approval. The use of GM-CSF as an adjuvant in GLSI-100 may also be included in the dossier as GM-CSF is only commercially available in the US at this time.

We have experienced significant interest from investors, strategics, analysts, and regulators in the 5 year follow-up data we published and the 3 and 4 year follow-up data independently published by the clinical investigators. The differences between these publications can be best explained by the increased maturity of the data as each year progressed. In all 3 publications, no recurrences or a 100% reduction in recurrence rate, were reported in the sub-population that the Flamingo-01 design has been based on and any differences between the number of patients in the treated or placebo groups has been shown to be immaterial.

We did not have responsibility for the conduct of the trial or for the data from the Phase II trial. After the trial had already started, we received the rights to the Phase II trial data pursuant to a license agreement with the Henry Jackson Foundation (HJF) that entitled us to all of the GP2 data from the Phase II trial and all prior trials, but did not provide us with the ability to participate in the Phase II trial as a regulatory clinical sponsor. The lead clinicians and HJF were responsible for project and site management, medical monitoring, data monitoring of case report forms (CRFs), correspondence with the FDA, and creation, data entry and management of the database. We were provided study updates but were not provided an opportunity to participate in any of the above activities or to review the publications of the 3 and 4 year follow-up data by the lead clinicians. Thus, the comprehensive study report will rely on cooperation from HJF and the clinical sites who are responsible for providing the final data accurately to us.

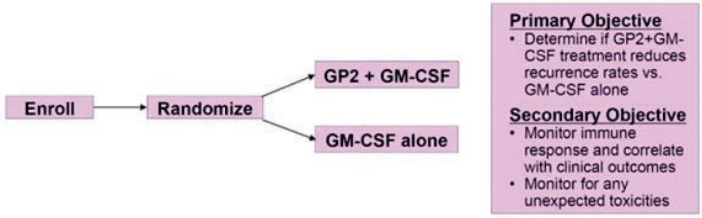
We are currently comparing the final CRFs and database provided by HJF and have noted the following inconsistencies as the comprehensive study report is being prepared. The lead clinicians reported in an annual report to the FDA and in their publication of 4 year follow-up data a 6th recurrence in the HER2 positive control arm of the study. We conservatively chose not to report this 6th recurrence since it was not reported in the data provided by HJF, even though adding this recurrence to the control arm would significantly lower the p-value and improve the evidence of efficacy of GLSI-100. As a result of detailed due diligence, we became aware in Q4 of 2023 of a potential recurrence in the HER2 positive treated arm. This patient was not reported as a recurrence in the database, on a CRF that should be used for a recurrence, in reports from the lead clinicians to the FDA, or in the 3 or 4 year follow-up data published by the lead clinicians. Some CRFs report a recurrence, but the critical CRF that confirms a recurrence was not completed or entered into the database provided by HJF. We have since initiated an effort to confirm with HJF and the clinicians who treated this patient the status of this patient, and if the final CRFs and database should be modified. It appears that this patient, who had completed treatment with GLSI-100, experienced a local recurrence that responded well to additional treatment and survived without additional evidence of disease or distant metastasis for the duration of study follow-up. Any discrepancies noted to date in the review of the censoring date recorded in the database do not materially change the study results and the median duration of follow-up remains 5 years.

While a recurrence in the control arm would decrease the p-value and still result in a 100% reduction in the recurrence rate, a recurrence in the treated arm would increase the p-value and would result in an 80% reduction in the recurrence rate. In either case, we believe that the reduction in recurrence rate is clinically meaningful and substantial compared to the approximately 20-50% reduction in recurrences of all other approved breast cancer drugs for this patient population. These findings have not materially affected the power of the Phase III study as the assumptions for that design were selected conservatively.

In a prospective, randomized, single-blinded, placebo-controlled, multi-center (16 sites led by MD Anderson Cancer Center) Phase IIb clinical trial of HLA-A*02 breast cancer patients, 46 HER2/*neu* 3+ over-expressor patients were treated with GLSI-100 and 50 placebo patients were treated with GM-CSF alone. After 5 years of follow-up, there was a substantial reduction in cancer recurrences in the HER2/*neu* 3+ patients who were treated with GLSI-100, followed, and remained disease free over the first 6 months, which we believe is the time required to reach peak immunity and thus maximum efficacy and protection. Based on this data, we believe that treatment with GLSI-100 starting approximately in the second year following surgery may dramatically lower breast cancer recurrences in this patient population.

The design of the Phase IIb trial was as follows:

- Prospective, randomized, single-blinded, placebo-controlled phase IIb clinical trial of GP2 + GM-CSF or GM-CSF alone in HER2/*neu* 1-3+, HLA-A*02 patients.
- High-risk breast cancer patients (Node Positive, High Risk Node Negative) who were disease-free and immunocompetent after having completed standard of care therapy.
- The primary endpoint was to determine if GP2 + GM-CSF reduces breast cancer recurrence rates versus GM-CSF alone. A recurrence is defined as either a pathologically confirmed recurrence or a new radiographic finding of recurrence during standard of care follow-up.

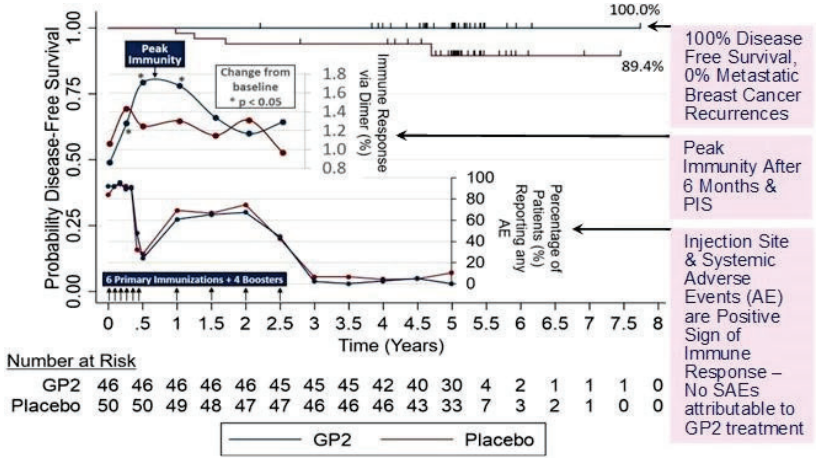


The Phase IIb clinical trial closed in December 2018. The final median 5 year follow-up data is presented below. A total 180 intent-to-treat patients enrolled in the clinical trial. HER2/*neu* status was determined based on the expression levels of the HER2/*neu* protein in each patient using standard of care HER2/*neu* diagnostic technology. The trial was prospectively designed to analyze these fully treated patients by 2 distinct patient populations, namely HER2/*neu* 3+ (positive or over expressors) and HER2/*neu* 1-2+ (low to intermediate expressors):

- HER2/*neu* 3+ Positive Over Expressors: In the 96 HER2/*neu* 3+, HLA-A*02 patients, a substantial reduction in recurrences was observed in the efficacy population. A patient was in the efficacy population if they were treated, followed, and remained disease free over the first 6 months, which is the time we believe is required to reach peak immunity and thus maximum efficacy and protection. This patient population was treated with GLSI-100 following the first year of trastuzumab treatment, which followed surgery.
- HER2/*neu* 1-2+ Low to Intermediate Expressors: In the 72 HER2/*neu* 1-2+, HLA-A*02 patients, no reduction in recurrence rates were observed, but trastuzumab was not administered to these patients. Thus, we may pursue a future trial with GP2 in combination with trastuzumab based therapy and other synergistic agents.

5 Year Data Set of GP2 Phase IIb Trial: HER2 3+ (Positive or Over Expressors) Patients Who are in the Efficacy Population

The figure below shows a time series of the GLSI-100 immunotherapy injections, adverse events ("AE"), immune response, and 100% disease-free survival (0% recurrence rate) in HER2 positive breast cancer patients over median 5 years. The Kaplan Meier curve and p value, which are based on recurrence rates or disease free survival and censoring data, is subject to change pending the completion of the Phase II Clinical Trial Study Report described above. This time series highlights that the 10 GLSI-100 immunotherapy injections over the first 2.5 years (as depicted by the 10 arrows on the x-axis) demonstrated a potent immune response that typically peaked at 6 months. The immune response also included injection site and systemic reactions that peaked at approximately 6 months. We believe that these AEs are a positive sign that the immune system responded to GLSI-100 immunotherapy and contributed to the decline in metastatic breast cancer recurrence. The observed AEs associated with GLSI-100 injections were temporary and declined after GLSI-100 injections ended.



Safety & Immune Response Data of GP2 Phase II Trial

In both the HER2/*neu* 3+ and the HER2/*neu* 1-2+ patient populations, GP2 was shown to be well tolerated. The observed AEs primarily consisted of injection site reactions which could be mitigated by reducing the GM-CSF dose (and then the GP2 dose, if necessary). No SAEs reported in the GP2 treated patients were considered attributable to GLSI-100.

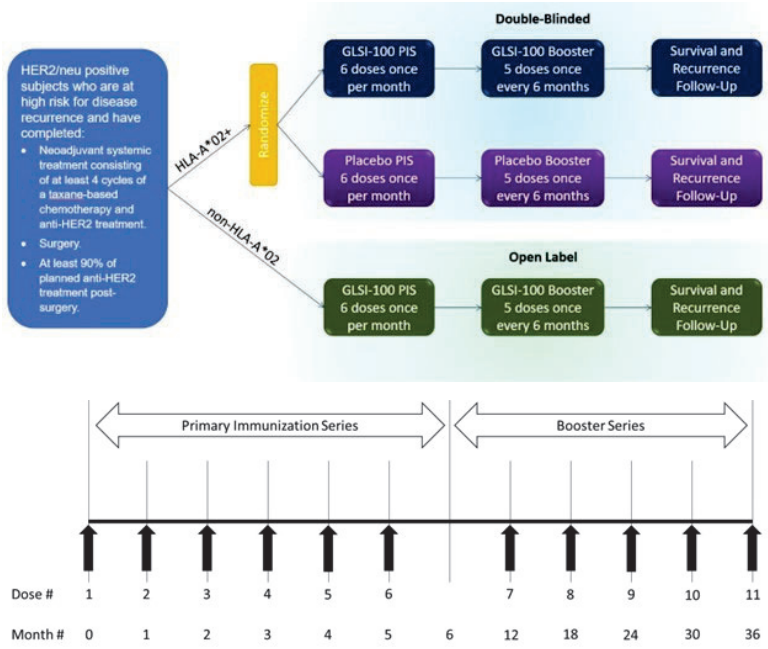
GLSI-100 immunotherapy demonstrated GP2-specific immune responses, which we believe supports GP2's mechanism of action. Statistically significant peak immunity was typically observed after 6 months of GLSI-100 treatment, as measured in both the Dimer Binding Assay and the Delayed Type Hypersensitivity (DTH) skin test. The HER2/*neu* 3+ population's immune response was similar to the HER2/*neu* 1-2+ population's immune response, suggesting the potential to treat the HER2/*neu* 1-2+ population (including triple negative breast cancer) with GP2 immunotherapy in combination with trastuzumab (Herceptin) based products and other synergistic clinically active agents. The broad based immune response suggests the potential for GP2 to treat other HER2/*neu* 1-3+ expressing cancers. Further, booster injections given every 6 months after the PIS were observed to elicit a prolonged immune response, which may provide longer term protection.

Phase III Trial, Flamingo-01

We have commenced Flamingo-01, a Phase III clinical trial with Baylor College of Medicine as the global primary investigator site. Flamingo-01includes an interim analysis and uses a similar treatment regime as the Phase IIb clinical trial.

The primary objective of Flamingo-01 is to assess the safety and efficacy of GLSI-100 compared to placebo in HLA-A*02 positive and HER2/*neu* positive breast cancer patients who have a high risk of disease recurrence (stage I, II, or III at presentation with residual disease at surgery or stage III at presentation with pathologic complete response ("pCR") at surgery) and have completed both neoadjuvant and postoperative adjuvant trastuzumab-based standard of care therapy.

An overview of the anticipated Phase III clinical trial design is shown below:



U.S. and European Breast Cancer Market

We believe that the market for GP2 is large. The American Cancer Society estimates that approximately 1 in 8 U.S. women (12.8%) will develop invasive breast cancer over her lifetime. The American Cancer Society, Economic Impact, & European Cancer Information System 2025 estimate approximately 700,000 new breast cancer patients per year and 9.5 million current breast cancer survivors in the U.S. and Europe in 2025. An estimated 42,000 female breast cancer deaths will occur in the U.S. in 2025. HER2/*neu* 3+ breast cancer patients comprise approximately 25% of all breast cancer patients. Approximately 40% to 50% of the U.S. and European population contains the HLA-A*02 allele, while node positive and high risk node negative patients comprise approximately 50% of the market. Therefore, we believe that the U.S. market for the first indication for GP2, if approved, could be the combination of the three populations above which together comprises approximately 6.25% of breast cancer patients who undergo surgery.

Competition

Cancer immunotherapy has become a significant growth area for the biopharmaceutical industry, attracting large pharmaceutical companies as well as small niche players. Generally, our principal competitors in the cancer immunotherapy market comprise both types of companies with currently approved products for various indications, such as manufacturers of approved bispecific antibodies, CAR-T cells, and checkpoint inhibitors, as well as companies currently engaged in cancer immunotherapy clinical development. The large and medium-size players who have successfully obtained approval for cancer immunotherapy products include Bristol-Myers Squib Company, Merck & Co., Inc., Genentech, Inc. (a subsidiary of Roche Holding AG), AstraZeneca PLC, Celgene Corporation, Johnson & Johnson, Amgen, Novartis, Juno Therapeutics, Inc. (a subsidiary of Celgene), Kite Pharma, Inc., a wholly-owned subsidiary of Gilead Sciences, Inc. and Pfizer, Inc./EMD Serono, Inc. Most of these companies, either alone or together with their collaborative partners, have substantially greater financial resources than we do.

Companies developing novel products with similar indications to those we are pursuing are expected to influence our ability to penetrate and maintain market share, if GLSI-100 is approved. For patients with early stage breast cancer, adjuvant or neoadjuvant therapy is often given to prevent recurrence and increase the chance of long-term disease free survival. Adjuvant or neoadjuvant therapy for breast cancer can include chemotherapy, hormonal therapy, radiation therapy, or combinations thereof. In addition, the HER2 targeted drug Herceptin (trastuzumab or biosimilar) alone or in combination with Perjeta (pertuzumab), both manufactured and marketed by Roche/Genentech, may currently only be given to patients with tumors with high expression of HER2/*neu*. Following adjuvant treatment in the first year following surgery, only Nerlynx is approved for extended andjuvant treatment and would potentially compete with GLSI-100 if not used synergistically. We believe that GP2 will act synergistically with Herceptin, Perjeta, Nerlynx, and the newest entrants Kadcyla and Enhertu.

There are a number of approved HER2/*neu* targeted therapies, some of which include the following: Genentech's Herceptin, Perjeta (pertuzumab) and Kadcyla (TDM-1, ado-trastuzumab emtansine); Puma's Nerlynx (neratinib); Daichi Sanko's Enhertu (TDXD, fam-trastuzumab deruxtecan-nxki), and Seattle Genetics' Tukysa (tucatanib). In addition, the following biosimilars to trastuzumab have been approved: Biocon/Mylan's (Ogivri — trastuzumab-dkst; Celltrion/Teva's (Herzuma — trastuzumab-pkrb); Samsung/Biogen/Merck's (Ontruzant — trastuzumab-dttb); Pfizer's (Trazimera — trastuzumab-qyyp); and Allergan/Amgen's (Kanjinti; trastuzumab-anns). Furthermore, the following immune checkpoint inhibitors have also been approved or are under review by the FDA to treat breast cancer patients: Merck's Keytruda (pembrolizumab) and Genentech's Tecentriq (atezolumab). Moreover we believe that drug candidates from Sellas (formerly Galena), Marker (formerly TapImmune), Epithany, Antigen Express (Generex subsidiary), and various companies pursuing neoantigen technologies are in clinical development and are being pursued for different sub-populations or are behind GP2 in clinic development.

Many of our competitors, either alone or with their strategic partners, have substantially greater financial, technical and human resources than we do, and more experience in obtaining FDA and other regulatory approvals of treatments and in commercializing those treatments. Accordingly, our competitors may be more successful than us in obtaining approval for cancer immunotherapy products and achieving widespread market acceptance. Our competitors' treatments may be more effectively marketed and sold than any products we may commercialize, thus causing limited market share before we can recover the expenses of developing and commercializing our cancer immunotherapy product candidate.

Mergers and acquisitions in the biotechnology and pharmaceutical 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 activities may lead to consolidated efforts that allow for more rapid development of cancer immunotherapy product candidates.

These competitors also compete with us in the recruiting and retaining of qualified scientific and management personnel, the ability to work with specific clinical contract organizations due to conflict of interest, and the conduct of trials in the ability to recruit clinical trial sites and patients for our clinical trials.

We expect any products that we develop and commercialize to compete on the basis of, among other things, efficacy, safety, price, and the availability of coverage and reimbursement from government and other third-party payors. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are viewed as safer, more convenient, or less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for our current product candidate or any other future product candidate, which could result in our competitors establishing a strong market position before we are able to enter the market.

Manufacturing

We do not own or operate manufacturing facilities for the production of our product candidate nor do we have plans to develop our own manufacturing operations in the foreseeable future. We currently depend on third-party contract manufacturers for all of our required raw materials, active pharmaceutical ingredients ("APIs"), and finished product candidate for our clinical trials and potential commercial supply.

Exclusive License

The Henry M. Jackson Foundation out-licenses technology of the U.S. military and it conducts research and manages clinical trials. HJF managed the GP2 Phase IIb clinical which was led by MD Anderson Cancer Center, oversaw all regulatory filings with the FDA for all 4 GP2 clinical trials (including the 3 Phase I and the Phase IIb clinical trials), and possesses all patient and manufacturing data from such trials.

In April 2009, we entered into an exclusive license agreement, as amended, with HJF pursuant to which HJF granted us exclusive worldwide rights to several U.S. and foreign patents and patent applications covering methods of using GP2 as an immunotherapy that elicits a targeted immune response against HER2/*neu*-expressing cancers. In consideration for such licensed rights, we issued HJF 202,619 shares of our common stock. In addition, we are required to pay an annual maintenance fee and milestone payments of up to an aggregate of $5.7 million. We are also required to make 2.5-5% royalty payments based on the sales of GP2 and to reimburse HJF for patent expenses. To date we have not been required to make any milestone or royalty payments to HJF. The term of the exclusive license shall terminate at such time that the last licensed patent or patent application expires or is abandoned, unless terminated earlier pursuant to the terms of the exclusive license agreement. We may terminate the license by giving 90 days notice. HJF may terminate the license if we do not make required payments, if we default in our performance obligations, if we do not sufficiently develop and advance GP2 towards commercialization, and for various other reasons.

In connection with the exclusive license agreement with HJF, we were the financial and corporate sponsors of the GP2 Phase IIb clinical trial. HJF has provided us with all FDA correspondences and GP2 patient and manufacturing data for the history of the drug's development for all 4 clinical trials, and we have incorporated this data into our corporate investigational new drug application ("IND") with the FDA.

Intellectual Property Portfolio

Our commercial success depends in part on our ability to avoid infringing the proprietary rights of third parties, our ability to obtain and maintain proprietary protection for our technologies where applicable, and our ability to prevent others from infringing our proprietary rights. We intend to protect our proprietary technologies by, among other methods, evaluating relevant patents, establishing defensive positions, monitoring European Union oppositions and pending intellectual property rights, preparing litigation strategies in view of the U.S. legislative framework, and filing U.S. and international patent applications on technologies, inventions and improvements that are important to our business. Patents and other intellectual property rights are crucial to our success. We intend to protect our intellectual property rights through available means including filing and prosecuting patent applications in the U.S. and other countries, protecting trade secrets, and utilizing regulatory protections such as data exclusivity. In addition, we include restrictions regarding use and disclosure of our proprietary information in our contracts with third parties, and utilize customary confidentiality agreements with our employees, consultants, clinical investigators, and scientific advisors to protect our confidential information and know-how. Together with our licensors, we also rely on trade secrets to protect our combined technology especially where we do not believe patent protection is appropriate or obtainable. It is our policy to operate without knowingly infringing on, or misappropriating, the proprietary rights of others.

An international patent law treaty ("PCT") provides a unified procedure for filing patent applications to protect inventions in each of its contracting states. Thus, a single PCT application can be converted into a national stage patent application in any of the more than 145 PCT contracting states, and is considered a simple, cost-effective means for seeking patent protection in numerous regions or countries. This nationalization (converting into an application in any of the contracting states) typically occurs 18 months after the PCT application filing date. We also rely on trade secrets, know-how, and continuing technological innovation to develop and maintain our proprietary position.

The term of individual patents depends upon the legal term of the patents in countries in which they are obtained. In most countries, including the U.S., the patent term is generally 20 years from the earliest date of filing a non-provisional patent application in the applicable country. In the U.S., a patent's term may, in certain cases, be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office in examining and granting a patent or may be shortened if a patent is terminally disclaimed over a commonly owned patent or a patent naming a common inventor and having an earlier expiration date.

HJF License

Pursuant to our exclusive license agreement with HJF, we were granted exclusive worldwide rights to several U.S. and foreign patents and patent applications covering methods of using GP2. The GP2 issued patents provide protection ranging from 2026 through 2032 in major markets such as the U.S., Europe, Japan, Australia, and Canada, with ongoing prosecution of pending patent applications in other markets. We plan to register GP2 as a biologic, which may be subject to 10-12 years market exclusivity in the U.S. upon receiving marketing approval.

The following summarizes the two patent families subject to our exclusive license agreement with HJF. We have licensed rights to issued patents and pending patent applications in certain countries with respect to the two patent families below and do not own or have rights to any other patents or patent applications for GP2 or any other products:

- GP2 + GM-CSF Patent Family — A patent application has been filed and licensed describing methods and compositions for the induction of a cytotoxic T-cell response to the GP2 peptide with the effect of inducing and maintaining a protective or therapeutic immunity against breast cancer. Patent claims describe the use of the GP2 technology including dosing, formulation, identification of patients, and use in combination with GM-CSF. Patents issued in the U.S. will expire in 2032 and 2029 and international patents will expire in 2029.

- GP2 + Herceptin Patent Family — A patent application has been filed and licensed describing methods and compositions of GP2 peptide in combination with a HER2/*neu* targeting antibody such as Herceptin. U.S. and certain foreign patent claims describe the method and timing of administration. Patents issued in the U.S. will expire in 2028 and 2026 and international patents will expire in 2026.

Corporate Strategy

We do not have a sales, marketing, or product distribution strategy for our GP2 immunotherapy or any future product candidates because GP2 is still in clinical development. Our future commercial strategy, if our GP2 immunotherapy or any future product candidates are approved, may include the use of strategic partners, distributors, a contract sales force, or the establishment of our own commercial and specialty sales force for the U.S. market, as well as similar strategies for regions and territories outside the U.S. We plan to further evaluate these options as we approach submission of a new drug application or biologics license application for one our product candidates for one or more indications.

The GP2 issued patents provide protection ranging from 2026 through 2032 in various markets, and we plan to register GP2 as a biologic, which may be subject to 10-12 years market exclusivity in the U.S. upon receiving marketing approval. During this period of exclusivity, we intend to advance GP2 into a Phase III clinical trial in the U.S. and pursue a European and global clinical trial strategy to support GP2 registration outside of the U.S. We are considering various options to fund the Phase III clinical trial including financing and/or strategic transactions. Our strategy during such time also includes building a commercialization team, pursuing additional funding, and pursuing strategic collaborations to support the future global marketing and sales of GP2, if approved. A long term global and regional licensing process has been initiated and will continue as the Phase III trial commences.

Pipeline Strategy — Including GP2 In Other HER2/*neu*-Expressing Cancers

We are developing follow-on indications for GP2 by designing and planning additional clinical trials to expand the breast cancer patient population and to pursue additional HER2/*neu*-expressing cancers. Pending the receipt of sufficient capital, the Phase III clinical trial can be supplemented with additional clinical trials designed to evaluate the safety and efficacy of GLSI-100 in (1) patients immediately upon diagnosis in parallel to neoadjuvant treatment and surgery to provide maximum protection against breast cancer recurrence as soon as possible, (2) other HLA patients in the same HER2/*neu* 3+ breast cancer patient population, (3) breast cancer patients who are low to intermediate expressors of HER2/*neu* (1-2+) or (4) other HER2/*neu*-expressing cancers including, but not limited to, ovarian, gastrointestinal, and colon cancers.

Government Regulations

The FDA and other regulatory authorities at federal, state, and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring, and post-approval reporting of biologics such as those we are developing. Along with third-party contractors, we will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct clinical trials or seek approval or licensure of our current product candidate or any future product candidates. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial resources. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label.

The process required by the FDA before biologic product candidates may be marketed in the U.S. generally involves the following:

- completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's current Good Laboratory Practices, or GLP, regulations;
- submission to the FDA of an IND, which must become effective before clinical trials may begin and must be updated annually or when significant changes are made;

- approval by an independent IRB or ethics committee at each clinical site before the trial is begun;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of product;
- manufacture of product with adequate controls so that the product has the purity and potency of the proposed biologic product candidate for its intended purpose;
- preparation of and submission to the FDA of a BLA, after completion of all pivotal clinical trials;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with cGMP and to assure that the facilities, methods and controls are adequate to preserve the biological product's continued safety, purity and potency, and of selected clinical investigations to assess compliance with GCP; and
- FDA review and approval of the BLA to permit commercial marketing of the product for particular indications for use in the U.S., which must be updated annually when significant changes are made.

The testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our current product candidate or any future product candidates will be granted on a timely basis, if at all. Prior to beginning the first clinical trial with a product candidate, a sponsor must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical trials. The IND also includes results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

Clinical trials involve the administration of the investigational product to human patients under the supervision of qualified investigators in accordance with GCP, which include the requirement that all research patients provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site and must monitor the clinical trial until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the patients are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some clinical trials also include oversight by a Data and Safety Monitoring Board, or DSMB, organized by the clinical trial sponsor, which provides authorization for whether or not a clinical trial may move forward at designated check points based on access to certain data from the clinical trial and may halt the clinical trial if it determines that there is an unacceptable safety risk for patients or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical trials and clinical trial results to public registries.

For purposes of BLA approval, human clinical trials are typically conducted in three sequential phases that may overlap.

- **Phase 1** — The investigational product is initially introduced into healthy human patients or patients with the target disease or condition. These clinical trials are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.

- **Phase 2** — The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

- **Phase 3** — The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

- **Phase 4** — In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called Phase 4 clinical trials may be made a condition to approval of the BLA.

Phase 1, Phase 2 and Phase 3 testing may not be completed successfully within a specified period, if at all, and there can be no assurance that the data collected will support FDA approval or licensure of the product. Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the biological characteristics of the product candidate and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product, or for biologics, the safety, purity and potency. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

BLA Submission and Review by the FDA

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. The BLA must include all relevant data available from pertinent preclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. Data can come from company-sponsored clinical trials intended to test the safety and effectiveness of a use of the product, or from a number of alternative sources, including clinical trials initiated by investigators. The submission of a BLA requires payment of a substantial user fee to FDA, and the sponsor of an approved BLA is also subject to annual product and establishment user fees. These fees are typically increased annually. A waiver of user fees may be obtained under certain limited circumstances.

Once a BLA has been submitted, the FDA's goal is to review the application within ten months after it accepts the application for filing, or, if the application relates to an unmet medical need in a serious or life-threatening indication, six months after the FDA accepts the application for filing. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed, or held meets standards designed to assure the product's continued safety, purity and potency. The FDA may convene an advisory committee to provide clinical insight on application review questions. Before approving a BLA, the FDA will typically 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. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

The testing and approval process requires substantial time, effort and financial resources, and each may take several years to complete. The FDA may not grant approval on a timely basis, or at all, and we may encounter difficulties or unanticipated costs in its efforts to secure necessary governmental approvals, which could delay or preclude us from marketing our product. After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application is not ready for approval. A Complete Response Letter may request additional information or clarification. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the BLA with a Risk Evaluation and Mitigation Strategy, or REMS, plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing regulatory standards is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase 4 post-market clinical trials and surveillance to further assess and monitor the product's safety and effectiveness after commercialization and may limit further marketing of the product based on the results of these post-marketing clinical trials. In addition, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our product under development.

A sponsor may seek approval of its product candidate under programs designed to accelerate FDA's review and approval of new drugs and biological products that meet certain criteria. Specifically, new drugs and biological products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. For a product candidate with Fast Track designation, the FDA may consider sections of the BLA for review on a rolling basis before the complete application is submitted if relevant criteria are met. A Fast Track designated product candidate may also qualify for priority review, under which the FDA sets the target date for FDA action on the BLA at six months after the FDA accepts the application for filing. Priority review is granted when there is evidence that the proposed product would be a significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of a serious condition. If criteria are not met for priority review, the application is subject to the standard FDA review period of 10 months after FDA accepts the application for filing. Priority review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

Under the Accelerated Approval program, the FDA may approve a BLA on the basis of either 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. Post-marketing clinical trials or completion of ongoing clinical trials after marketing approval are generally required to verify the biologic's clinical benefit in relationship to the surrogate endpoint or ultimate outcome in relationship to the clinical benefit.

In addition, a sponsor may seek FDA designation of its product candidate as a Breakthrough Therapy, if the product candidate is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the therapy may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. If the FDA designates a breakthrough therapy, it may take actions appropriate to expedite the development and review of the application. Breakthrough designation also allows the sponsor to file sections of the BLA for review on a rolling basis.

Fast Track, Priority Review and Breakthrough Therapy designations do not change the standards for approval but may expedite the development or approval process.

Other Healthcare Laws and Compliance Requirements

Our sales, promotion, medical education and other activities following product approval will be subject to regulation by numerous regulatory and law enforcement authorities in the U.S. in addition to FDA, including potentially the Federal Trade Commission, the Department of Justice, the Centers for Medicare and Medicaid Services, other divisions of the Department of Health and Human Services and state and local governments. Our promotional and scientific/educational programs must comply with the federal Anti-Kickback Statute, the Foreign Corrupt Practices Act, the False Claims Act, or FCA, the Veterans Health Care Act, physician payment transparency laws, privacy laws, security laws, and additional state laws similar to the foregoing.

The federal Anti-Kickback Statute prohibits, among other things, the offer, receipt, or payment of remuneration in exchange for or to induce the referral of patients or the use of products or services that would be paid for in whole or part by Medicare, Medicaid or other federal health care programs. Remuneration has been broadly defined to include anything of value, including cash, improper discounts, and free or reduced price items and services. The government has enforced the Anti-Kickback Statute to reach large settlements with healthcare companies based on sham research or consulting and other financial arrangements with physicians. Further, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation. In addition, 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 FCA. Many states have similar laws that apply to their state health care programs as well as private payors.

The FCA imposes liability on persons who, among other things, present or cause to be presented false or fraudulent claims for payment by a federal health care program. The FCA has been used to prosecute persons submitting claims for payment that are inaccurate or fraudulent, that are for services not provided as claimed, or for services that are not medically necessary. Actions under the FCA may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. Violations of the FCA can result in significant monetary penalties and treble damages. The federal government is using the FCA, and the accompanying threat of significant liability, in its investigation and prosecution of pharmaceutical and biotechnology companies throughout the country, for example, in connection with the promotion of products for unapproved uses and other sales and marketing practices. The government has obtained multi-million and multibillion dollar settlements under the FCA in addition to individual criminal convictions under applicable criminal statutes. In addition, companies have been forced to implement extensive corrective action plans, and have often become subject to consent decrees or corporate integrity agreements, restricting the manner in which they conduct their business. The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, also created 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. Given the significant size of actual and potential settlements, it is expected that the government will continue to devote substantial resources to investigating healthcare providers' and manufacturers' compliance with applicable fraud and abuse laws.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians and other healthcare providers. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Affordable Care Act, among other things, imposed new reporting requirements on drug manufacturers for payments or other transfers of value made by them to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to submit required information may result in civil monetary penalties**.** Certain states also mandate implementation of commercial compliance programs, impose restrictions on drug manufacturer marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to physicians and other healthcare professionals.

We may also be subject to data privacy and security regulation by both the federal government and the states in which it conducts its business. HIPAA, as amended by HITECH, and their respective implementing regulations, imposes specified requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and 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 differ from each other in significant ways and may not have the same effect.

If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to it, we may be subject to penalties, including, without limitation, civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to operate our business and our financial results.

Also, the U.S. Foreign Corrupt Practices Act and similar worldwide anti-bribery laws generally prohibit companies and their intermediaries from making improper payments to foreign officials for the purpose of obtaining or retaining business. We cannot assure you that our internal control policies and procedures will protect us from reckless or negligent acts committed by our employees, future distributors, partners, collaborators or agents. Violations of these laws, or allegations of such violations, could result in fines, penalties or prosecution and have a negative impact on our business, results of operations and reputation.

Coverage and Reimbursement

Sales of pharmaceutical products depend significantly on the availability of third-party coverage and reimbursement. Third-party payors include government health administrative authorities, managed care providers, private health insurers and other organizations. Although we currently believe that third-party payors will provide coverage and reimbursement for our product candidate, if approved, these third-party payors are increasingly challenging the price and examining the cost-effectiveness of medical products and services. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare products. We may need to conduct expensive clinical trials to demonstrate the comparative cost-effectiveness of our product candidate. Seeking coverage and reimbursement from third-party payors can be time consuming and expensive. Moreover, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Reimbursement may not be available or sufficient to allow us to sell our product on a competitive and profitable basis.

Foreign Regulation

In addition to regulations in the U.S., we are and will be subject, either directly or through our distribution partners, to a variety of regulations in other jurisdictions governing, among other things, clinical trials and commercial sales and distribution of our product, if approved.

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in non-U.S. countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the U.S. have processes that require the submission of a clinical trial application much like an IND prior to the commencement of human clinical trials. In Europe, for example, a clinical trial application, or CTA, must be submitted to the competent national health authority and to independent ethics committees in each country in which a company plans to conduct clinical trials. Once the CTA is approved in accordance with a country's requirements, clinical trials may proceed in that country.

The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country, even though there is already some degree of legal harmonization in the European Union member states resulting from the national implementation of underlying E.U. legislation. In all cases, the clinical trials are conducted in accordance with GCP and other applicable regulatory requirements.

To obtain regulatory approval of a new drug or medicinal product in the European Union, a sponsor must obtain approval of a marketing authorization application. The way in which a medicinal product can be approved in the European Union depends on the nature of the medicinal product.

The centralized procedure results in a single marketing authorization granted by the European Commission that is valid across the European Union, as well as in Iceland, Liechtenstein and Norway. The centralized procedure is compulsory for human drugs that are: (i) derived from biotechnology processes, such as genetic engineering, (ii) contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative diseases, autoimmune and other immune dysfunctions and viral diseases, (iii) officially designated as "orphan drugs" and (iv) advanced-therapy medicines, such as gene-therapy, somatic cell-therapy or tissue-engineered medicines. The centralized procedure may, at the request of the applicant, also be used for human drugs which do not fall within the above mentioned categories if the human drug (a) contains a new active substance which was not authorized in the European Community; or (b) the applicant shows that the medicinal product constitutes a significant therapeutic, scientific or technical innovation or that the granting of authorization in the centralized procedure is in the interests of patients or animal health at the European Community level.

Under the centralized procedure in the European Union, the maximum timeframe for the evaluation of a marketing authorization application by the EMA is 210 days (excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the Committee for Medicinal Products for Human Use, or CHMP), with adoption of the actual marketing authorization by the European Commission thereafter. Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest from the point of view of therapeutic innovation, defined by three cumulative criteria: the seriousness of the disease to be treated; the absence of an appropriate alternative therapeutic approach, and anticipation of exceptional high therapeutic benefit. In this circumstance, EMA ensures that the evaluation for the opinion of the CHMP is completed within 150 days and the opinion issued thereafter.

The mutual recognition procedure, or MRP, for the approval of human drugs is an alternative approach to facilitate individual national marketing authorizations within the European Union. The MRP may be applied for all human drugs for which the centralized procedure is not obligatory. The MRP is applicable to the majority of conventional medicinal products, and is based on the principle of recognition of an already existing national marketing authorization by one or more member states.

The characteristic of the MRP is that the procedure builds on an already existing marketing authorization in a member state of the E.U. that is used as reference in order to obtain marketing authorizations in other E.U. member states. In the MRP, a marketing authorization for a drug already exists in one or more member states of the E.U. and subsequently marketing authorization applications are made in other European Union member states by referring to the initial marketing authorization. The member state in which the marketing authorization was first granted will then act as the reference member state. The member states where the marketing authorization is subsequently applied for act as concerned member states.

The MRP is based on the principle of the mutual recognition by European Union member states of their respective national marketing authorizations. Based on a marketing authorization in the reference member state, the applicant may apply for marketing authorizations in other member states. In such case, the reference member state shall update its existing assessment report about the drug in 90 days. After the assessment is completed, copies of the report are sent to all member states, together with the approved summary of product characteristics, labeling and package leaflet. The concerned member states then have 90 days to recognize the decision of the reference member state and the summary of product characteristics, labeling and package leaflet. National marketing authorizations shall be granted within 30 days after acknowledgement of the agreement.

Should any Member State refuse to recognize the marketing authorization by the reference member state, on the grounds of potential serious risk to public health, the issue will be referred to a coordination group. Within a timeframe of 60 days, member states shall, within the coordination group, make all efforts to reach a consensus. If this fails, the procedure is submitted to an EMA scientific committee for arbitration. The opinion of this EMA Committee is then forwarded to the Commission, for the start of the decision-making process. As in the centralized procedure, this process entails consulting various European Commission Directorates General and the Standing Committee on Human Medicinal Products or Veterinary Medicinal Products, as appropriate.

For other countries outside of the European Union, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials are conducted in accordance with GCP and the other applicable regulatory requirements.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension of clinical trials, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Human Capital Management

As of April 11, 2025 we had 4 full-time employees and 4 part-time employees. We are not a party to any collective bargaining agreements. We believe that we maintain good relations with our employees. We do not have any employees that are represented by a labor union or covered under a collective bargaining agreement. Our future success depends on our ability to attract, develop and retain key personnel, maintain our culture, and ensure diversity and inclusion in our board, management and broader workforce. Our human resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees.

ITEM 1A. RISK FACTORS

An investment in our securities involves a high degree of risk. An investor should carefully consider the risks described below as well as other information contained in this Annual Report on Form 10-K and our other reports filed with the U.S. Securities and Exchange Commission ("SEC"). The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently believe are immaterial may also impair our business operations. If any of the following risks actually occur, our business, financial condition or results of operations could be materially adversely affected, the value of our securities could decline, and investors in our company may lose all or part of their investment.

Risks Relating to Our Financial Position and Capital Needs

We have incurred substantial losses since our inception and anticipate that we will continue to incur substantial and increasing losses for the foreseeable future.

We are a clinical stage biopharmaceutical company focused on the development of our novel cancer immunotherapy GP2, for breast cancer and potentially for a broad range of other HER2/*neu*-expressing cancers. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate will fail to prove effective, gain regulatory approval or become commercially viable. We do not have any products approved by regulatory authorities and have not generated any revenues from collaboration and licensing agreements or product sales to date, and have incurred significant research, development and other expenses related to our ongoing operations and expect to continue to incur such expenses. As a result, we have not been profitable and have incurred significant operating losses since our inception. For the years ended December 31, 2024 and 2023, we reported a net loss of $15.8 million and $8.9 million, respectively. As of December 31, 2024, we had an accumulated deficit of $66.2 million.

We do not expect to generate revenues for many years, if at all. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate these losses to increase as we continue to research, develop and seek regulatory approvals for our product candidate and any additional product candidates we may acquire, and potentially begin to commercialize product candidates that may achieve regulatory approval. We may also encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues. Our expenses will further increase as we:

- conduct clinical trials of our lead product candidate, GP2;
- in-license or acquire the rights to, and pursue development of, other products, product candidates or technologies;
- hire additional clinical, manufacturing, quality control, quality assurance and scientific personnel;
- seek marketing approval for any product candidates that successfully complete clinical trials;
- develop our outsourced manufacturing and commercial activities and establish sales, marketing and distribution capabilities, if we receive, or expect to receive, marketing approval for any product candidates;
- maintain, expand and protect our intellectual property portfolio; and
- add operational, financial and management information systems and personnel.

We need significant additional financing to fund our operations and complete the development and, if approved, the commercialization of our product candidate. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.

We expect our existing cash as of December 31, 2024 will enable us to fund our operating expenses through and capital expenditure requirements for at least twelve months from the date of this Annual Report on Form 10-K; however, our existing cash will not be sufficient to complete development and obtain regulatory approval for our product candidate, and we will need to raise significant additional capital to help us do so. In addition, our operating plan may change as a result of many factors currently unknown to us, and we may need additional funds sooner than planned.

We expect to expend substantial resources for the foreseeable future to continue the clinical development and manufacturing of our product candidate and the advancement and expansion of our preclinical research pipeline. These expenditures will include costs associated with research and development, potentially acquiring new product candidates or technologies, conducting preclinical studies and clinical trials and potentially obtaining regulatory approvals and manufacturing products, as well as marketing and selling products approved for sale, if any.

The total cost to complete an interim analysis and file a BLA application for drug approval in the U.S. could exceed $30 million; however, we believe that we have budget flexibility with respect to the design of the Phase III clinical trial. We believe that we may be able to alter the cost of our Phase III clinical trial by adjusting the enrollment rate, the number of patients, and/or the number of immunological assays. While our budget for such Phase III trial may be flexible, our ability to reduce or modify costs may be adversely affected by, among other things, unexpected or higher costs associated with the trial, time required to complete the trial and other factors that may be beyond our control. Our budgets and future capital requirements depend on many factors, including:

- the scope, progress, results and costs of our ongoing and planned development programs for our product candidate, as well as any additional clinical trials we undertake to obtain data sufficient to seek marketing approval for our product candidate;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidate if our clinical trials are successful;
- the cost of commercialization activities for our product candidate, if our product candidate is approved for sale, including marketing, sales and distribution costs;
- the cost of manufacturing our product candidate for clinical trials in preparation for regulatory approval, including the cost and timing of process development, manufacturing scale-up and validation activities;
- our ability to establish and maintain strategic licensing or other arrangements and the financial terms of such agreements;
- the costs to in-license future product candidates or technologies;
- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- the costs in defending and resolving future derivative and securities class action litigation;
- our operating expenses; and
- the emergence of competing technologies or other adverse market developments.

Additional funds may not be available when we need them on terms that are acceptable to us, or at all. We have no committed source of additional capital. If adequate funds are not available to us on a timely basis, we may not be able to continue as a going concern or we may be required to delay, limit, reduce or terminate preclinical studies, clinical trials or other development activities for our product candidate or target indications, or delay, limit, reduce or terminate our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize our product candidate.

We may consider strategic alternatives in order to maximize stockholder value, including financings, strategic alliances, acquisitions or the possible sale of the Company. We may not be able to identify or consummate any suitable strategic alternatives.

We may consider all strategic alternatives that may be available to us to maximize stockholder value, including financings, strategic alliances, acquisitions or the possible sale of the Company. We currently have no agreements or commitments to engage in any specific strategic transactions, and our exploration of various strategic alternatives may not result in any specific action or transaction. To the extent that this engagement results in a transaction, our business objectives may change depending upon the nature of the transaction. There can be no assurance that we will enter into any transaction as a result of the engagement. Furthermore, if we determine to engage in a strategic transaction, we cannot predict the impact that such strategic transaction might have on our operations or stock price. We also cannot predict the impact on our stock price if we fail to enter into a transaction.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our product candidate on unfavorable terms to us.

We may seek additional capital through a variety of means, including through private and public equity offerings and debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, or through the issuance of shares under management or other types of contracts, or upon the exercise or conversion of outstanding derivative securities, the ownership interests of our stockholders will be diluted, and the terms of such financings may include liquidation or other preferences, anti-dilution rights, conversion and exercise price adjustments and other provisions that adversely affect the rights of our stockholders, including rights, preferences and privileges that are senior to those of our holders of common stock in the event of a liquidation. In addition, debt financing, if available, could include covenants limiting or restricting our ability to take certain actions, such as incurring additional debt, making capital expenditures, entering into licensing arrangements, or declaring dividends and may require us to grant security interests in our assets, including our intellectual property. If we raise additional funds through collaborations, strategic alliances, or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, product or product candidate 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 need to curtail or cease our operations.

We currently have no source of revenues. We may never generate revenues or achieve profitability.

Currently, we do not generate any revenues from product sales or otherwise. Even if we are able to successfully achieve regulatory approval for our product candidate, we do not know when we will generate revenues or become profitable, if at all. Our ability to generate revenues from product sales and achieve profitability will depend on our ability to successfully commercialize products, including our current product candidate, GP2, and other product candidates that we may develop, in-license or acquire in the future. Our ability to generate revenues and achieve profitability also depends on a number of additional factors, including our ability to:

- successfully complete development activities, including the necessary clinical trials;
- complete and submit either Biologics License Applications, or BLAs, or New Drug Applications, or NDAs, to the FDA and obtain U.S. regulatory approval for indications for which there is a commercial market;
- complete and submit applications to foreign regulatory authorities;
- obtain regulatory approval in territories with viable market sizes;
- obtain coverage and adequate reimbursement from third parties, including government and private payors;
- set commercially viable prices for our product, if any;
- establish and maintain supply and manufacturing relationships with reliable third parties and/or build our own manufacturing facility and ensure adequate, legally globally compliant manufacturing of bulk drug substances and drug products to maintain that supply;
- develop distribution processes for our product candidate;
- develop commercial quantities of our product candidate, once approved, at acceptable cost levels; obtain additional funding, if required to develop and commercialize our product candidate;
- develop a commercial organization capable of sales, marketing and distribution for any products we intend to sell ourselves, in the markets in which we choose to commercialize on our own;
- achieve market acceptance of our product;
- attract, hire and retain qualified personnel; and
- protect our rights in our intellectual property portfolio.

Our revenues for any product candidate for which regulatory approval is obtained will be dependent, in part, upon the size of the markets in the territories for which it gains regulatory approval, the accepted price for the product, the ability to get reimbursement at any price, and whether we own the commercial rights for that territory. If the number of our addressable disease patients is not as significant as our estimates, the indication approved by regulatory authorities is narrower than we expect, or the reasonably accepted population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenues from sales of such products, even if approved. In addition, we anticipate incurring significant costs associated with commercializing any approved product candidate. As a result, even if we generate revenues, we may not become profitable and may need to obtain additional funding to continue operations. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and may be forced to reduce our operations.

The Tax Cuts and Jobs Act could adversely affect our business and financial condition.

H.R. 1, "An Act to provide for reconciliation pursuant to title II and V of the concurrent resolution on the budget for fiscal year 2018," informally entitled the Tax Cuts and Jobs Act ("Tax Act") enacted on December 22, 2017, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a single rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted taxable income (except for certain small businesses), limitation of the deduction for net operating losses carried forward from taxable years beginning after December 31, 2017 to 80% of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), providing immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits (including reduction of tax credits under the Orphan Drug Act). Notwithstanding the reduction in the corporate income tax rate, the overall impact of the Tax Act is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the Tax Act.

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

As of December 31, 2024, we had federal net operating loss, or NOLs, carryforwards of approximately $30.0 million. Our NOLs generated in tax years ending on or prior to December 31, 2017 are only permitted to be carried forward for 20 years under applicable U.S. tax laws, and will begin to expire, if not utilized, beginning in 2027. These NOL carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the Tax Act, federal NOLs incurred in tax years ending after December 31, 2017 may be carried forward indefinitely, but the deductibility of such federal NOLs is limited. It is uncertain if and to what extent various states will conform to the Tax Act, or whether any further regulatory changes may be adopted in the future that could minimize its applicability. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, and certain 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 the ownership of its equity over a three-year period, the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income may be limited.

Risks Related to the Development and Regulatory Approval of Our Product Candidate

Clinical-stage biopharmaceutical companies with product candidates in clinical development face a wide range of challenging activities which may entail substantial risk.

We are a clinical-stage biopharmaceutical company with a product candidate in clinical development. The success of our product candidate will depend on several factors, including the following:

- designing, conducting and successfully completing preclinical development activities, including preclinical efficacy and IND-enabling studies, for our product candidate or product candidates we may, in the future, in-license or acquire;
- designing, conducting and completing clinical trials for our product candidate with positive results;
- receipt of regulatory approvals from applicable authorities;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidate;
- making arrangements with third-party manufacturers, receiving regulatory approval of our manufacturing processes and our third-party manufacturers' facilities from applicable regulatory authorities and ensuring adequate supply of drug product;
- manufacturing our product candidate at an acceptable cost;
- effectively launching commercial sales of our product candidate, if approved, whether alone or in collaboration with others;
- achieving acceptance of our product candidate, if approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- if our product candidate is approved, obtaining and maintaining coverage and adequate reimbursement by third-party payors, including government payors, for our product candidate;
- complying with all applicable regulatory requirements, including FDA current Good Clinical Practices ("GCP"), current Good Manufacturing Practices ("cGMP"), and standards, rules and regulations governing promotional and other marketing activities;
- maintaining a continued acceptable safety profile of the product during development and following approval; and
- maintaining and growing an organization of scientists and business people who can develop and commercialize our product and technology.

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 develop and commercialize our product candidate, which could materially harm our business.

We may find it difficult to enroll patients in our clinical trials given the limited number of patients who have the diseases for which our product candidate is being studied which could delay or prevent the start of clinical trials for our product candidate.

Identifying and qualifying patients to participate in clinical trials of our product candidate is essential to our success. The timing of our clinical trials depends in part on the rate at which we can recruit patients to participate in clinical trials of our product candidate, and we may experience delays in our clinical trials if we encounter difficulties in enrollment. If we experience delays in our clinical trials, the timeline for obtaining regulatory approval of our product candidate will most likely be delayed.

Many factors may affect our ability to identify, enroll and maintain qualified patients, including the following:

- eligibility criteria of our ongoing and planned clinical trials with specific characteristics appropriate for inclusion in our clinical trials;
- design of the clinical trial;
- size and nature of the patient population;
- patients' perceptions as to risks and benefits of the product candidate under study and the participation in a clinical trial generally in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating;
- the availability and efficacy of competing therapies and clinical trials;
- pendency of other trials underway in the same patient population;
- ability of clinical sites to staff sufficiently for the start-up and conduct of our clinical trial;
- willingness of physicians to participate in our planned clinical trials;
- severity of the disease under investigation;
- proximity of patients to clinical sites;
- patients who do not complete the trials for personal reasons; and
- issues with CROs and/or with other vendors that handle our clinical trials.

We may not be able to initiate or continue to support clinical trials of our product candidate for one or more indications, or any future product candidates if we are unable to locate and enroll a sufficient number of eligible participants in these trials as required by the FDA or other regulatory authorities. Even if we are able to enroll a sufficient number of patients in our clinical trials, if the pace of enrollment is slower than we expect, the development costs for our product candidate may increase and the completion of our trials may be delayed or our trials could become too expensive to complete.

If we experience delays in the completion of, or termination of, any clinical trials of our product candidate, the commercial prospects of our product candidate could be harmed, and our ability to generate product revenue from any of our product candidate could be delayed or prevented. In addition, any delays in completing our clinical trials would likely increase our overall costs, impair product candidate development and jeopardize our ability to obtain regulatory approval relative to our current plans. Any of these occurrences may harm our business, financial condition, and prospects significantly.

The results of preclinical studies or earlier clinical trials are not necessarily predictive of future results. Our existing product candidate in clinical trials, and any other product candidates that may advance into clinical trials, may not have favorable results in later clinical trials or receive regulatory approval.

Success in preclinical studies and early clinical trials does not ensure that later clinical trials will generate adequate data to demonstrate the efficacy and safety of an investigational drug. A number of companies in the pharmaceutical and biotechnology industries, including those with greater resources and experience than us, have suffered significant setbacks in clinical trials, even after seeing promising results in earlier preclinical studies or clinical trials.

Despite the results reported in earlier preclinical studies or clinical trials for our product candidate, we do not know whether the clinical trials we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market our product candidate for a particular indication, in any particular jurisdiction. Efficacy data from prospectively designed trials may differ significantly from those obtained from retrospective subgroup analyses. If later-stage clinical trials do not produce favorable results, our ability to achieve regulatory approval for our product candidate may be adversely impacted. Even if we believe that we have adequate data to support an application for regulatory approval to market our current product candidate or any future product candidates, the FDA or other regulatory authorities may not agree and may require that we conduct additional clinical trials.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome, including the risk of a clinical trial being placed on clinical hold.

Clinical testing is expensive and can take many years to complete, with the outcome inherently uncertain. Failure can occur at any time during the clinical trial process. Before obtaining approval from regulatory authorities for the sale of our product candidate, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidate in humans. Prior to initiating clinical trials, a sponsor must complete extensive preclinical testing of a product candidate, including, in most cases, preclinical efficacy experiments as well as IND-enabling toxicology studies. These experiments and studies may be time-consuming and expensive to complete. The necessary preclinical testing may not be completed successfully for a preclinical product candidate and a potentially promising product candidate may therefore never be tested in humans. Once it commences, 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 testing. 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. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. We may experience numerous unforeseen events during drug development that could delay or prevent our ability to receive marketing approval or commercialize our product candidate. In particular, clinical trials of our product candidate may produce inconclusive or negative results. We have limited data regarding the safety, tolerability and efficacy of GP2 administered in combination with GM-CSF. Clinical trials also require the review and oversight of an institutional review board ("IRB"). An inability or delay in obtaining IRB approval could prevent or delay the initiation and completion of clinical trials, and the FDA may decide not to consider any data or information derived from a clinical investigation not subject to initial and continuing IRB review and approval.

As previously disclosed in our Quarterly Report on Form 10-Q for the three months ended March 31, 2022, the FDA placed our evaluation of GLSI-100 in certain HER2/*neu* positive patients and Flamingo-01 on clinical hold prohibiting us from commencing Flamingo-01 until we provided such manufacturing information. On July 11, 2022, we received a letter from the FDA stating that we have satisfactorily addressed all clinical hold issues identified and that the clinical hold has been removed and we may proceed with the clinical trial. There can be no assurance that the FDA will not place future clinical trials of our product candidate on additional clinical holds in the future. Clinical trials may be delayed, suspended or prematurely terminated for a variety of reasons, such as:

- delay or failure in reaching agreement with the FDA or a comparable foreign regulatory authority on a clinical trial design that we are able to execute;
- delay or failure in obtaining authorization to commence a trial or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a clinical trial;
- delay or failure in reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delay or failure in obtaining IRB approval or the approval of other reviewing entities, including comparable foreign regulatory authorities, to conduct a clinical trial at each site;
- withdrawal of clinical trial sites from our clinical trials or the ineligibility of a site to participate in our clinical trials;
- delay or failure in recruiting and enrolling suitable patients to participate in a clinical trial;
- delay or failure in patients completing a clinical trial or returning for post-treatment follow-up;
- clinical sites and investigators deviating from clinical trial protocol, failing to conduct the clinical trial in accordance with regulatory requirements, or dropping out of a clinical trial;
- inability to identify and maintain a sufficient number of clinical trial sites, many of which may already be engaged in other clinical trial programs, including some that may be for the same indication;
- failure of our third-party clinical trial managers, CROs, clinical trial sites, contracted laboratories or other third-party vendors to satisfy their contractual duties, meet expected deadlines or return trustworthy data;
- delay or failure in adding new clinical trial sites;
- interim results or data that are ambiguous or negative or are inconsistent with earlier results or data;
- alteration of clinical trial design necessitated by re-evaluation of design assumptions based upon observed data;
- feedback from the FDA, the IRB or a comparable foreign regulatory authority, or results from earlier stage or concurrent preclinical studies and clinical trials, that might require modification to the protocol for a clinical trial;
- a decision by the FDA, the IRB, a comparable foreign regulatory authority, or us to suspend or terminate clinical trials at any time for safety issues or for any other reason;
- unacceptable risk-benefit profile, unforeseen safety issues or adverse side effects;
- failure to demonstrate a benefit from using a product candidate;
- difficulties in manufacturing or obtaining from third parties sufficient quantities of a product candidate to start or to use in clinical trials;
- lack of adequate funding to continue a clinical trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional clinical trials or increased expenses associated with the services of our CROs and other third parties; or
- changes in governmental regulations or administrative actions or lack of adequate funding to continue a clinical trial.

If we experience delays in the completion or termination of any clinical trial of our product candidate, the approval and commercial prospects of our product candidate will be harmed, delaying our ability to generate product revenues from such product candidate and our costs will most likely increase. The required regulatory approvals may also be delayed, thereby jeopardizing our ability to commence product sales and generate revenues and the period of commercial exclusivity for our product may be decreased. Regulatory approval of our product candidate may be denied for the same reasons that caused the delay.

Data from our clinical trials that we announce or publish from time to time may change as more patient data become available either through long-term patient follow-up and/or as such data is audited and verified, which could result in material changes to clinical and safety profiles for our products.

From time to time, we may disclose data from our preclinical studies and clinical trials. Such data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available or as patients from our clinical trials continue other treatments for their disease. In addition, the clinical trials evaluating our products and product candidates generally require that we continue to monitor and evaluate safety and efficacy in patients over an extended period of time following treatment which may result in the safety or efficacy profile to change over time. Changes in the efficacy and safety profile of our product or product candidates over time could significantly harm our business prospects including resulting in volatility in the price of our common stock.

Additionally, from time to time, we may publicly disclose preliminary or top-line data from our preclinical studies and clinical trials, which are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, top-line data should be viewed with caution until the final data are available.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our Company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If others, including regulatory authorities, disagree with the conclusions reached with respect to such information and assessments, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

In the clinical trials using GP2, improper intradermal injections or poor HLA binding by GP2 may potentially jeopardize the outcome of the trials.

GP2 is administered intradermally to patients with and without the HLA-A*02 allele. The effectiveness of GP2 is dependent upon attracting sufficient antigen presenting cells in the patient's intradermal space and the association of GP2 with the HLA type of a patient to adequately train T cells to kill cancer cells, which may or may not be possible or consistent across all HLA types. It is possible that nurses may not successfully inject GP2 in the intradermal space or that certain HLA types may form weak or no association with GP2, potentially leading to weak or no immune response to GP2 and thus no benefit to patients with some or any HLA type.

Risks associated with out-licensing GP2 or future product candidates in foreign countries could materially adversely affect the commercialization of our products.

We may not be able to market products abroad if we cannot complete out-licensing transactions of GP2 or future product candidates by signing licensing agreements with regional companies in countries where we plan to commercialize our products but where we do not have any operations. Risks associated with out-licensing transactions of our products in foreign countries include:

- failure to obtain regulatory approval or intellectual property rights in any country which could lead to the termination of a licensing transaction in that country;
- the inability to obtain the issuance of patent claims or regulatory status in a foreign country that provide periods of market exclusivity or data exclusivity prior to the entry of generic or biosimilar forms of our products;
- the difficulty of pursuing legal remedies to disputes or to secure monetary damages in foreign countries;
- the inability to repatriate income from a licensing transaction in a foreign country to the U.S. or to other foreign countries where cash is needed; and
- The potential to not realize or to delay development or commercialization milestone payments due to unanticipated outcomes that prevent or delay the milestone.

Risks associated with operating in foreign countries could materially adversely affect our product development.

We may conduct future clinical trials in countries outside of the U.S. Consequently, we may be subject to risks related to operating in foreign countries. Risks associated with conducting operations in foreign countries include:

- differing regulatory requirements for drug approvals and regulation of approved drugs in foreign countries; more stringent privacy requirements for data to be supplied to our operations in the U.S., *e.g.*, General Data Protection Regulation in the European Union;
- unexpected changes in tariffs, trade barriers and 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;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems and price controls;
- foreign currency fluctuations, which could result in increased operating expenses or reduced revenues, and other obligations incident to doing business or operating in another country;
- workforce uncertainty in countries where labor unrest is more common than in the U.S.;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism.

Our current and future product candidates, the methods used to deliver them or their dosage levels may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following any regulatory approval.

Undesirable side effects caused by our current or future product candidates, their delivery methods or dosage levels could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval or termination of clinical trials by the FDA or other comparable foreign regulatory authorities; or an IRB, that approves and, monitors biomedical research to protect the rights and welfare of human patients. As a result of safety or toxicity issues that we may experience in our clinical trials, or negative or inconclusive results from the clinical trials of others for drug candidates similar to our own, we may not receive approval to market our current product candidate or any product candidates we may pursue, which could prevent us from ever generating revenues or achieving profitability. Results of our trials could reveal an unacceptably high severity and incidence of side effects. In such an event, our trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our current or any future product candidates for any or all targeted indications. The drug-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may have a material adverse effect on our business, results of operations, financial condition, cash flows and future prospects.

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

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

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

Our product development program may not uncover all possible adverse events that patients who take our product candidate may experience. The number of patients exposed to our product candidate and the average exposure time in the clinical development program may be inadequate to detect rare adverse events or chance findings that may only be detected once the product is administered to more patients and for greater periods of time.

Clinical trials by their nature utilize a sample of the potential patient population. However, with a limited number of patients and limited duration of exposure, we cannot be fully assured that rare and severe side effects of our product candidate will be uncovered. Such rare and severe side effects may only be uncovered with a significantly larger number of patients exposed to our product candidate. If such safety problems occur or are identified after our product candidate reaches the market, the FDA may require that we amend the labeling of the product or recall the product, or may even withdraw approval for the product.

Failure to successfully validate and develop a companion diagnostic for our product candidate could harm our drug development strategy and operational results.

Our product development program is dependent on the validation and development of an in vitro companion diagnostic by us or by third-party collaborators. Companion diagnostics are developed in conjunction with clinical programs for the associated product and are subject to regulation as medical devices. The approval of a companion diagnostic as part of the product labeling may limit the use of the product candidate to only those patients who express the specific genetic alteration it was developed to detect.

Companion diagnostics are subject to regulation by the FDA and comparable foreign regulatory authorities as medical devices and require separate clearance or approval prior to their commercialization. To date, the FDA has required premarket approval of all companion diagnostics for cancer therapies, either at the time of initial drug approval, or as a post-marketing commitment. We, and our third-party collaborators, may encounter difficulties in developing and obtaining approval for these companion diagnostics. Our third-party collaborators may de-prioritize, abandon or fail to execute against our development projects. Any delay or failure by us or third-party collaborators to develop or obtain regulatory approval of a companion diagnostic could delay or prevent approval of our related product candidates.

Our future success is dependent on the regulatory approval of our product candidate.

Our business is dependent on our ability to obtain regulatory approval for our product candidate in a timely manner. We cannot commercialize our product candidate in the U.S. without first obtaining regulatory approval for the product from the FDA. Similarly, we cannot commercialize our product candidate outside of the U.S. without obtaining regulatory approval from comparable foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of our product candidate for a target indication, we must demonstrate with substantial evidence gathered in preclinical studies and clinical trials, that the product candidate is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate with respect to such product candidate.

The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of preclinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions.

Even if a product candidate were to successfully obtain approval from the FDA and comparable foreign regulatory authorities, any approval might contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, or may be subject to burdensome post-approval clinical trial or risk management requirements. Also, any regulatory approval of our current product candidate or any future product candidates we may pursue, once obtained, may be withdrawn.

Our current product candidate and future product candidates could fail to receive regulatory approval from the FDA.

We have not obtained regulatory approval for our product candidate and it is possible that our existing product candidate or any future product candidates will not obtain regulatory approval, for many reasons, including:

- disagreement with the regulatory authorities regarding the scope, design or implementation of our clinical trials;
- failure to demonstrate that a product candidate is safe and effective for our proposed indication;
- failure of clinical trials to meet the level of statistical significance required for approval;
- failure to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- disagreement with our interpretation of data from preclinical studies or clinical trials;
- the insufficiency of data collected from clinical trials of our product candidate to support the submission and filing of a BLA, NDA or other submission or to obtain regulatory approval;
- failure to obtain approval of our manufacturing processes or facilities of third-party manufacturers with whom we contract for clinical and commercial supplies or our own manufacturing facility; or
- changes in the approval policies or regulations that render our preclinical and clinical data insufficient for approval.

The FDA or a comparable foreign regulatory authority may require more information, including additional preclinical or clinical data to support approval or additional clinical trials, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program. If we were to obtain approval, regulatory authorities may approve our current product candidate and any future product candidates we may pursue for fewer or more limited indications than we request (including failing to approve the most commercially promising indications), may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate.

If we are unable to obtain regulatory approval for our product candidate in one or more jurisdictions, or any approval contains significant limitations, we may not be able to obtain sufficient funding to continue the development of that product or generate revenues attributable to that product candidate.

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

In addition to regulations in the U.S., to market and sell our product candidate in the European Union, United Kingdom, many Asian countries and other jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the U.S. does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. The regulatory approval process outside the U.S. generally includes all of the risks associated with obtaining FDA approval as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. 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. We may not be able to obtain approvals from regulatory authorities outside the U.S. on a timely basis, if at all. Clinical trials accepted in one country may not be accepted by regulatory authorities in other countries. In addition, many countries outside the U.S. require that a product be approved for reimbursement before it can be approved for sale in that country. A product candidate that has been approved for sale in a particular country may not receive reimbursement approval in that country.

We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our product in any market. If we are unable to obtain approval of any of our current product candidate or any future product candidates we may pursue by regulatory authorities in the European Union, United Kingdom, Asia or elsewhere, the commercial prospects of that product candidate may be significantly diminished, our business prospects could decline and this could materially adversely affect our business, results of operations and financial condition.

Even if our current candidate receives regulatory approval, it may still face future development and regulatory difficulties.

Even if we obtain regulatory approval for our product candidate, that approval would be subject to ongoing requirements by the FDA and comparable foreign regulatory authorities governing the manufacture, quality control, further development, labeling, packaging, storage, distribution, adverse event reporting, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting of safety and other post-marketing information. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance by us and/or our CMOs and CROs for any post-approval clinical trials that we may conduct. The safety profile of any product will continue to be closely monitored by the FDA and comparable foreign regulatory authorities after approval. If the FDA or comparable foreign regulatory authorities become aware of new safety information after approval of our product candidate, they may require labeling changes or establishment of a risk evaluation and mitigation strategy, impose significant restrictions on such product's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval clinical trials or post-market surveillance.

In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP, GCP, and other regulations. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. If we, our product candidate or the manufacturing facilities for our product candidate fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or untitled letters;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications filed by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products, refuse to permit the import or export of products, or require us to initiate a product recall.

The occurrence of any event or penalty described above may inhibit our ability to successfully commercialize our product and generate revenues.

Advertising and promotion of any product candidate that obtains approval in the U.S. is heavily scrutinized by the FDA, the Department of Justice, the Office of Inspector General of Health and Human Services, state attorneys general, members of Congress and the public. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. Additionally, advertising and promotion of any product candidate that obtains approval outside of the U.S. is heavily scrutinized by comparable foreign regulatory authorities. Violations, including actual or alleged promotion of our product for unapproved or off-label uses, are subject to enforcement letters, inquiries and investigations, and civil and criminal sanctions by the FDA, as well as prosecution under the federal False Claims Act. Any actual or alleged failure to comply with labeling and promotion requirements may have a negative impact on our business.

Risks Related to Our Manufacturing

We have limited to no manufacturing, sales, marketing or distribution capability and must rely upon third parties for such.

We currently have purchase orders with various third-party manufacturing facilities for production of our product candidate for research and development and testing purposes. We depend on these manufacturers to meet our deadlines, quality standards and specifications. Our reliance on third parties for the manufacture of our active pharmaceutical ingredient and drug product and, in the future, any approved products, creates a dependency that could severely disrupt our research and development, our clinical testing, and ultimately our sales and marketing efforts if the source of such supply proves to be unreliable or unavailable. If the contracted manufacturing source is unreliable or unavailable, we may not be able to manufacture clinical drug supplies of our product candidate, and our preclinical and clinical testing programs may not be able to move forward and our entire business plan could fail.

The active pharmaceutical ingredient for our product candidate is currently sourced from Polypeptide Laboratories located in San Diego, California. We believe this single source is currently capable of supplying all anticipated needs of our proposed clinical trials, as well as initial commercial introduction. We will be developing a source or sources for drug product manufacturing. If we are able to commercialize our product in the future, there is no assurance that our manufacturers will be able to meet commercialized scale production requirements in a timely manner or in accordance with applicable standards or cGMP. Once the nature and scope of additional indications and their commensurate drug product demands are established, we will seek secondary suppliers of both the active pharmaceutical ingredient and drug product for our product candidate, but we cannot assure that such secondary suppliers will be found on terms acceptable to us, or at all.

We are subject to a multitude of manufacturing risks, any of which could substantially increase our costs and limit supply of our product candidate.

We and our CMOs will need to conduct significant development work for our product candidate for each target indication for studies, clinical trials and commercial launch readiness. Developing commercially viable manufacturing processes is a difficult, expensive and uncertain task, and there are risks associated with scaling to the level required for advanced clinical trials or commercialization, including cost overruns, potential problems with process scale-up, process reproducibility, stability issues, consistency and timely availability of reagents or raw materials. The manufacturing facilities in which our product candidate will be made could be adversely affected by earthquakes and other natural disasters, medical pandemics, equipment failures, labor shortages, power failures, and numerous other factors.

Additionally, the process of manufacturing our product candidate is complex, highly regulated and subject to several risks, including but not limited to:

- product loss due to contamination, equipment failure or improper installation or operation of equipment, or vendor or operator error;
- reduced production yields, product defects, and other supply disruptions due to deviations, even minor, from normal manufacturing and distribution processes;
- unexpected product defects; and
- microbial, viral, or other contaminations in our product candidate or in the manufacturing facilities in which our product candidate is made, which may result in the closure of such manufacturing facilities for an extended period of time to allow for the investigation and remediation of the contamination.

Any adverse developments affecting manufacturing operations for our product candidate may result in shipment delays, inventory shortages, lot failures, withdrawals or recalls or other interruptions in the supply of our drug substance and drug product, which could delay the development of our product candidate. We may also have to write off inventory, incur other charges and expenses for supply of drug product that fails to meet specifications, undertake costly remediation efforts, or seek more costly manufacturing alternatives. Inability to meet the demand for our product candidate could damage our reputation and the reputation of our product among physicians, healthcare payors, patients or the medical community, and cancer treatment centers, which could adversely affect our ability to operate our business and our results of operations.

In the clinical trials using GP2, GM-CSF is also administered and its availability is dependent upon a third-party manufacturer, which may or may not reliably provide GM-CSF, thus jeopardizing the completion of the trials.

GP2 is administered in combination with GM-CSF which is available in both liquid and lyophilized forms exclusively from one manufacturer. We will continue to be dependent on such manufacturer for our supply of GM-CSF in combination with GP2 in the ongoing GP2 trials and upon the potential commercialization of GP2. We have not entered into a supply agreement with the manufacturer for GM-CSF, and instead rely on purchase orders to meet our supply needs. Any temporary interruptions or discontinuation of the availability of GM-CSF could have a material adverse effect on our operations.

If any of our CMOs' clinical manufacturing facilities are damaged or destroyed or production at such facilities is otherwise interrupted, our business and prospects would be negatively affected.

If our CMOs' manufacturing facilities or the equipment in them is damaged or destroyed, we may not be able to quickly or inexpensively replace our manufacturing capacity or replace it at all. In the event of a temporary or protracted loss of this facility or equipment, we might not be able to transfer manufacturing to another CMO. Even if we could transfer manufacturing to another CMO, the shift would likely be expensive and time-consuming, particularly because the new facility would need to comply with the necessary regulatory requirements and we would need FDA approval before selling any products manufactured at that facility. Such an event could delay our clinical trials or reduce our product sales.

Although we do not currently maintain insurance coverage against damage to our property and to cover business interruption and research and development restoration expenses, any insurance coverage we obtain in the future may not reimburse us, or may not be sufficient to reimburse us, for any expenses or losses we may suffer. We may be unable to meet our requirements for our product candidate if there were a catastrophic event or failure of our current manufacturing facility or processes.

Risks Related to Our Dependence on Third Parties and Our License Agreements

We rely on third parties to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, or if we lose any of our CROs or other key third-party vendors, we may not be able to obtain regulatory approval for or commercialize our current or future product candidates on a timely basis, if at all.

Our internal capacity for clinical trial execution and management is limited and therefore we rely heavily on third parties. We have relied upon and plan to continue to rely upon third-party CROs, vendors and contractors to monitor and manage data for our ongoing preclinical and clinical programs. For example, our collaborating investigators along with their clinical and clinical operations teams may manage the conduct of any future clinical trials for GP2 as well as perform the analysis, publication and presentation of data and results related to this program.

We plan to rely on CROs and other third-party vendors for all currently contemplated clinical trials. We rely on these parties for the execution of our preclinical studies and clinical trials, including the proper and timely conduct of our clinical trials, and we control only some aspects of their activities. Outsourcing these functions involves risk that third parties may not perform to our standards, may not produce results or data in a timely manner or may fail to perform at all.

While we may have agreements governing the commitments of our third-party vendor services, we will have limited influence over their actual performance. Nevertheless, we will be responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs will not relieve us of our regulatory responsibilities.

If our Company, or any of our partners or CROs, fail to comply with applicable regulations and good clinical practices, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our regulatory applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with applicable requirements. In addition, our clinical trials must be conducted with product produced under cGMP and other requirements. We are also required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, *clinicaltrials.gov*, within a specified timeframe. Failure to comply also would violate federal requirements in the U.S. and could result in other penalties, which would delay the regulatory approval process and result in adverse publicity.

Our CROs, third-party vendors and contractors are not and will not be our employees, and except for remedies available to us under our agreements with such CROs, third-party vendors and contractors, we cannot control whether or not they devote sufficient time and resources, including experienced staff, to our ongoing clinical, nonclinical and preclinical programs. They may also have relationships with other entities, some of which may be our competitors. If CROs, third-party vendors and contractors do not successfully carry out their contractual duties or obligations or meet expected deadlines or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our current or future product candidates. CRO, vendor or contractor errors could cause our results of operations and the commercial prospects for our current or future product candidates to be harmed, our costs to increase and our ability to generate revenues to be delayed.

In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. To the extent we are unable to identify and successfully manage the performance of third-party service providers in the future, our business may be adversely affected. Though, once engaged, we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We are dependent on technologies we license, and if we lose the right to license such technologies or we fail to license new technologies in the future, our ability to develop new products would be harmed, and if we fail to meet our obligations under our license agreements, we may lose the ability to develop our product candidate.

We currently are dependent on a license from HJF for technologies relating to our product candidate. The license imposes, and any future licenses we enter into are likely to impose, various development, funding, royalty, diligence, sublicensing, insurance and other obligations on us. If our license with respect to any of these technologies is terminated for any reason, the development of the products contemplated by the licenses would be delayed, or suspended altogether, while we seek to license similar technology or develop new non-infringing technology which could have a material adverse effect on our business.

Our operations or those of the third parties upon whom we depend might be affected by the occurrence of a natural disaster, pandemic, war or other catastrophic event.

We depend on our employees, consultants, CMOs, CROs, as well as regulatory agencies and other parties, for the continued operation of our business. Despite any precautions we take for natural disasters or other catastrophic events, these events, including terrorist attacks, pandemics, hurricanes, fires, floods and ice and snowstorms, could result in significant disruptions to our research and development, preclinical studies, clinical trials, and, ultimately, commercialization of our products. Long-term disruptions in the infrastructure caused by events, such as natural disasters, the outbreak of war (including expansion of the current armed conflict between Russia and Ukraine), the escalation of hostilities and acts of terrorism or other “acts of God,” particularly involving cities in which we have offices, manufacturing or clinical trial sites, could adversely affect our businesses. Although we carry business interruption insurance policies and typically have provisions in our contracts that protect us in certain events, our coverage might not include or be adequate to compensate us for all losses that may occur. Any natural disaster or catastrophic event affecting us, our CMOs, our CROs, regulatory agencies or other parties with which we are engaged could have a material adverse effect on our operations and financial performance.

We may not realize the benefits of our strategic alliances that we may form in the future.

We may form strategic alliances, create joint ventures or collaborations or enter into licensing arrangements with third parties that we believe will complement or augment our existing business. These relationships, or those like them, may require us to incur nonrecurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic alliances and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic alliance or other alternative arrangements for or current product candidate or any future product candidates and programs because our research and development pipeline may be insufficient, our current product candidate and future product candidates and programs may be deemed to be at too early a stage of development for collaborative effort and third parties may not view such product candidates and programs as having the requisite potential to demonstrate safety and efficacy. If we license products or acquire businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. We cannot be certain that, following a strategic transaction or license, we will achieve the revenues or specific net income that justifies such transaction. Any delays in entering into new strategic alliances agreements related to our current product candidate or future product candidates could also delay the development and commercialization of such product candidates and reduce their competitiveness even if they reach the market.

Our business involves the use of hazardous materials and we and our third-party manufacturers and suppliers must comply with environmental, health and safety laws and regulations, which can be expensive and restrict how we do business.

Our third-party manufacturers' and suppliers' activities involve the controlled storage, use and disposal of hazardous materials. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials even after we sell or otherwise dispose of the products. In some cases, these hazardous materials and various wastes resulting from their use will be stored at our contractors or manufacturers' facilities pending use and disposal. We cannot completely eliminate the risk of contamination, which could cause injury to our employees and others, environmental damage resulting in costly cleanup and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we expect that the safety procedures utilized by our third-party contractors and manufacturers for handling and disposing of these materials will generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this will be the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources. We do not currently carry biological or hazardous waste insurance coverage and any future property and casualty, and general liability insurance policies may exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination.

We may not be able to establish or maintain the third-party relationships that are necessary to develop or potentially commercialize our product candidate.

We expect to depend on collaborators, partners, licensees, CROs and other third parties to formulate our product candidate, to manufacture our product candidate, and to conduct clinical trials for our product candidate. We cannot guarantee that we will be able to successfully negotiate agreements for or maintain relationships with collaborators, partners, licensees, clinical investigators, vendors and other third parties on favorable terms, if at all. Our ability to successfully negotiate such agreements will depend on, among other things, potential partners' evaluation of the superiority of our technology over competing technologies and the quality of the preclinical and clinical data that we have generated, and the perceived risks specific to developing our product candidate. If we are unable to obtain or maintain these agreements, we may not be able to clinically develop, formulate, manufacture, obtain regulatory approvals for or commercialize our product candidate. We cannot necessarily control the amount or timing of resources that our contract partners will devote to our product candidate, and we cannot guarantee that these parties will fulfill their obligations to us under these arrangements in a timely fashion. We may not be able to readily terminate any such agreements with contract partners even if such contract partners do not fulfill their obligations to us.

In addition, we may receive notices from third parties from time to time alleging that our technology or product candidate infringes upon the intellectual property rights of those third parties. Any assertion by third parties that our activities or product candidate infringes upon the intellectual property rights of third parties may adversely affect our ability to secure strategic partners or licensees for our technology or product candidate or our ability to secure or maintain manufacturers for our compounds.

Risks Related to Our Intellectual Property

We rely on an exclusive license granted to us by HJF with respect to GP2, and if HJF does not adequately defend such license, our business may be harmed.

We have been granted an exclusive license to GP2, our product candidate, from HJF. The GP2 patent rights were assigned to HJF by certain third parties including the Uniformed Services University of the Health Sciences. We rely on HJF to maintain the patents already issued with respect to GP2, to continue to pursue patent applications pending in certain countries with respect to GP2, and otherwise protect the intellectual property covered by our exclusive license agreement. We have limited control over the activities of HJF or over any other intellectual property that may be related to GP2. For example, we cannot be certain that activities by HJF have been or will be conducted in compliance with applicable laws and regulations and/or any agreements between HJF and the third party assignors. We have no control or input over whether, and in what manner, HJF may enforce or defend the patents against a third-party. HJF may enforce or defend the patent less vigorously than if we had enforced or defended the patents ourselves. Further, HJF may not necessarily seek enforcement in scenarios in which we would feel that enforcement was in our best interests. For example, HJF may not enforce the patents against a competitor of ours who is not a direct competitor of HJF. If our in-licensed intellectual property is found to be invalid or unenforceable, then HJF may not be able to enforce the patents against a competitor of ours. If we fail to meet our obligations under our exclusive license agreement with HJF, then HJF may terminate such agreement. Although we may choose to terminate our license agreement with HJF, doing so would allow a third party to seek and obtain an exclusive license to GP2. If a third party obtains an exclusive license to intellectual property with respect to GP2, then the third party may seek to enforce the intellectual property against us which may have a material adverse effect on our business.

It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection. If our patent position does not adequately protect our product candidate, others could compete against us more directly, which would harm our business, possibly materially.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of our current product candidate and future product candidates, the processes used to manufacture them and the methods for using them, as well as successfully defending these patents against third-party challenges. As of the date of this Annual Report on Form 10-K, we only have licensed rights from HJF to certain issued patents as well as patent applications which are currently pending in certain countries with respect to GP2. Our ability to stop third parties from making, using, selling, offering to sell or importing our product candidate is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities.

The patent positions of biotechnology and pharmaceutical companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in pharmaceutical patents has emerged to date in the U.S. or in foreign jurisdictions outside of the U.S. Changes in either the patent laws or interpretations of patent laws in the U.S. and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be enforced in the patents that may be issued from the applications we currently or may in the future own or license from third parties. Further, if any patents we obtain or license are deemed invalid and unenforceable, our ability to commercialize or license our technology could be adversely affected.

Others have filed, and in the future are likely to file, patent applications covering products and technologies that are similar, identical or competitive to ours or important to our business. We cannot be certain that any patent application owned by a third party will not have priority over patent applications filed or in-licensed by us, or that we or our licensors will not be involved in interference, opposition, reexamination, review, reissue, post grant review or invalidity proceedings before U.S. or non-U.S. patent offices.

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

- others may be able to make compounds that are similar to our product candidate, but that are not covered by the claims of our licensed patents;
- HJF might not have been the first to make the inventions covered by its pending patent applications;
- we or HJF might not have been the first to file patent applications for these inventions;
- HJF's pending patent applications may not result in issued patents;
- the claims of HJF's issued patents or patent applications when issued may not cover our product or product candidate;
- any patents that we obtain from licensing or otherwise may not provide us with any competitive advantages;
- any granted patents that we rely upon may be held invalid or unenforceable as a result of legal challenges by third parties; and
- the patents of others may have an adverse effect on our business.

If we fail to comply with our obligations in the agreements under which we may license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose rights that are important to our business.

We may be required to enter into intellectual property license agreements that are important to our business. These license agreements may impose various diligence, milestone payment, royalty and other obligations on us. For example, we may enter into exclusive license agreements with various universities and research institutions, we may be required to use commercially reasonable efforts to engage in various development and commercialization activities with respect to licensed products, and may need to satisfy specified milestone and royalty payment obligations. If we fail to comply with any obligations under our agreements with any of these licensors, we may be subject to termination of the license agreement in whole or in part; increased financial obligations to our licensors or loss of exclusivity in a particular field or territory, in which case our ability to develop or commercialize products covered by the license agreement will be impaired.

In addition, disputes may arise regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;

- our diligence obligations under the license agreement and what activities satisfy those obligations;
- if a third-party expresses interest in an area under a license that we are not pursuing, under the terms of certain of our license agreements, we may be required to sublicense rights in that area to a third party, and that sublicense could harm our business; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize our product candidate.

We may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidate. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidate, which could harm our business significantly.

We may incur substantial costs as a result of litigation or other proceedings relating to patents and other intellectual property rights.

If we choose to commence a proceeding or litigation to prevent another party from infringing HJF's patents, that party will have the right to ask the examiner or court to rule that such patents are invalid or should not be enforced against them. There is a risk that the examiner or court will decide that HJF's patents are not valid and that HJF does not have the right to stop the other party from using the related inventions. There is also the risk that, even if the validity of such patents is upheld, the examiner or court will refuse to stop the other party on the ground that such other party's activities do not infringe our rights to such patents. In addition, the U.S. Supreme Court has recently modified some tests used by the U.S. Patent and Trademark Office (the "USPTO") in granting patents over the past 20 years, which may decrease the likelihood that we or HJF will be able to obtain patents and increase the likelihood of challenge to any patents we obtain or license. Any proceedings or litigation to enforce our intellectual property rights or defend ourselves against claims of infringement of third-party intellectual property rights could be costly and divert the attention of managerial and scientific personnel, regardless of whether such litigation is ultimately resolved in our favor. We may not have sufficient resources to bring these actions to a successful conclusion. Moreover, if we are unable to successfully defend against claims that we have infringed the intellectual property rights of others, we may be prevented from using certain intellectual property and may be liable for damages, which in turn could materially adversely affect our business, financial condition or results of operations.

We may infringe the intellectual property rights of others, which may prevent or delay our product development efforts and stop us from commercializing or increase the costs of commercializing our product candidate.

Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. We cannot guarantee that our product candidate, or manufacture or use of our product candidate, will not infringe third-party patents. Furthermore, a third party may claim that we are using inventions covered by the third party's patent rights and may go to court to stop us from engaging in our normal operations and activities, including making or selling our product candidate. These lawsuits are costly and could affect our results of operations and divert the attention of managerial and scientific personnel. Some of these third parties may be better capitalized and have more resources than us. There is a risk that a court would decide that we are infringing the third party's patents and would order us to stop the activities covered by the patents. In that event, we may not have a viable way around the patent and may need to halt commercialization of our product candidate. In addition, there is a risk that a court will order us to pay the other party damages for having violated the other party's patents. In addition, we may be obligated to indemnify our licensors and collaborators against certain intellectual property infringement claims brought by third parties, which could require us to expend additional resources. The pharmaceutical and biotechnology industries have produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform.

If we are sued for patent infringement, we would need to demonstrate that our product candidate or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Proving invalidity is difficult. For example, in the U.S., proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and divert management's time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, which may not be available, defend an infringement action or challenge the validity of the patents in court. Patent litigation is costly and time consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non-infringing technology, fail to defend an infringement action successfully or have infringed patents declared invalid, we may incur substantial monetary damages, encounter significant delays in bringing our product candidate to market and be precluded from manufacturing or selling our product candidate.

We cannot be certain that others have not filed patent applications for technology covered by HJF's pending applications, or that HJF the first to invent the technology, because:

- some patent applications in the U.S. may be maintained in secrecy until the patents are issued;
- patent applications in the U.S. are typically not published until 18 months after the priority date; and
- publications in the scientific literature often lag behind actual discoveries.

Our competitors may have filed, and may in the future file, patent applications covering technology similar to ours. Any such patent application may have priority over HJF's patent applications, which could require us to obtain rights to issued patents covering such technologies. If another party has filed U.S. patent applications on inventions similar to HJF that claims priority to any applications filed prior to the priority dates of HJF's applications, HJF may have to participate in an interference proceeding declared by the USPTO to determine priority of invention in the U.S. It is possible that such efforts would be unsuccessful if, unbeknownst to HJF, the other party had independently arrived at the same or similar inventions prior to HFJ's inventions, resulting in a loss of HFJ's U.S. patent position with respect to such inventions which could in turn have a material adverse effect on our operations. Other countries have similar laws that permit secrecy of patent applications, and may be entitled to priority over our applications in such jurisdictions.

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

If we are not able to adequately prevent disclosure of trade secrets and other proprietary information, the value of our technology and product could be significantly diminished.

We also rely on trade secrets to protect our proprietary technologies, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Furthermore, any license agreements we enter into in the future may require us to notify, and in some cases license back to the licensor, certain additional proprietary information or intellectual property that we developed using the rights licensed to us under these agreements. Any such licenses back to the licensor could allow our licensors to use that proprietary information or intellectual property in a manner that could harm our business. In addition, others may independently discover our trade secrets and proprietary information. For example, the FDA, as part of its transparency initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future, if at all. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed alleged trade secrets.

As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we could lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Our intellectual property may not be sufficient to protect our product candidate from competition, which may negatively affect our business as well as limit our partnership or acquisition appeal.

We may be subject to competition despite the existence of intellectual property we license or own. We can give no assurances that our intellectual property claims will be sufficient to prevent third parties from designing around patents we own or license and developing and commercializing competitive products. The existence of competitive products that avoid our intellectual property could materially adversely affect our operating results and financial condition. Furthermore, limitations, or perceived limitations, in our intellectual property may limit the interest of third parties to partner, collaborate or otherwise transact with us, if third parties perceive a higher than acceptable risk to commercialization of our product candidate or future product candidates.

We may elect to sue a third party, or otherwise make a claim, alleging infringement or other violation of patents, trademarks, trade dress, copyrights, trade secrets, domain names or other intellectual property rights that we either own or license from a third party. If we do not prevail in enforcing our intellectual property rights in this type of litigation, we may be subject to:

- paying monetary damages related to the legal expenses of the third party;
- facing additional competition that may have a significant adverse effect on our product pricing, market share, business operations, financial condition, and the commercial viability of our product; and
- restructuring our company or delaying or terminating select business opportunities, including, but not limited to, research and development, clinical trial, and commercialization activities, due to a potential deterioration of our financial condition or market competitiveness.

A third party may also challenge the validity, enforceability or scope of the intellectual property rights that we license or own; and, the result of these challenges may narrow the scope or claims of or invalidate patents that are integral to our product candidate in the future. There can be no assurance that we will be able to successfully defend patents we own or license in an action against third parties due to the unpredictability of litigation and the high costs associated with intellectual property litigation, amongst other factors.

Intellectual property rights and enforcement may be less extensive in jurisdictions outside of the U.S.; thus, we may not be able to protect our intellectual property and third parties may be able to market competitive products that may use some or all of our intellectual property.

Changes to patent law, including the Leahy-Smith America Invests Act, AIA or Leahy-Smith Act, of 2011 and the Patent Reform Act of 2009 and other future article of legislation, may substantially change the regulations and procedures surrounding patent applications, issuance of patents, and prosecution of patents. We can give no assurances that the patents of our licensor can be defended or will protect us against future intellectual property challenges, particularly as they pertain to changes in patent law and future patent law interpretations.

In addition, enforcing and maintaining our intellectual property protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by the USPTO, courts and foreign government patent agencies, and HJF's patent protection could be reduced or eliminated for non-compliance with these requirements which may have a material adverse effect on our business.

Risks Related to Commercialization of Our Current Product Candidate and Future Product Candidates

Our commercial success depends upon attaining significant market acceptance of our current product candidate and future product candidates, if approved, among physicians, patients, healthcare payors and cancer treatment centers.

Even if we obtain regulatory approval for our current product candidate or any future product candidates, the products may not gain market acceptance among physicians, healthcare payors, patients or the medical community, including cancer treatment centers. Market acceptance of any product candidates for which we receive approval depends on a number of factors, including:

- the efficacy and safety of such product candidates as demonstrated in clinical trials;
- the clinical indications and patient populations for which the product candidate is approved;
- acceptance by physicians, major cancer treatment centers and patients of the drug as a safe and effective treatment;
- the adoption of novel immunotherapies by physicians, hospitals and third-party payors;
- the potential and perceived advantages of product candidates over alternative treatments;
- the safety of product candidates seen in a broader patient group, including our use outside the approved indications;
- any restrictions on use together with other medications;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- the timing of market introduction of our product as well as competitive products;
- the development of manufacturing and distribution processes for commercial scale manufacturing for our current product candidate and any future product candidates;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement from third-party payors and government authorities;
- relative convenience and ease of administration; and
- the effectiveness of our sales and marketing efforts and those of our collaborators.

If our current product and any future product candidates are approved but fail to achieve market acceptance among physicians, patients, healthcare payors or cancer treatment centers, we will not be able to generate significant revenues, which would compromise our ability to become profitable.

Even if we are able to commercialize our current product candidate or any future product candidates, the products may not receive coverage and adequate reimbursement from third-party payors in the U.S. and in other countries in which we seek to commercialize our products, which could harm our business.

Our ability to commercialize any product successfully will depend, in part, on the extent to which coverage and adequate reimbursement for such product and related treatments will be available from third-party payors, including government health administration authorities, private health insurers and other organizations.

Third-party payors determine which medications they will cover and establish reimbursement levels. A primary trend in the healthcare industry is cost containment. 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 medical products. Third-party payors may also seek additional clinical evidence, beyond the data required to obtain regulatory approval, demonstrating clinical benefit and value in specific patient populations before covering our product for those patients. We cannot be sure that coverage and adequate reimbursement will be available for any product that we commercialize and, if coverage is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain regulatory approval. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize any product candidate for which we obtain regulatory approval.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may only be temporary. 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 third-party 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 U.S. No uniform policy for coverage and reimbursement exists in the U.S., and coverage and reimbursement can differ significantly from payor to payor. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies, but also have their own methods and approval process apart from Medicare determinations. Our inability to promptly obtain coverage and profitable reimbursement rates from both government-funded and private payors for any approved product that we develop could have a material adverse effect on our operating results, ability to raise capital needed to commercialize our product and overall financial condition.

Healthcare legislative measures aimed at reducing healthcare costs may have a material adverse effect on our business and results of operations.

Third-party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In both the U.S. and certain international jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our product profitably. In particular, in 2010, the Affordable Care Act ("ACA") was enacted, which, among other things, subjected biologic products to potential competition by lower-cost biosimilars, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program, extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, subjected manufacturers to new annual fees and taxes for certain branded prescription drugs, and provided incentives to programs that increase the federal government's comparative effectiveness research. Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the current U.S. administration to repeal or repeal and replace certain aspects of the ACA. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, or the Texas District Court Judge, ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as a part of the Tax Act, the remaining provisions of the ACA are invalid as well. While the Texas District Court Judge, as well as the Trump Administration and CMS, have stated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals and other efforts to repeal and replace the ACA will impact the ACA. Until there is more certainty concerning the future of the ACA, it will be difficult to predict its full impact and influence on our business.

In addition, other legislative changes have been proposed and adopted in the U.S. since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in 2013, and will remain in effect through 2027 unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012 further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our product candidate, if we obtain regulatory approval;
- our ability to receive or set a price that we believe is fair for our product;
- our ability to generate revenue and achieve or maintain profitability;

- the level of taxes that we are required to pay; and
- the availability of capital.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, lower reimbursement and new payment methodologies. This could lower the price that we receive for any approved product. Any denial in coverage or reduction in reimbursement from Medicare or other government-funded programs may result in a similar denial or reduction in payments from private payors, which may prevent us from being able to generate sufficient revenue, attain profitability or commercialize our product candidate, if approved.

Price controls may be imposed in foreign markets, which may adversely affect our future profitability.

In some countries, particularly member states of the European Union, the pricing of prescription drugs is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of regulatory approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices.

In some countries, we or our collaborators may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our product candidate to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of our product is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be adversely affected.

Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidate, which could make it difficult for us to sell our product candidates, if licensed, profitably.

Successful commercialization of our product candidate will depend in part on the extent to which reimbursement for those drug products will be available from government health administration authorities, private health insurers, and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drug products they will pay for and establish reimbursement levels. The availability and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford a drug product. Sales of drug products depend substantially, both domestically and abroad, on the extent to which the costs of drugs products are paid for by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. Any product candidate for which we seek regulatory approval and reimbursement will need to meet or surpass our target product profile to be deemed a viable alternative to currently approved therapies.

Third-party payors decide which drugs and treatments they will cover and the amount of reimbursement. Reimbursement by a third-party payor may depend upon a number of factors, including, but not limited to, the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide the payor with supporting scientific, clinical and cost-effectiveness data for the use of our products, if licensed. In the U.S., the principal decisions about reimbursement for new drug products are typically made by the Centers for Medicare and Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, or HHS. CMS decides whether and to what extent a new drug product will be covered and reimbursed under Medicare, and private payors tend to follow CMS to a substantial degree. However, no uniform policy of coverage and reimbursement for drug products exists among third-party payors and coverage and reimbursement levels for drug products can differ significantly from payor to payor. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the 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 product development.

Even if we obtain coverage for a given product, if the resulting reimbursement rates are insufficient, hospitals may not approve our product for use in their facility or third-party payors may require co-payments that patients find unacceptably high. Patients are unlikely to use our product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our product candidates. Separate reimbursement for the product itself may or may not be available. Instead, the hospital or administering physician may be reimbursed only for providing the treatment or procedure in which our product is used. Further, from time to time, CMS revises the reimbursement systems used to reimburse health care providers, including the Medicare Physician Fee Schedule and Outpatient Prospective Payment System, which may result in reduced Medicare payments. In some cases, private third-party payors rely on all or portions of Medicare payment systems to determine payment rates. Changes to government healthcare programs that reduce payments under these programs may negatively impact payments from private third-party payors, and reduce the willingness of physicians to use our product candidates.

The marketability of any product candidates for which we receive regulatory approval for commercial sale may suffer if government and other third-party payors fail to provide coverage and adequate reimbursement. We expect downward pressure on pharmaceutical pricing to continue. Further, coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

We expect the product candidates we develop will be regulated as biological products, or biologics, and therefore they may be subject to competition.

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, was enacted as part of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, to establish an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to a licensed biologic. Under the BPCIA, an application for a biosimilar product cannot be licensed by the FDA until 12 years after the reference product was licensed under a BLA. The law is complex and is still being interpreted and implemented by the FDA.

We believe that any of the product candidates we develop that is licensed in the U.S. as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider the subject product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Moreover, the extent to which a biosimilar, once licensed, will be substituted for any one of the reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

Risks Related to Healthcare Compliance Regulations

Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings. If we or they are unable to comply with these provisions, we may become subject to civil and criminal investigations and proceedings that could have a material adverse effect on our business, financial condition and prospects.

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain regulatory approval. Our current and future arrangements with healthcare providers, healthcare entities, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research, develop and will market, sell and distribute our product. As a pharmaceutical company, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are applicable to our business. Restrictions under applicable federal and state healthcare laws and regulations that may affect our ability to operate include the following:

- the federal healthcare Anti-Kickback Statute which prohibits, among other things, individuals and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, overtly or covertly, 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 a federal healthcare program such as Medicare and Medicaid;

- federal civil and criminal false claims laws, including the federal False Claims Act that can be enforced through civil whistleblower or qui tam actions, and civil monetary penalty laws, prohibit individuals or entities from knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment or approval 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 ("HIPAA") which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also created federal criminal laws that prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items or services, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH") which imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information on entities subject to the law, such as certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, and their respective business associates that perform services for them that involve the creation, use, maintenance or disclosure of, individually identifiable health information;

- the federal physician sunshine requirements under the ACA which requires certain manufacturers of drugs, devices, biologics and medical supplies, with certain exceptions, to report annually to HHS information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations;

- 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; some state laws which require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or pricing information; and certain state and local laws which require the registration of pharmaceutical sales representatives; and

- state and foreign laws govern the privacy and security of health information in specified 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 will 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, damages, fines, imprisonment, disgorgement, exclusion from government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, and the curtailment or restructuring of our operations. If any physicians or other healthcare providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.

We are exposed to the risk of employee fraud or other misconduct, including intentional failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, provide accurate information to the FDA or comparable foreign regulatory authorities, comply with manufacturing standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, report financial information or data accurately or disclose unauthorized activities to us. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity 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, those actions could have a significant impact on our business and results of operations, including the imposition of significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and integrity oversight and reporting obligations.

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

We face an inherent risk of product liability exposure related to the testing of our current product candidate or future product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. Product liability claims may be brought against us by patients enrolled in our clinical trials, patients, healthcare providers or others using, administering or selling our product. If we cannot successfully defend ourselves against claims that our product candidate or product caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;

- termination of clinical trial sites or entire clinical trial programs;

- injury to our reputation and significant negative media attention;

- withdrawal of clinical trial participants;

- significant costs to defend the related litigation;

- substantial monetary awards to clinical trial patients;

- loss of revenue;

- diversion of management and scientific resources from our business operations; and

- the inability to commercialize any products that we may develop.

Prior to engaging in future clinical trials, we intend to obtain product liability insurance coverage at a level that we believe is customary for similarly situated companies and adequate to provide us with insurance coverage for foreseeable risks; however, we may be unable to obtain such coverage at a reasonable cost, if at all. If we are able to obtain product liability insurance, 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 and such insurance may not be adequate to cover all liabilities that we may incur. Furthermore, we intend to expand our insurance coverage for products to include the sale of commercial products if we obtain regulatory approval for our product candidate in development, but we may be unable to obtain commercially reasonable product liability insurance for any products that receive regulatory approval. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

Laws and regulations governing any international operations we may have in the future may preclude us from developing, manufacturing and selling certain products outside of the U.S. and require us to develop and implement costly compliance programs.

If we expand our operations outside of the U.S., we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the U.S. to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and Executive Orders also restrict the use and dissemination outside of the U.S., or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the U.S., it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, marketing or selling certain products and product candidates outside of the U.S., which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

Risks Related to our Business Operations

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

We face competition from numerous pharmaceutical and biotechnology enterprises, as well as from academic institutions, government agencies and private and public research institutions for our current product candidate. Our commercial opportunities will be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer side effects or are less expensive than any products that we may develop. Competition could result in reduced sales and pricing pressure on our current product candidate, if approved, which in turn would reduce our ability to generate meaningful revenues and have a negative impact on our results of operations. In addition, significant delays in the development of our product candidate could allow our competitors to bring products to market before we do and impair our ability to commercialize our product candidate. The biotechnology industry, including the cancer immunotherapy market, is intensely competitive and involves a high degree of risk. We compete with other companies that have far greater experience and financial, research and technical resources than us. Potential competitors in the U.S. and worldwide are numerous and include pharmaceutical and biotechnology companies, educational institutions and research foundations, many of which have substantially greater capital resources, marketing experience, research and development staffs and facilities than ours. Some of our competitors may develop and commercialize products that compete directly with those incorporating our technology or may introduce products to market earlier than our product or on a more cost-effective basis. Our competitors compete with us in recruiting and retaining qualified scientific and management personnel as well as in acquiring technologies complementary to our technology. We may face competition with respect to product efficacy and safety, ease of use and adaptability to various modes of administration, acceptance by physicians, the timing and scope of regulatory approvals, availability of resources, reimbursement coverage, price and patent position, including the potentially dominant patent positions of others. An inability to successfully complete our product development or commercializing our product candidate could result in our having limited prospects for establishing market share or generating revenue.

Many of our competitors or potential competitors have significantly greater established presence in the market, financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do, and as a result may have a competitive advantage over us. 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 third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies and technology licenses complementary to our programs or potentially advantageous to our business.

As a result of these factors, these competitors may obtain regulatory approval of their products before we are able to obtain patent protection or other intellectual property rights, which will limit our ability to develop or commercialize our current product candidate. Our competitors may also develop drugs that are safer, more effective, more widely used and cheaper than ours, and may also be more successful than us in manufacturing and marketing their products. These appreciable advantages could render our product candidate obsolete or noncompetitive before we can recover the expenses of development and commercialization.

The COVID-19 coronavirus could adversely impact our business in the U.S. and in other countries, including several key activities, including clinical trial activities, manufacturing of drugs and clinical supplies, exportation of drug and supplies, and management of international payments and cash flow that are critical to our success.

The global outbreak of COVID-19 continues to rapidly evolve, including the emergence of new strains that could have the potential to be as harmful as or more harmful than the original strains in 2020. As a result, businesses may close, staffing may be reduced, including clinical staffs, and limits may be placed on travel. The extent to which COVID-19 may impact our business will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate impact of the disease on specific geographies, the duration of the outbreak, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

The spread of COVID-19 throughout the world has also created global economic uncertainty, which may cause partners, suppliers and potential customers to closely monitor their costs and reduce their spending budget. Any of the foregoing could materially adversely affect our research and development activities, clinical trials, supply chain, financial condition and cash flows.

If the COVID-19 outbreak continues to spread and evolve, we may need to limit operations or implement other limitations on our activities. There is a risk that countries or regions outside the United States may be less effective at vaccinations and containing COVID-19, in which case the risks described herein could be elevated significantly.

Data collection is governed by restrictive regulations governing the use, processing, and cross-border transfer of personal information.

We are subject to stringent privacy and data protection requirements and these requirements may become more complex as we grow our business and begin to operate in other jurisdictions. For example, the collection, use, storage, disclosure, transfer, or other processing of personal data, including health-related information, regarding individuals in the European Economic Area, or EEA, is governed by the European General Data Protection Regulation, or the GDPR, which became effective on May 25, 2018. The GDPR applies to any business, regardless of its location, that provides goods or services to residents in the EU or monitors the behavior of individuals within the European Union. The GDPR is wide ranging in scope and imposes stringent operational requirements for processors and controllers of personal data, including, for example, special protections for "sensitive information" which includes health and genetic information, expanded disclosures to individuals about how their personal data is to be used, limitations on retention of information, increased requirements pertaining to health data and pseudonymized (*i.e.*, key-coded) data, implementing safeguards to protect the security and confidentiality of personal data, mandatory data breach notification requirements and higher standards for controllers to demonstrate that they have obtained valid consent for certain data processing activities. The GDPR grants individuals the opportunity to object to the processing of their personal information, allows them to request deletion of personal information in certain circumstances, and provides the individual with an express right to seek legal remedies in the event the individual believes his or her rights have been violated. Further, the GDPR imposes strict rules on the transfer of personal data out of the European Union to the U.S. and other jurisdictions that have not been deemed to offer "adequate" privacy protections.

In addition to the requirement of the GDPR, European Union Member States may make their own further laws and regulations in relation to the processing of genetic, biometric or health data, which could result in differences between Member States, limit our ability to use and share personal data or could cause our costs to increase, and harm our business and financial condition. Should we commence clinical trial activity within the member states of the European Union, such activity will be regulated by the GDPR as well as applicable member state laws. In addition, we are subject to evolving and strict rules on the transfer of personal data out of the European Union to the U.S.. For example, evolution of laws governing the cross-border transfer of data, such as the invalidation of the EU–U.S. Privacy Shield, creates additional uncertainty around the legality and mechanics of such transfers. Compliance with the GDPR will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with any future European activities. We could be adversely affected if we fail to comply fully with all of these requirements. Failure to comply with European Union data protection laws may result in fines (for example, of up to €20,000,000 or up to 4% of the total worldwide annual turnover of the preceding financial year (whichever is higher) under the GDPR) and other administrative penalties, which may be onerous and adversely affect our business, financial condition, results of operations and prospects.

In addition, further to the United Kingdom's (UK) exit from the EU on January 31, 2020, the GDPR ceased to apply in the UK at the end of the transition period on December 31, 2020. However, as of January 1, 2021, the UK's European Union (Withdrawal) Act 2018 incorporated the GDPR (as it existed on December 31, 2020 but subject to certain UK specific amendments) into UK law (referred to as the 'UK GDPR'). The UK GDPR and the UK Data Protection Act 2018 set out the UK's data protection regime, which is independent from but aligned to the EU's data protection regime. Non-compliance with the UK GDPR may result in monetary penalties of up to £17.5 million or 4% of worldwide revenue, whichever is higher. Although the UK is regarded as a third country under the EU's GDPR, the European Commission has now issued a decision recognizing the UK as providing adequate protection under the EU GDPR and, therefore, transfers of personal data originating in the EU to the UK remain unrestricted. Like the EU GDPR, the UK GDPR restricts personal data transfers outside the UK to countries not regarded by the UK as providing adequate protection. The UK government has confirmed that personal data transfers from the UK to the EEA remain free flowing.

This lack of clarity on future UK laws and regulations and their interaction with EU laws and regulations could add legal risk, uncertainty, complexity and cost to our handling of EU personal information and our privacy and data security compliance programs. It is possible that over time the UK Data Protection Act could become less aligned with the EU General Data Protection Regulation, or GDPR, which could require us to implement different compliance measures for the UK and the European Union and result in potentially enhanced compliance obligations for EU personal data.

In the U.S., there has been a flurry of activity at the state level. In California, the California Consumer Privacy Act, or CCPA, was enacted in June 2018, became effective on January 1, 2020, and became subject to enforcement by the California Attorney General's office on July 1, 2020. The CCPA broadly defines personal information, and creates new individual privacy rights and protections for California consumers (as defined in the law), places increased privacy and security obligations on entities handling personal data of consumers or households, and provides for civil penalties for violations and a private right of action for data breaches. The CCPA requires covered companies to provide certain disclosures to consumers about its data collection, use and sharing practices, and to provide affected California residents with ways to opt-out of certain sales or transfers of personal information. While there is an exception for protected health information that is subject to HIPAA and clinical trial regulations, the CCPA may impact our business activities if we become a "Business" regulated by the scope of the CCPA.

In addition to the CCPA, new privacy and data security laws have been proposed in more than half of the states in the U.S. and in the U.S. Congress, reflecting a trend toward more stringent privacy legislation in the U.S., which trend may accelerate depending on the new U.S. presidential administration. The effects of the CCPA, and other similar state or federal laws, are potentially significant and may require us to modify our data processing practices and policies and to incur substantial costs and potential liability in an effort to comply with such legislation.

Further, various jurisdictions around the world continue to propose new laws that regulate the privacy and/or security of certain types of personal data. Complying with these laws, if enacted, would require significant resources and leave us vulnerable to possible fines and penalties if we are unable to comply. The regulatory framework governing the collection, processing, storage, use and sharing of certain information is rapidly evolving and is likely to continue to be subject to uncertainty and varying interpretations. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our existing data management practices or the features of our services and platform capabilities. Any failure or perceived failure by us, or any third parties with which we do business, to comply with our posted privacy policies, evolving laws, rules and regulations, industry standards, or contractual obligations to which we or such third parties are or may become subject, may result in actions or other claims against

Significant disruptions of information technology systems, computer system failures or breaches of information security could adversely affect our business.

We rely to a large extent upon sophisticated information technology systems to operate our business. In the ordinary course of business, we collect, store and transmit large amounts of confidential information (including, but not limited to, personal information and intellectual property). The size and complexity of our information technology and information security systems, and those of our third-party vendors with whom we may contract, make such systems potentially vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees or vendors, or from malicious attacks by third parties. Such attacks are of ever-increasing levels of sophistication and are made by groups and individuals with a wide range of motives (including, but not limited to, industrial espionage and market manipulation) and expertise. While we intend to invest in the protection of data and information technology, there can be no assurance that our efforts will prevent service interruptions or security breaches.

Our internal computer systems, and those of our CROs, our CMOs, and other business vendors on which we may rely, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, fire, terrorism, war and telecommunication and electrical failures. We exercise little or no control over these third parties, which increases our vulnerability to problems with their systems. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. Any interruption or breach in our systems could adversely affect our business operations and/or result in the loss of critical or sensitive confidential information or intellectual property, and could result in financial, legal, business and reputational harm to us or allow third parties to gain material, inside information that they use to trade in our securities. For example, the loss of clinical trial data from completed or ongoing clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, the further development of our current and future product candidates could be delayed and our business could be otherwise adversely affected.

We will need to grow the size of our organization in the future, and we may experience difficulties in managing this growth.

As of April 11, 2025, we had 4 full-time employees and 4 part-time employees. We will need to grow the size of our organization in order to support our continued development and potential commercialization of our product candidate. As our development and commercialization plans and strategies continue to develop, our need for additional managerial, operational, manufacturing, sales, marketing, financial and other resources may increase. Our management, personnel and systems currently in place may not be adequate to support this future growth. Future growth would impose significant added responsibilities on members of management, including:

- managing our clinical trials effectively;
- identifying, recruiting, maintaining, motivating and integrating additional employees;
- managing our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors and other third parties;
- improving our managerial, development, operational, information technology, and finance systems; and
- expanding our facilities.

If our operations expand, we will also need to manage additional relationships with various strategic partners, suppliers and other third parties. Our future financial performance and our ability to commercialize our product candidate and to compete effectively will depend, in part, on our ability to manage any future growth effectively, as well as our ability to develop a sales and marketing force when appropriate for our company. To that end, we must be able to manage our development efforts and preclinical studies and clinical trials effectively and hire, train and integrate additional management, research and development, manufacturing, administrative and sales and marketing personnel. The failure to accomplish any of these tasks could prevent us from successfully growing our company.

Our future success depends on our ability to retain our executive officers and to attract, retain and motivate qualified personnel.

We are highly dependent upon our personnel, including Snehal Patel, our Chief Executive Officer and member of our board of directors. The loss of Mr. Patel's services could impede the achievement of our research, development and commercialization objectives. We have not obtained, do not own, nor are we the beneficiary of, key-person life insurance. Our future growth and success depend on our ability to recruit, retain, manage and motivate our employees. The loss of any member of our senior management team or the inability to hire or retain experienced management personnel could compromise our ability to execute our business plan and harm our operating results. Because of the specialized scientific and managerial nature of our business, we rely heavily on our ability to attract and retain qualified scientific, technical and managerial personnel. The competition for qualified personnel in the pharmaceutical field is intense and as a result, we may be unable to continue to attract and retain qualified personnel necessary for the development of our business.

Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

We are periodically involved in various litigation and/or regulatory proceedings that, if adversely decided or settled, could materially and adversely affect our business, financial condition, and results of operations.

We are periodically party to or the subject of litigation, investigations, regulatory proceedings or other disputes. In general, claims made by or against us in disputes and other legal or regulatory proceedings can be expensive and time consuming to bring or defend against, requiring us to expend significant resources and divert the efforts and attention of our management and other personnel from our business operations. While we intend to pursue any claims made by us, or vigorously defend against any claims brought against us, we cannot predict the outcomes of such claims. Any failure to prevail in any claims made by us or any adverse determination against us in these legal and/or regulatory proceedings, or even the allegations contained in such proceedings, regardless of whether they are ultimately found to be without merit, may also result in settlements, injunctions, fines, penalties, or damages that could have a material adverse effect on our business, financial condition and results of operations.

We may hold cash and cash equivalents at various foreign subsidiaries and in countries outside of the US that may not be readily available to meet cash requirements.

Currently a majority of our cash and cash equivalents is held by our U.S. parent company, however, our foreign subsidiary may in the future hold cash. Our U.S. parent company or our foreign subsidiary may hold cash balances outside the United States which may not be readily available, or may not be available without an additional tax burden, to meet our domestic or foreign cash requirements. U.S. tax laws may allow for reductions to the potential tax burden on repatriation of foreign cash; however, such actions would require us to record additional income tax expense and remit additional taxes, which could have a material adverse effect on our results of operations, cash flows and financial condition. In addition, foreign exchange rates may fluctuate leading to unexpected losses and inefficient utilization of cash in countries outside of the U.S.

We may be adversely affected by the effects of *inflation* ***and a potential recession.***

Inflation has the potential to adversely affect our liquidity, business, financial condition, and results of operations by increasing our overall cost structure. The existence of inflation in the economy has resulted in, and may continue to result in, higher interest rates and capital costs, shipping costs, supply shortages, increased costs of labor, weakening exchange rates, and other similar effects. As a result of inflation, we have experienced and may continue to experience, cost increases. In addition, poor economic and market conditions, including a potential recession, may negatively impact market sentiment, which would adversely affect our results of operations. If we are unable to take effective measures in a timely manner to mitigate the impact of the inflation as well as a potential recession, our business, financial condition, and results of operations could be adversely affected.

Risks Related to Owning our Common Stock

The price of our common stock may fluctuate substantially.

You should consider an investment in our common stock to be risky, and you should invest in our common stock only if you can withstand a significant loss and wide fluctuations in the market value of your investment. Some factors that may cause the market price of our common stock to fluctuate, in addition to the other risks mentioned in this "Risk Factors" section and elsewhere in this Annual Report on Form 10-K, are:

- sale of our common stock by our stockholders, executives and directors;
- volatility and limitations in trading volumes of our shares of common stock;
- our ability to obtain financings to conduct and complete research and development activities including, but not limited to, our clinical trials, and other business activities;
- possible delays in the expected recognition of revenue due to lengthy and sometimes unpredictable sales timelines;
- the timing and success of introductions of new products by us or our competitors or any other change in the competitive dynamics of our industry, including consolidation among competitors, customers or strategic partners;
- network outages or security breaches;
- our ability to attract new customers;
- our ability to secure resources and the necessary personnel to conduct clinical trials on our desired schedule;
- commencement, enrollment or results of our clinical trials for our product candidate or any future clinical trials we may conduct;

- changes in the development status of our product candidate;
- any delays or adverse developments or perceived adverse developments with respect to the FDA's review of our planned preclinical and clinical trials;
- any delay in our submission for studies or product approvals or adverse regulatory decisions, including failure to receive regulatory approval for our product candidate;
- unanticipated safety concerns related to the use of our product candidate;
- failures to meet external expectations or management guidance;
- changes in our capital structure or dividend policy, future issuances of securities, sales of large blocks of common stock by our stockholders;
- our cash position;
- announcements and events surrounding financing efforts, including debt and equity securities;
- our inability to enter into new markets or develop new products;
- reputational issues;
- competition from existing technologies and products or new technologies and products that may emerge;
- announcements of acquisitions, partnerships, collaborations, joint ventures, new products, capital commitments, or other events by us or our competitors;
- changes in general economic, political and market conditions in or any of the regions in which we conduct our business;
- changes in industry conditions or perceptions;
- changes in valuations of similar companies or groups of companies;
- analyst research reports, recommendation and changes in recommendations, price targets, and withdrawals of coverage;
- departures and additions of key personnel;
- disputes and litigations related to intellectual properties, proprietary rights, and contractual obligations;
- changes in applicable laws, rules, regulations, or accounting practices and other dynamics; and
- other events or factors, many of which may be out of our control.

In addition, if the market for stocks in our industry or industries related to our industry, or the stock market in general, experiences a loss of investor confidence, the trading price of our common stock could decline for reasons unrelated to our business, financial condition and results of operations. If any of the foregoing occurs, it could cause our stock price to fall and may expose us to lawsuits that, even if unsuccessful, could be costly to defend and a distraction to management.

Market and economic conditions may negatively impact our business, financial condition and share price.

Concerns over medical epidemics, energy costs, geopolitical issues, the U.S. mortgage market and a deteriorating real estate market, unstable global credit markets and financial conditions, and volatile oil prices have led to periods of significant economic instability, diminished liquidity and credit availability, declines in consumer confidence and discretionary spending, diminished expectations for the global economy and expectations of slower global economic growth, increased unemployment rates, and increased credit defaults in recent years. Our general business strategy may be adversely affected by any such economic downturns (including the downturn related to the current COVID-19 pandemic), volatile business environments and continued unstable or unpredictable economic and market conditions. If these conditions continue to deteriorate or do not improve, it may make any necessary debt or equity financing more difficult to complete, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance, and share price and could require us to delay or abandon development or commercialization plans.

If securities or industry analysts do not publish research or reports, or publish unfavorable research or reports about our business, our stock price and trading volume may decline.

The trading market for our common stock relies in part on the research and reports that industry or financial analysts publish about us, our business, our markets and our competitors. We do not control these analysts. If securities analysts do not cover our common stock, the lack of research coverage may adversely affect the market price of our common stock. Furthermore, if one or more of the analysts who do cover us downgrade our stock or if those analysts issue other unfavorable commentary about us or our business, our stock price would likely decline. If one or more of these analysts cease coverage of us or fails to regularly publish reports on us, we could lose visibility in the market and interest in our stock could decrease, which in turn could cause our stock price or trading volume to decline and may also impair our ability to expand our business with existing customers and attract new customers.

Because certain of our stockholders control a significant number of shares of our common stock, they may have effective control over actions requiring stockholder approval.

As of April 11, 2025, our directors, executive officers and principal stockholders, and their respective affiliates, beneficially own approximately 52% of our outstanding shares of common stock. As a result, these stockholders, acting together, have the ability to control the outcome of matters submitted to our stockholders for approval, including the election of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, these stockholders, acting together, have the ability to control the management and affairs of our company. Accordingly, this concentration of ownership might harm the market price of our common stock by:

- delaying, deferring or preventing a change in corporate control;
- impeding a merger, consolidation, takeover or other business combination involving us; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

Future sales and issuances of our common stock could result in additional dilution of the percentage ownership of our stockholders and could cause our share price to fall.

We expect that significant additional capital will be needed in the future to continue our planned operations, including increased marketing, hiring new personnel, commercializing our product, and continuing activities as an operating public company. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

We do not intend to pay cash dividends on our shares of common stock so any returns will be limited to the value of our shares.

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the increase, if any, of our share price.

We are an "emerging growth company" and will be able to avail ourselves of reduced disclosure requirements applicable to emerging growth companies, which could make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. In addition, pursuant to Section 107 of the JOBS Act, as an "emerging growth company" we intend to take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act, for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an "emerging growth company." We will remain an "emerging growth company" until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of our initial public offering; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

We may be at risk of securities class action litigation.

We may be at risk of securities class action litigation. In the past, biotechnology and pharmaceutical companies have experienced significant stock price volatility, particularly when associated with binary events such as clinical trials and product approvals. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business and results in a decline in the market price of our common stock.

Our common stock is currently listed on The Nasdaq Capital Market. If we are unable to maintain listing of our securities on Nasdaq or any stock exchange, our stock price could be adversely affected and the liquidity of our stock and our ability to obtain financing could be impaired and it may be more difficult for our stockholders to sell their securities.

Although our common stock is currently listed on The Nasdaq Capital Market, we may not be able to continue to meet the exchange's minimum listing requirements or those of any other national exchange. If we are unable to maintain listing on Nasdaq or if a liquid market for our common stock does not develop or is sustained, our common stock may remain thinly traded.

The listing rules of Nasdaq require listing issuers to comply with certain standards in order to remain listed on its exchange. If, for any reason, we should fail to maintain compliance with these listing standards and Nasdaq should delist our securities from trading on its exchange and we are unable to obtain listing on another national securities exchange, a reduction in some or all of the following may occur, each of which could have a material adverse effect on our stockholders:

- the liquidity of our common stock;
- the market price of our common stock;
- our ability to obtain financing for the continuation of our operations;
- the number of institutional and general investors that will consider investing in our common stock;
- the number of market makers in our common stock;
- the availability of information concerning the trading prices and volume of our common stock; and
- the number of broker-dealers willing to execute trades in shares of our common stock.

Our second amended and restated certificate of incorporation ("Amended and Restated Certificate of Incorporation") and our second amended and restated bylaws (the "Amended and Restated Bylaws") and Delaware law may have anti-takeover effects that could discourage, delay or prevent a change in control, which may cause our stock price to decline.

Our Amended and Restated Certificate of Incorporation and our Amended and Restated Bylaws and Delaware law could make it more difficult for a third party to acquire us, even if closing such a transaction would be beneficial to our stockholders. We are authorized to issue up to 10 million shares of preferred stock. This preferred stock may be issued in one or more series, the terms of which may be determined at the time of issuance by our board of directors without further action by stockholders. The terms of any series of preferred stock may include voting rights (including the right to vote as a series on particular matters), preferences as to dividend, liquidation, conversion and redemption rights and sinking fund provisions. The issuance of any preferred stock could materially adversely affect the rights of the holders of our common stock, and therefore, reduce the value of our common stock. In particular, specific rights granted to future holders of preferred stock could be used to restrict our ability to merge with, or sell our assets to, a third party and thereby preserve control by the present management.

Provisions of our Amended and Restated Certificate of Incorporation and our Amended and Restated Bylaws and Delaware law also could have the effect of discouraging potential acquisition proposals or making a tender offer or delaying or preventing a change in control, including changes a stockholder might consider favorable. Such provisions may also prevent or frustrate attempts by our stockholders to replace or remove our management. In particular, the certificate of incorporation and bylaws and Delaware law, as applicable, among other things:

- provide the board of directors with the ability to alter the Amended and Restated Bylaws without stockholder approval;
- place limitations on the removal of directors;
- establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings; and
- provide that vacancies on the board of directors may be filled by a majority of directors in office, although less than a quorum.

Financial reporting obligations of being a public company in the U.S. are expensive and time-consuming, and our management is required to devote substantial time to compliance matters.

As a publicly traded company we incur significant additional legal, accounting and other expenses. The obligations of being a public company in the U.S. require significant expenditures and place significant demands on our management and other personnel, including costs resulting from public company reporting obligations under the Exchange Act and the rules and regulations regarding corporate governance practices, including those under the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, and the listing requirements of The Nasdaq Capital Market. These rules require the establishment and maintenance of effective disclosure and financial controls and procedures, internal control over financial reporting and changes in corporate governance practices, among many other complex rules that are often difficult to implement, monitor and maintain compliance with. Moreover, despite recent reforms made possible by the JOBS Act, the reporting requirements, rules, and regulations will make some activities more time-consuming and costly, particularly after we are no longer an "emerging growth company." Our management and other personnel will need to devote a substantial amount of time to ensure that we comply with all of these requirements and to keep pace with new regulations, otherwise we may fall out of compliance and risk becoming subject to litigation or being delisted, among other potential problems.

Our Amended and Restated Bylaws provides that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for substantially all disputes between the Company and its stockholders, which could limit stockholders' ability to obtain a favorable judicial forum for disputes with the Company or its directors, officers or employees.

Our Amended and Restated Bylaws provides that unless we consent in writing to the selection of an alternative forum, the State of Delaware is the sole and exclusive forum for: (i) any derivative action or proceeding brought on behalf of us, (ii) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of our Company to us or our stockholders, (iii) any action asserting a claim against us, our directors, officers or employees arising pursuant to any provision of the Delaware General Corporation Law (the "DGCL") or our Amended and Restated Certificate of Incorporation or our Amended and Restated Bylaws, or (iv) any action asserting a claim against us, our directors, officers, employees or agents governed by the internal affairs doctrine, except for, as to each of (i) through (iv) above, any claim as to which the Court of Chancery determines that there is an indispensable party not subject to the jurisdiction of the Court of Chancery (and the indispensable party does not consent to the personal jurisdiction of the Court of Chancery within ten days following such determination), which is vested in the exclusive jurisdiction of a court or forum other than the Court of Chancery, or for which the Court of Chancery does not have subject matter jurisdiction. This exclusive forum provision would not apply to suits brought to enforce any liability or duty created by the Securities Act or the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. To the extent that any such claims may be based upon federal law claims, Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder.

Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. However, our Amended and Restated Bylaws contain a federal forum provision which provides that unless we consent in writing to the selection of an alternative forum, the U.S. federal district courts will be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock are deemed to have notice of and consented to this provision.

These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find our choice of forum provisions contained in either our Amended and Restated Bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations, and financial condition.

If we fail to maintain an effective system of internal control over financial reporting in the future, we may not be able to accurately report our financial condition, results of operations or cash flows.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. We are required to furnish a report by management on, among other things, the effectiveness of internal control over financial reporting. This assessment will include disclosure of any material weaknesses identified by management in our internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting that results in more than a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis. Section 404 of the Sarbanes-Oxley Act also generally requires an attestation from an issuer's independent registered public accounting firm on the effectiveness of its internal control over financial reporting. However, for as long as we remain an emerging growth company under the JOBS Act, we may take advantage of the exemption permitting us not to comply with the independent registered public accounting firm attestation requirement.

Our compliance with Section 404 of the Sarbanes-Oxley Act may require that we incur substantial accounting expense and expend significant management efforts. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we may be unable to assert that our internal control over financial reporting is effective. In connection with management's assessment of internal controls over financial reporting for the quarter ended September 30, 2020, we identified a material weakness due to inadequate segregation of duties within our accounting processes due to limited personnel and insufficient written policies and procedures for accounting, IT and financial reporting and record keeping. Although we are developing a plan to remediate the material weaknesses, we cannot assure you that we will be able to remediate such weaknesses or that there will not be new material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, we could lose investor confidence in the accuracy and completeness of our financial reports, the value of our common stock could decline, and we could be subject to sanctions or investigations by regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 1C. CYBERSECURITY

We believe cybersecurity is critical to advancing our technological developments. As a biopharmaceutical company, we face a multitude of cybersecurity threats that range from attacks common to most industries, such as ransomware and denial-of service. Our customers, suppliers, subcontractors, and business partners face similar cybersecurity threats, and a cybersecurity incident impacting us or any of these entities could materially adversely affect our business strategy, performance, and results of operations. These cybersecurity threats and related risks make it imperative that we expend resources on cybersecurity.

Risk Management

We engage third-party services to conduct evaluations of our security controls, whether through penetration testing, independent audits, or consulting on best practices to address new challenges. We have established cybersecurity security awareness training and ongoing monitoring.

In the event of an incident, we intend to follow our cybersecurity incident response plan, which outlines the steps to be followed from incident detection to mitigation, and notification. We contract with external firms that have extensive information technology and program management experience. We have implemented a governance structure and processes to assess, identify, manage, and report cybersecurity risks. As a biopharmaceutical company, we must comply with extensive regulations, including requirements imposed by the Federal Drug Administration related to adequately safeguarding patient information and reporting cybersecurity incidents to the SEC. We believe we are positioned to meet the requirements of the SEC. In addition to following SEC guidance and implementing pre-existing third party frameworks, we have developed our own practices and frameworks, which we believe enhance our ability to identify and manage cybersecurity risks. Assessing, identifying, and managing cybersecurity related risks are factored into our overall business approach. We rely heavily on our supply chain to deliver our products and services, and a cybersecurity incident at a clinical site, subcontractor, or business partner could materially adversely impact us. We require that our subcontractors report cybersecurity incidents to us so that we can assess the direct impact of the incident.

Governance

The Audit Committee has oversight responsibility for risks and incidents relating to cybersecurity threats, including compliance with disclosure requirements, cooperation with law enforcement, and related effects on financial and other risks, and it reports any findings and recommendations, as appropriate, to the full board of directors for consideration. Senior management regularly discusses cyber risks and trends and, should they arise, any material incidents with the Audit Committee.

While we have not experienced any material cybersecurity threats or incidents in recent years, there can be no guarantee that we will not be the subject of future threats or incidents. Notwithstanding the extensive approach we take to cybersecurity, we may not be successful in preventing or mitigating a cybersecurity incident that could have a material adverse effect on us. While we maintain cybersecurity insurance, the costs related to cybersecurity threats or disruptions may not be fully insured. See "Risk Factors" for a discussion of cybersecurity risks.

ITEM 2. PROPERTIES

We sublease a facility to support our clinical trial operations and research and development.

ITEM 3. LEGAL PROCEEDINGS

We may be involved from time to time in ordinary litigation, negotiation, and settlement matters that will not have a material effect on our operations or finances. We are not currently party to any material legal proceedings, and we are not aware of any pending or threatened litigation against us.

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

Our common stock has traded on The Nasdaq Capital Market under the symbol "GLSI" since September 25, 2020.

Number of Stockholders

As of April 11, 2025, we had approximately 16 stockholders of record of our common stock.

Dividend Policy

Historically, we have not paid any dividends to the holders of shares of our common stock and we do not expect to pay any such dividends in the foreseeable future as we expect to retain our future earnings for use in the operation and expansion of our business.

ITEM 6. [Reserved.]

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

Overview

We are a clinical-stage biopharmaceutical company focused on our Phase III clinical trial, Flamingo-01, which is evaluating GLSI-100, an immunotherapy to prevent breast cancer recurrences. GP2 is a 9 amino acid transmembrane peptide of the HER2/neu protein, a cell surface receptor protein that is expressed in a variety of common cancers, including expression in 75% of breast cancers at low (1+), intermediate (2+), and high (3+ or over-expressor) levels. The combination of GP2 + GM-CSF is called GLSI-100. We are currently expanding Flamingo-01 into Europe with plans to open up to 150 sites globally. Flamingo-01 is designed to evaluate the safety and efficacy of GLSI-100 in HER2/*neu* positive patients with residual disease or high-risk pathologic complete response at surgery and who have completed both neoadjuvant and postoperative adjuvant trastuzumab based treatment.

To date, we have not generated any revenue and we have incurred net losses. Our net losses were approximately $15.8 million and $8.9 million for the years ended December 31, 2024 and 2023, respectively.

Our net losses have resulted from costs incurred in developing the drug in our pipeline, planning and preparing for clinical trials and general and administrative activities associated with our operations. We expect to continue to incur significant expenses and corresponding increased operating losses for the foreseeable future as we continue to develop our pipeline. Our costs may further increase as we conduct clinical trials and seek regulatory approval for and prepare to commercialize our product candidate. We expect to incur significant expenses to continue to build the infrastructure necessary to support our expanded operations, clinical trials, commercialization, including manufacturing, marketing, sales and distribution functions. We will also experience increased costs associated with operating as a public company.

Basis of Presentation

The accompanying financial statements are presented in conformity with accounting principles generally accepted in the U.S. ("GAAP") and pursuant to the rules and regulations of the SEC.

Results of Operations For the Years Ended December 31, 2024 and 2023

Research and Development Expenses

Research and development expenses increased by $5,253,407, or approximately 68%, to $12,952,029 for the year ended December 31, 2024 from $7,698,622 for the year ended December 31, 2023. The increase was primarily the result of increases in clinical expenses for the Phase III clinical trial and the one-time upfront vesting of 25% of an options grant to employees, management and the board of directors.

General and Administrative Expenses

General and administrative expenses increased by $1,430,544, or approximately 88% to $3,059,788 for the year ended December 31, 2024 from $1,629,244 for the year ended December 31, 2023. The increase was primarily the result of the one-time upfront vesting of 25% of an options grant to employees, management and the board of directors.

Liquidity and Capital Resources

Since our inception in 2006, we have devoted most of our cash resources to research and development and general and administrative activities. We have not yet achieved commercialization of our product and have a cumulative net loss from our operations. We will continue to incur net losses for the foreseeable future.

We will require additional capital to meet our long-term operating requirements. We expect to raise additional capital through the sale of equity and/or debt securities; however, there is no assurance that we will be successful at raising additional capital in the future. If our plans are not achieved and/or if significant unanticipated events occur, we may have to further modify our business plan, which may require us to raise additional capital. As of December 31, 2024 and December 31, 2023, our principal source of liquidity was our cash, which totaled $4,091,990 and $6,989,424, respectively, and additional loans and accrued unreimbursed expenses from related parties. Historically, our principal sources of cash have included proceeds from the sale of common stock and preferred stock and related party loans. Our principal uses of cash have included cash used in operations. We expect that the principal uses of cash in the future will be for continuing operations, funding of research and development, including our clinical trials, and general working capital requirements.

Between January 1, 2025 and April 11, 2025, the Company completed At The Market ("ATM") offerings pursuant to its ATM agreement with H. C. Wainwright, in which it issued and sold a total of 120,810 shares of its common stock at an average offering price of $10.42 per share for gross proceeds of $1,259,198 and net proceeds of $1,232,026, after deducting underwriting discounts and commissions and offering expenses borne by the Company, which totaled $27,172.

Cash Flow Activities for the Years Ended December 31, 2024 and 2023

We incurred net losses of $15,788,809 and $8,891,803 during the years ended December 31, 2024 and 2023, respectively, and the increase was primarily the result of increases in clinical expenses for the Phase III clinical trial and the one-time upfront vesting of 25% of an options grant to employees, management and the board of directors. Cash was $4,091,990 at December 31, 2024 and $6,989,424 at December 31, 2023 and decreased due to the following reasons:

Operating Activities

Net cash used in operating activities was $7,266,543 for the year ended December 31, 2024 and $6,478,602 for the year ended December 31, 2023. The increase was primarily the result of increases in clinical expenses for the Phase III clinical trial.

Investing Activities

We did not use or generate cash from investing activities during the year ended December 31, 2024 and December 31, 2023.

Financing Activities

Net cash provided by financing activities was $4,369,109 during the year ended December 31, 2024, attributable to the sale of common stock via the ATM program and a private placement. There was no net cash provided by or used in financing activities during the year ended December 31, 2023.

Contractual Obligations and Commitments

As of December 31, 2024, we did not have any material contractual obligations, other than employment and shareholder agreements and the license for GP2 from HJF.

Off-Balance Sheet Arrangements

As of December 31, 2024, we did not have any off-balance sheet arrangements as described by Item 303(a)(4) of Regulation S-K.

Critical Accounting Policies and Estimates

Our financial statements are prepared in conformity with U.S. GAAP, which require the use of estimates, judgments and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent liabilities at the date of the financial statements, and the reported amounts of expenses in the periods presented.

On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses and stock-based compensation. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the reported amounts of expenses that are not readily apparent from other sources. Actual results could differ from those estimates, particularly given the significant social and economic disruptions and uncertainties associated with the ongoing coronavirus pandemic and the COVID-19 control responses.

Recent Adopted Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13, Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments. The main objective of the standard is to provide financial statement users with more decision-useful information about the expected credit losses on financial instruments and other commitments to extend credit held by a reporting entity at each reporting date. To achieve this objective, the amendments in this standard replace the incurred loss impairment methodology in current GAAP with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. The update is effective for the Company beginning January 1, 2023 with early adoption permitted. The Company adopted the standard on January 1, 2023. The adoption of this standard did not have a material effect on the Company's audited consolidated financial statements and related disclosures.

Recently Issued Accounting Pronouncements Not Yet Adopted

In October 2023, the FASB issued ASU 2023-06—Codification Amendments in Response to the SEC's Disclosure Update and Simplification Initiative. The main objective of the amendment is to modify the disclosure or presentation requirements of various Topics in the Codification. Certain amendments represent clarifications to or technical corrections of the current requirements. to eliminate disclosure requirements that were redundant, duplicative, overlapping, outdated, or superseded. The effective date for each amendment will be when the SEC's removal of that related disclosure from Regulation S-X or Regulation S-K becomes effective, with early adoption prohibited. The Company is still evaluating the impact of the adoption of this standard.

JOBS Act

On April 5, 2012, the JOBS Act was enacted. Section 107 of the JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended ("Securities Act") for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies.

We have chosen to take advantage of the extended transition periods available to emerging growth companies under the JOBS Act for complying with new or revised accounting standards until those standards would otherwise apply to private companies provided under the JOBS Act. As a result, our financial statements may not be comparable to those of companies that comply with public company effective dates for complying with new or revised accounting standards.

Subject to certain conditions set forth in the JOBS Act, as an "emerging growth company," we intend to rely on certain of these exemptions, including, without limitation, (i) providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (ii) complying with any requirement that may be adopted by the Public Company Accounting Oversight Board ("PCAOB") regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. We will remain an "emerging growth company" until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of our initial public offering; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are a smaller reporting company, as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, and are not required to provide the information required under this Item 7A.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

All financial information required by this Item is attached hereto at the end of this report beginning on page F-1 and is hereby incorporated by reference.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," as defined in Rule 13a-15(e) and Rule 15d-15(e) under the Exchange Act that are 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 recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. 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 our management, including our principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

Our management, with the participation of our principal executive officer and principal accounting and financial officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of the end of the period covered by this Annual Report on Form 10-K. Based on such evaluation, our principal executive officer and principal accounting and financial officer has concluded that as of December 31, 2024, our disclosure controls and procedures were not effective as of such date as a result of material weaknesses in our internal control over financial reporting due to inadequate segregation of duties within account processes due to limited personnel and insufficient written policies and procedures for accounting, IT and financial reporting and record keeping. Under the direction of our principal executive officer and principal financial and accounting officer, we are developing a plan to remediate the material weaknesses.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as such term is defined in Exchange Act Rule 13a-15(f). Internal control over financial reporting is a process designed under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the U.S.. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

As of December 31, 2024, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control-Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, our management concluded that, as of December 31, 2024, our internal control over financial reporting had material weaknesses that lack adequate segregation of duties within account processes due to limited personnel and insufficient written policies and procedures for accounting, IT and financial reporting and record keeping and we are implementing plans to improve such internal control.

Changes in Internal Control Over Financial Reporting

There has been no change in our internal control over financial reporting during the quarter ended December 31, 2024 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

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Executive Officers, Directors and Key Employees

The following table sets forth the name, age and position of each of our executive officers, key employees and directors as of April 11, 2025. All directors hold office until the next annual meeting of stockholders and the election and qualification of their successors. Officers serve at the discretion of the board.

Name	Age	Position
Snehal Patel	61	Chief Executive Officer, Chief Financial Officer and Director
F. Joseph Daugherty	74	Chief Medical Officer and Director
Jaye Thompson	59	Vice President Clinical & Regulatory Affairs
David McWilliams	81	Chairman of the Board
Eric Rothe	50	Director
Kenneth Hallock	76	Director

Biographies

The principal occupations for the past five years (and, in some instances, for prior years) of each of our directors and executive officers are as follows:

Snehal Patel. Snehal Patel has over 30 years of experience in executive management, corporate development, operations, and investment banking in the healthcare industry. Mr. Patel has served as our Chief Executive Officer since June 2016 and our Chief Financial Officer and a member of our board of directors since February 2010. In addition, since 2009, Mr. Patel has served as a consultant, manager, and advisor at various levels in multiple private start-up biotech companies helping to develop clinical and pre-clinical assets in cancer and other therapeutic areas. Prior to 2010, Mr. Patel served as a consultant to public and private companies focused on stem cell therapy, multiple sclerosis t-cell therapy, oncolytic viruses, and disposable biotech manufacturing equipment. In addition, Mr. Patel previously served as an investment banker at Sanders Morris Harris, Ferghana Partners, and JP Morgan Chase focusing on healthcare and biotech financing and strategic transactions. Mr. Patel also previously worked in operations and business development at Bayer Corporation and in design and operations consulting firms. Mr. Patel received a Bachelor of Science degree in chemical engineering and a Master of Science degree in biochemical engineering from the Massachusetts Institute of Technology and a Masters of Business Administration degree from the University of Chicago. We believe Mr. Patel is qualified to serve as a member of our board of directors because of his executive and management experience working with biotech companies.

F. Joseph Daugherty. F. Joseph Daugherty has over 35 years of experience in managing and overseeing biotechnology and biomedical projects. Dr. Daugherty has served as our Chief Medical Officer since September 2019 and a member of our board of directors since September 2019. In addition, since 2002, Dr. Daugherty has served as the Managing Partner of Phenolics, LLC and PharmaPrint, LLC which was spun off from Phenolics, LLC, both of which are nutraceutical companies. From 2002 until 2018, he served first as President, and since 2008 as Chief Executive Officer, Chief Medical Officer and the Chairman of the board of directors of Eleos Inc., a clinical stage private biotech company focused on anti-sense technology in cancer. Dr. Daugherty also served in various other capacities as a management consultant as well as an officer and director to over 20 public and private biomedical companies including Dupont. In addition, Dr. Daugherty was President of ConAgra's biotech division. Dr. Daugherty received a Bachelor of Arts degree in biology from Washington University, a Doctor of Medicine degree from the University of Nebraska Medical Center and a Masters of Science in Industrial Administration from Carnegie-Mellon University (Tepper). We believe Dr. Daugherty is qualified to serve as a member of our board of directors because of his executive and management experience, including his experience working with biotech companies.

Jaye Thompson. Jaye Thompson has over 30 years of experience in pharmaceutical and device product development. Dr. Thompson has served as our Vice President Clinical & Regulatory Affairs since September 2019. Since December 2017, Dr. Thompson has served as a co-founder and Chief Operating Officer of Proxima Clinical Research, Inc., a clinical research service provider. Dr. Thompson previously served as Senior Vice President of Clinical and Regulatory Affairs of Repros Therapeutics, a reproductive health company, from March 2013 to May 2017 and as a member of the board of directors of Repros Therapeutics from November 2009 to March 2013. Dr. Thompson previously served as Senior Vice President of Clinical Development and Regulatory Affairs of Opexa Therapeutics, a multiple sclerosis cell therapy company, from September 2009 to March 2013. In addition, Dr. Thompson has served at clinical stage biotech companies, in various senior clinical and regulatory roles and at inVentiv Clinical Solutions, a clinical research service provider. Dr. Thompson was the president and founder of SYNERGOS, Inc., a clinical research service provider, which was founded in 1991, and acquired by inVentiv Health, as a wholly-owned subsidiary in 2006. Dr. Thompson has advised several of the region's leading life science companies on strategic and regulatory planning as well as clinical product development. She has directed and managed statistical analysis, data management, report writing, and the conduct of clinical trials for a wide variety of indications. Dr. Thompson has been actively involved in over 200 clinical trials for drugs, biologics and devices, and has been associated with numerous FDA regulatory submissions. Dr. Thompson has often represented sponsor companies at FDA meetings and advisory committee meetings, and she was appointed to the Governor's Texas Emerging Technology Fund Advisory Committee. Dr. Thompson received a BS in applied mathematics from Texas A&M University and an MS and a PhD in biostatistics from the University of Texas Health Science Center in Houston.

David McWilliams. David McWilliams has over 40 years of experience in building biopharmaceutical and healthcare companies. Mr. McWilliams has served as a member of our board of directors since February 2009. He previously served as the Chief Executive Officer from February 2010 to June 2016 and Chairman of the board of directors of the Company since February 2009. In addition, since 2008, Mr. McWilliams has served as a consultant and an advisor at various levels in multiple private start-up biotech companies to help develop clinical and pre-clinical assets in cancer and other therapeutic areas. Mr. McWilliams previously served as the Chief Executive Officer and a member of the board of directors of Opexa Therapeutics, Inc., a multiple sclerosis cell therapy company, from 2004 until 2008. Mr. McWilliams also previously served as the Chief Executive Officer, President and a member of the board of directors of Bacterial Barcodes, Inc., a bacteria and fungi diagnostic company, and the Chief Executive Officer and a member of the board of directors of Signase, Inc., a cancer therapeutics company. Mr. McWilliams has also served in various other capacities including Chief Executive Officer, President and a member of the board of directors of both Encysive Pharmaceuticals, Inc. and Repros Therapeutics Inc.; Chief Executive Officer and President of Kallestad Diagnostics (Erbamont); President of Harleco Diagnostics Division (EM Industries); General Manager and Program Manager of Abbott Laboratories; and Management Consultant at McKinsey & Company. In addition to the foregoing, Mr. McWilliams currently serves as the Chairman of the board of directors of BioHouston, an advocate of the life sciences industry in Houston. Mr. McWilliams received a Bachelor of Arts degree in chemistry from Washington and Jefferson College and a Master of Business Administration degree from the University of Chicago. We believe Mr. McWilliams is qualified to serve as a member of our board of directors because of his executive experience, management experience and experience working with biotech companies.

Eric Rothe. Eric Rothe is the founder of the Company and has over 12 years of industry and academic experience in gene-based therapies and vaccines, including six years of laboratory experience. Mr. Rothe previously served as President of the Company from October 2006 to February 2010, Chief Executive Officer of the Company from October 2007 to February 2010 and Chairman of the Company's board of directors from October 2006 to February 2009. In addition, Mr. Rothe has served as a member of the Company's board of directors since August 2006. Since August 2017, Mr. Rothe has served as the Global Product Line Leader at Baker Hughes, an energy technology company. Previously, from September 2014 until its acquisition by GE Oil & Gas' acquisition of Baker Hughes in July 2017, Mr. Rothe served as Vice President of Mid-Continent and NE US Geomarket and Global Product Line Leader of GE Oil & Gas. From 2012 to 2014, Mr. Rothe served as the International Sales and Operations Director at National Oilwell Varco, one of the world's largest oil field equipment providers. Before joining the oil & gas sector, Mr. Rothe was Director of the Clinical Cancer Genetics program at U.T. M.D. Anderson Cancer Center, Project Manager at Introgen, a developer of cancer products in advanced clinical trials, and provided consulting services for start-up/small biotechnology companies in Texas. Mr. Rothe received a Bachelor of Arts degree in molecular and cell biology from the University of California at Berkeley and a Master of Business Administration degree from Rice University. We believe Mr. Rothe is qualified to serve as a member of our board of directors because of his expertise in cancer immunology, GMP manufacturing, and clinical research, and his experience in various senior management positions in global commercial operations at large corporations.

Kenneth Hallock. Kenneth Hallock has over 40 years of experience in general management and new venture start-ups and is a major investor in our Company. Mr. Hallock has served as a member of our board of directors since September 2019. Mr. Hallock is currently a senior manager and partner in a private start-up equipment manufacturing company and has been in this role for over 10 years. Previously, Mr. Hallock worked in large industrial corporations such as NL Industries and Anderson Clayton, which were subsequently acquired. Mr. Hallock received a Bachelor of Engineering degree in chemical engineering from Princeton University and a Master of Business Administration degree from Harvard Business School. We believe Mr. Hallock is qualified to serve as a member of our board of directors because of his experience in various management positions for several Fortune 500 companies.

Family Relationships and Other Arrangements

There are no family relationships among our directors and executive officers. There are no arrangements or understandings between or among our executive officers and directors pursuant to which any director or executive officer was or is to be selected as a director or executive officer.

Board Leadership Structure and Role in Risk Oversight

We have historically separated the roles of Chairman of the board ("Chairman") and Chief Executive Officer. Although the separation of roles has been appropriate for us, in the view of the board, the advisability of the separation of these roles depends upon the specific circumstances and dynamics of our leadership.

The board, as a unified body and through committee participation, organizes the execution of its monitoring and oversight roles and does not expect its Chairman to organize those functions.

The board has three standing committees-Audit, Compensation and Corporate Governance/Nominating. The membership of each of the committees of the board is comprised of independent directors, with each of the committees having a chairman, each of whom is an independent director. Our non-management members of the board meet in executive session at each regular board meeting.

Risk is inherent with every business, and how well a business manages risk can ultimately determine its success. Management is responsible for the day-to-day management of the risks we face, while the board, as a whole and through its committees, has responsibility for the oversight of risk management. In its risk oversight role, the board is responsible for satisfying itself that the risk management processes designed and implemented by management are adequate and functioning as designed.

The board believes that establishing the right "tone at the top" and that full and open communication between executive management and the board are essential for effective risk management and oversight. Our CEO communicates frequently with members of the board to discuss strategy and challenges facing our company. Senior management usually attends our regular quarterly board meetings and is available to address any questions or concerns raised by the board on risk management-related and any other matters. Each quarter, the Board receives presentations from senior management on matters involving our key areas of operations.

Committees of Our Board of Directors

Our board directs the management of our business and affairs, as provided by Delaware law, and conducts its business through meetings of the board and its standing committees. We have a standing audit committee and compensation committee. Our entire board serves in place of a nominating and corporate governance committee. In addition, from time to time, special committees may be established under the direction of the board when necessary to address specific issues.

Audit Committee

Our audit committee is responsible for, among other things:

- approving and retaining the independent auditors to conduct the annual audit of our financial statements;
- reviewing the proposed scope and results of the audit;
- reviewing and pre-approving audit and non-audit fees and services;
- reviewing accounting and financial controls with the independent auditors and our financial and accounting staff;
- reviewing and approving transactions between us and our directors, officers and affiliates;
- establishing procedures for complaints received by us regarding accounting matters;
- overseeing internal audit functions, if any; and
- preparing the report of the audit committee that the rules of the SEC require to be included in our annual meeting proxy statement.

Our audit committee consists of David McWilliams, Eric Rothe and Kenneth Hallock, with David McWilliams serving as chair. Our board of directors has affirmatively determined that David McWilliams, Eric Rothe and Kenneth Hallock each meet the definition of "independent director" under the Nasdaq rules, and that they meet the independence standards under Rule 10A-3. Each member of our audit committee meets the financial literacy requirements of the Nasdaq rules. In addition, our board of directors has determined that David McWilliams qualifies as an "audit committee financial expert," as such term is defined in Item 407(d)(5) of Regulation S-K. Our board of directors adopted a written charter for the audit committee, which is available on our principal corporate website at *www.greenwichlifesciences.com*.

Compensation Committee

Our compensation committee is responsible for, among other things:

- reviewing and recommending the compensation arrangements for management, including the compensation for our president and chief executive officer;
- establishing and reviewing general compensation policies with the objective to attract and retain superior talent, to reward individual performance and to achieve our financial goals;
- administering our stock incentive plans; and
- preparing the report of the compensation committee that the rules of the SEC require to be included in our annual meeting proxy statement.

Our compensation committee consists of David McWilliams, Eric Rothe and Kenneth Hallock, with David McWilliams serving as chair. Our board has determined that David McWilliams, Eric Rothe and Kenneth Hallock are independent directors under Nasdaq rules. Our board of directors adopted a written charter for the compensation committee, which is available on our principal corporate website at *www.greenwichlifesciences.com*.

Nominating and Governance Committee

Although our entire board of directors serves in place of a nominating and corporate governance committee, our independent directors on the board are responsible for, among other things:

- nominating members of the board of directors;
- developing a set of corporate governance principles applicable to our company; and
- overseeing the evaluation of our board of directors.

Our entire board of directors serves in place of a nominating and corporate governance committee. Our board of directors adopted resolutions addressing, among other things, the nomination process.

Code of Business Conduct and Ethics

We have adopted a formal Code of Business Conduct and Ethics applicable to all board members, officers and employees. Our Code of Business Conduct and Ethics can be found on our website (www.greenwichlifesciences.com). A copy of our Code of Business Conduct and Ethics may be obtained without charge upon written request to Secretary, Greenwich LifeSciences, Inc., 3992 Bluebonnet Dr., Building 14, Stafford, TX 77477. If we make any substantive amendments to our Code of Business Conduct and Ethics or grant any waiver from a provision of the Code of Business Conduct and Ethics to any executive officer or director, we will promptly disclose the nature of the amendment or waiver on our website (www.greenwichlifesciences.com) and/or in our public filings with the SEC.

Hedging and Pledging Policies

As part of our Insider Trading Policy, all of our officers, all of our directors, certain of our employees and consultants and family members or others sharing a household with any of the foregoing are prohibited from engaging in short sales of our securities, any hedging or monetization transactions involving our securities and in transactions involving puts, calls or other derivative securities based on our securities. Our Insider Trading Policy further prohibits such persons from purchasing our securities on margin, borrowing against any account in which our securities are held or pledging our securities as collateral for a loan unless pre-cleared by our Insider Trading Compliance Officer. As of April 11, 2025, none of our directors or executive officers had pledged any shares of our common stock.

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ITEM 11. EXECUTIVE COMPENSATION

Summary Compensation Table

The following table presents the compensation awarded to, earned by or paid to each of our named executive officers for the year ended December 31, 2024.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock awards ($)[1]	Total ($)
Snehal Patel, *Chief Executive Officer*	2024	612,563	306,281	5,322,841	6,241,685
	2023	556,875	528,438	1,664,716	2,750,028

(1) For 2024 fiscal year, Mr. Patel received deferred bonus compensation of $306,281 and options to purchase 630,000 shares of common stock for services rendered and as incentive for services to be rendered. For 2023 fiscal year, Mr. Patel received options to purchase 262,181 shares of common stock for services rendered and as incentive for services to be rendered. The options may or may not vest based on certain additional performance milestones.

Outstanding Equity Awards at Fiscal Year-End

The following table provides information regarding awards held by each of our named executive officers that were outstanding as of December 31, 2024.

	Option Awards			
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date
Snehal Patel[1]	132,403	916,320	7.63	June 21, 2032
	100,000	1,048,723	12.16	December 23, 2034

(1) We granted Mr. Patel options to purchase shares of common stock on June 22, 2022 for compensation and incentives to be earned in equal installments over 48 months. Between the 30 month period, June, 22, 2022 to December 31, 2024, Mr. Patel earned 662,006 options which may or may not vest based on certain additional performance milestones and of which 20% is currently vested and exercisable, totaling 132,403 shares, and the balance, or 916,320 options, may or may not vest over the 18 month period commencing on January 1, 2025 or thereafter.

We granted Mr. Patel 100,000 options to purchase shares of common stock on December 24, 2024 for compensation and incentives which vest immediately. We granted Mr. Patel an additional 1,048,723 options to purchase shares of common stock on December 24, 2024 for compensation and incentives of which 25% are earned immediately and the remainder are to be earned in equal installments over 36 months. Between December 24, 2024 to December 31, 2024, Mr. Patel earned 367,819 options which may or may not vest based on certain additional time based milestones of which 100,000 options are currently vested and exercisable, and the balance, or 1,048,723 options, may or may not vest over the 36 month period commencing on January 1, 2025 or thereafter.

Non-Employee Director Compensation

The following table presents the total compensation for each person who served as a non-employee member of our board and received compensation for such service during the fiscal year ended December 31, 2024. Other than as set forth in the table and described more fully below, we did not pay any compensation, make any equity awards or non-equity awards to, or pay any other compensation to any of the non-employee members of our board in 2024.

Name	Fees Earned or Paid in Cash ($)	Stock and Option Awards ($)	All Other Compensation ($)	Total ($)
David McWilliams[1]		255,818		255,818
Eric Rothe[2]		170,650		170,650
Kenneth Hallock[3]		170,650		170,650

(1) We granted Mr. McWilliams options to purchase shares of common stock on June 22, 2022 for compensation and incentives to be earned in equal installments over 48 months of which 15,496 options vested between January 1, 2024 and December 31, 2024 over the 12 month period, and the balance, or 22,856 options, vest over 18 equal monthly installments commencing on January 1, 2025.

We granted Mr. McWilliams options to purchase shares of common stock on December 24, 2024 for compensation and incentives to be earned in equal installments over 36 months of which 15,829 options vested between January 1, 2024 and December 31, 2024 over the 12 month period, and the balance, or 46,155 options, vest over 36 equal monthly installments commencing on January 1, 2025.

(2) We granted Mr. Rothe options to purchase shares of common stock on June 22, 2022 for compensation and incentives to be earned in equal installments over 48 months of which 10,337 options vested between January 1, 2024 and December 31, 2024 over the 12 month period, and the balance, or 15,247 options, vest over 18 equal monthly installments commencing on January 1, 2025.

We granted Mr. Rothe options to purchase shares of common stock on December 24, 2024 for compensation and incentives to be earned in equal installments over 48 months of which 10,559 options vested between January 1, 2024 and December 31, 2024 over the 12 month period, and the balance, or 30,790 options, vest over 36 equal monthly installments commencing on January 1, 2025.

(3) We granted Mr. Hallock options to purchase shares of common stock on June 22, 2022 for compensation and incentives to be earned in equal installments over 48 months of which 10,337 options vested between January 1, 2024 and December 31, 2024 over the 12 month period, and the balance, or 15,247 options, vest over 18 equal monthly installments commencing on January 1, 2025.

We granted Mr. Hallock options to purchase shares of common stock on December 24, 2024 for compensation and incentives to be earned in equal installments over 48 months of which 10,559 options vested between January 1, 2024 and December 31, 2024 over the 12 month period, and the balance, or 30,790 options, vest over 36 equal monthly installments commencing on January 1, 2025.

Employment Agreements

Snehal Patel Employment Agreement

On September 29, 2020, we entered into an employment agreement (the "Employment Agreement") with Snehal Patel, our Chief Executive Officer in connection with our initial public offering (the "IPO"). The term of the Employment Agreement will continue until December 31, 2021 and automatically renews for successive one year periods at the end of each term until either party delivers written notice of their intent not to renew at least 60 days prior to the expiration of the then effective term. Pursuant to the terms of the Employment Agreement, Mr. Patel shall, among other things, (i) receive a base salary of $450,000, subject to increase, (ii) shall be eligible to receive equity grants, (iii) shall be eligible to receive an annual bonus of up to 50% of his then base salary and (iv) shall be eligible to receive a strategic transaction bonus. In addition, Mr. Patel shall also be eligible to participate in all employee welfare and benefit plans and shall receive such other fringe benefits as we offer to our senior executives and directors.

In the event Mr. Patel's employment is terminated by us for Cause (as defined in the Employment Agreement), as a result of Mr. Patel's death or Disability (as defined in the Employment Agreement), voluntarily by Mr. Patel without Good Reason (as defined in the Employment Agreement), or upon expiration of the term, we shall pay Mr. Patel (i) a lump sum amount equal to (A) any unpaid base salary and equity grants then due plus (B) any bonus earned but not paid and (ii) any unpaid expenses (collectively, the "Patel Compensation"). In addition, if Mr. Patel's employment is terminated for death, Disability or as a result of the expiration of the term of the Employment Agreement as a result of the non-renewal of such term by us, we shall pay Mr. Patel any pro-rated bonus for the target year in which the termination occurs. In the event Mr. Patel's employment is terminated by us without Cause or by Mr. Patel for Good Reason, we shall pay Mr. Patel (i) the Patel Compensation, (ii) any pro-rated bonus for the target year in which the termination occurs and (iii) provided that Mr. Patel executes the Release (as defined in the Employment Agreement), (A) the Severance Payment (as defined in the Employment Agreement) and (B) COBRA premiums for twelve months from the date of termination. In the event of Mr. Patel's termination (i) by us without Cause or by Mr. Patel for Good Reason within six months prior to the consummation of a Change of Control (as defined in the Employment Agreement) transaction, if, prior to or as of such termination, a Change of Control transaction was Pending (as defined in the Employment Agreement), at any time during such six month period, (ii) by Mr. Patel for Good Reason at any time within twelve months after the consummation of a Change of Control, or (iii) by us without Cause at any time within twelve months after the consummation of a Change of Control, Mr. Patel shall receive (A) the Patel Compensation, (B) any pro-rated bonus for the target year in which the termination occurs and (C) provided that Mr. Patel executes the Release, (a) a lump sum amount equal to twelve months of Mr. Patel's then base salary and equity grants at the rate in effect as of the date of termination and (b) COBRA premiums for six months from the date of termination. Furthermore, all of the shares that are then unvested shall immediately vest and, all options, warrants and other convertible securities beneficially held by Mr. Patel shall become fully exercisable for (i) a period of six months following the date of termination only if at the time of such termination there is a Change of Control transaction Pending but in no event beyond expiration of the original term of the award or (ii) if clause (i) does not apply, then such period of time set forth in the agreement evidencing the security. The Employment Agreement also contains covenants restricting Mr. Patel from: (i) engaging in any activity competitive with our business during the term of the Employment Agreement and for a period of one year thereafter; and (ii) soliciting our customers, suppliers or employees during the term of the Employment Agreement and for a period of one year thereafter.

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

The following table sets forth certain information regarding the beneficial ownership of our common stock as of April 11, 2025 by:

- each of our named executive officers;
- each of our directors;
- all of our current directors and executive officers as a group; and
- each stockholder known by us to own beneficially more than 5% of our common stock.

Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to the securities. Shares of common stock that may be acquired by an individual or group within 60 days of April 11, 2025, pursuant to the exercise of options or warrants, vesting of common stock or conversion of preferred stock or convertible debt, are deemed to be outstanding for the purpose of computing the percentage ownership of such individual or group, but are not deemed to be outstanding for the purpose of computing the percentage ownership of any other person shown in the table. Percentage of ownership is based on 13,273,539 shares of common stock issued and outstanding as of April 11, 2025.

Except as indicated in footnotes to this table, we believe that the stockholders named in this table have sole voting and investment power with respect to all shares of common stock shown to be beneficially owned by them, based on information provided to us by such stockholders. Unless otherwise indicated, the address for each director and executive officer listed is: c/o Greenwich LifeSciences, Inc., 3992 Bluebonnet Dr, Building 14, Stafford, TX 77477.

Name of Beneficial Owner	Shares of Common Stock Beneficially Owned	Percentage
Executive officers and directors:		
Snehal Patel	5,848,646(1)	41.58%
F. Joseph Daugherty	109,964(2)	*
David McWilliams	690,777(3)	5.19%
Eric Rothe	360,250(4)	2.71%
Kenneth Hallock	444,328(5)	3.34%
All current named executive officers and directors as a group (5) persons	7,453,965	52.29%

* Represents beneficial ownership of less than 1%

(1) Consists of (i) 1,496,604 shares of common stock owned by Snehal Patel, (ii) 1,494,863 shares of common stock owned by Snehal Patel IRA, (iii) 28,600 shares of common stock owned by Snehal Patel 401k (iv) 919,234 shares of common stock owned by Patel Family Trust 1, (v) 743,218 shares of common stock owned by Patel Family Trust 2, (vi) 743,218 shares of common stock owned by Patel Family Trust 3, and (vii) 135,865 shares of common stock owned by Kinnary Patel IRA. Includes 287,044 shares of common stock exercisable upon exercise of vested stock options and stock options that vest within 60 days. Snehal Patel and Kinnary Patel, the spouse of Snehal Patel, are the Trustees of the Patel Family Trust 1, Patel Family Trust 2 and Patel Family Trust 3. Snehal Patel is the Trustee of the Snehal Patel IRA. Kinnary Patel is the Trustee of the Kinnary Patel IRA. In such capacities, Snehal Patel is deemed to hold voting and dispositive power over the securities held by such entities.

(2) Includes 19,831 shares of common stock exercisable upon exercise of vested stock options and stock options that vest within 60 days.

(3) Includes 70,450 shares of common stock exercisable upon exercise of vested stock options and stock options that vest within 60 days.

(4) Includes 46,995 shares of common stock exercisable upon exercise of vested stock options and stock options that vest within 60 days.

(5) Includes 46,995 shares of common stock exercisable upon exercise of vested stock options and stock options that vest within 60 days. Kenneth Hallock and Annette Hallock are the Trustees of the Hallock Trust and in such capacities share voting and dispositive power over the securities held by such entity.

Section 16(A) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our officers and directors, and persons who own more than ten percent of a registered class of our equity securities, to file reports of ownership and changes in ownership with the SEC. Officers, directors and greater than ten percent stockholders are required by SEC regulations to furnish us with copies of all Section 16(a) forms they file.

Based on a review of the copies of such forms received, we believe that during 2024, all filing requirements applicable to our officers, directors and greater than ten percent beneficial owners were complied with.

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

The following includes a summary of transactions since January 1, 2023 to which we have been a party, including transactions in which the amount involved in the transaction exceeds the lesser of $120,000 or 1% of the average of our total assets at year-end for the last two completed fiscal years, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described elsewhere in this Annual Report on Form 10-K. We are not otherwise a party to a current related party transaction, and no transaction is currently proposed, in which the amount of the transaction exceeds the lesser of $120,000 or 1% of the average of our total assets at year-end for the last two completed fiscal years and in which a related person had or will have a direct or indirect material interest.

Related Person Transaction Policy

We adopted a related person transaction policy that sets forth our procedures for the identification, review, consideration and approval or ratification of related person transactions. For purposes of our policy only, a related person transaction is a transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we and any related person are, were or will be participants in which the amount involved exceeds the lesser of $120,000 or 1% of the average of our total assets at year-end. Transactions involving compensation for services provided to us as an employee or director are not covered by this policy. A related person is any executive officer, director or beneficial owner of more than 5% of any class of our voting securities, including any of their immediate family members and any entity owned or controlled by such persons.

Under the policy, if a transaction has been identified as a related person transaction, including any transaction that was not a related person transaction when originally consummated or any transaction that was not initially identified as a related person transaction prior to consummation, our management must present information regarding the related person transaction to our audit committee, or, if audit committee approval would be inappropriate, to another independent body of our board of directors, for review, consideration and approval or ratification. The presentation must include a description of, among other things, the material facts, the interests, direct and indirect, of the related persons, the benefits to us of the transaction and whether the transaction is on terms that are comparable to the terms available to or from, as the case may be, an unrelated third party or to or from employees generally. Under the policy, we will collect information that we deem reasonably necessary from each director, executive officer and, to the extent feasible, significant stockholder to enable us to identify any existing or potential related-person transactions and to effectuate the terms of the policy. In addition, under our code of business conduct and ethics, our employees and directors have an affirmative responsibility to disclose any transaction or relationship that reasonably could be expected to give rise to a conflict of interest. In considering related person transactions, our audit committee, or other independent body of our board of directors, will take into account the relevant available facts and circumstances including, but not limited to:

- the risks, costs and benefits to us;
- the impact on a director's independence in the event that the related person is a director, immediate family member of a director or an entity with which a director is affiliated;
- the availability of other sources for comparable services or products; and
- the terms available to or from, as the case may be, unrelated third parties or to or from employees generally.

The policy requires that, in determining whether to approve, ratify or reject a related person transaction, our audit committee, or other independent body of our board of directors, must consider, in light of known circumstances, whether the transaction is in, or is not inconsistent with, our best interests and those of our stockholders, as our audit committee, or other independent body of our board of directors, determines in the good faith exercise of its discretion.

Director Independence

Our board of directors undertook a review of the independence of our directors and considered whether any director has a relationship with us that could compromise that director's ability to exercise independent judgment in carrying out that director's responsibilities. Our board of directors has affirmatively determined that David McWilliams, Eric Rothe and Kenneth Hallock are each an "independent director," as defined under the Nasdaq rules.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Audit Fees

The aggregate fees billed to us by MaloneBailey, LLP and RBSM, LLP, our independent registered public accounting firms, for the indicated services for each of the last two fiscal years were as follows:

	2024	2023
Audit fees (1)	$ 64,000	$ 69,000
Audit-related fees (2)	$ 88,000	$ 26,000
Tax fees	$ -	$ -
All other fees	$ -	$ -

(1) Audit fees consist of fees for professional services performed by MaloneBailey and RBSM for the audit and review of our financial statements.
(2) Audit-related fees consist of fees for professional services performed by MaloneBailey and RBSM related to the filing of our registration statements, including issuance of comfort letters.

Policy on Audit Committee Pre-Approval of Audit and Permissible Non-Audit Services of Independent Auditors

Consistent with SEC policies and guidelines regarding audit independence, the Audit Committee is responsible for the pre-approval of all audit and permissible non-audit services provided by our independent registered public accounting firm on a case-by-case basis. Our Audit Committee has established a policy regarding approval of all audit and permissible non-audit services provided by our principal accountants. Our Audit Committee pre-approves these services by category and service. Our Audit Committee has pre-approved all of the services provided by our independent registered public accounting firm.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

Exhibit Number	Description of Exhibit
	(a)(1) ***Financial Statements***
	The financial statements required by this item are submitted in a separate section beginning on page F-1 of this Annual Report on Form 10-K.

(b) Exhibits

Exhibit Number	Description
3.1	Second Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to Form 8-K filed on October 1, 2020)
3.2	Second Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to Form 8-K filed on October 1, 2020)
4.1	Form of Underwriter Warrant (incorporated by reference to Exhibit 4.2 to Amendment No. 1 to Form S-1 filed on June 23, 2020)
4.2	Description of the Registrant's securities registered pursuant to Section 12 of the Securities Exchange Act of 1934 (incorporated by reference to Exhibit 4.2 to Form 10-K filed on March 31, 2021).
10.1+	2019 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to Form S-1 filed on May 29, 2020)
10.2	Form of Indemnification Agreement with directors and executive officers (incorporated by reference to Exhibit 10.1 to Form S-1 filed on May 29, 2020)
10.3	Exclusive License Agreement between The Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. and the Company (incorporated by reference to Exhibit 10.3 to Amendment No. 1 to Form S-1 filed on June 23, 2020)
10.4	First Amendment to Exclusive License Agreement between The Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. and the Company (incorporated by reference to Exhibit 10.4 to Amendment No. 1 to Form S-1 filed on June 23, 2020)
10.5	Second Amendment to Exclusive License Agreement between The Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. and the Company (incorporated by reference to Exhibit 10.5 to Amendment No. 1 to Form S-1 filed on June 23, 2020)
10.6	American Arbitration Association Award of Arbitrators (incorporated by reference to Exhibit 10.6 to Amendment No. 1 to Form S-1 filed on June 23, 2020)
10.7+	Employment Agreement between the Company and Snehal Patel dated September 29, 2020 (incorporated by reference to Exhibit 10.1 to Form 8-K filed on October 1, 2020)
10.8	Registration Rights Agreement (incorporated by reference to Exhibit 10.8 to Amendment No. 1 to Form S-1 filed on June 23, 2020)
19.1	Greenwich LifeSciences, Inc. Insider Trading Policy
23.1	Consent of RBSM LLP
24	Power of Attorney (included on signature page hereto).
31.1	Certification of Principal Executive Officer and Principal Financial Officer required under Rule 13a-14(a)/15d-14(a) under the Exchange Act.
32.1	Certification 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.
97	Clawback Policy (incorporated by reference to Exhibit 97.1 to Form 10-K filed on April 15, 2024).
101.INS	Inline XBRL Instance Document.
101.SCH	Inline XBRL Taxonomy Extension Schema.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase.
101.LAB	Inline XBRL Taxonomy Extension Labels Linkbase.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

+ Indicates a management contract or compensatory plan or arrangement.

ITEM 16. FORM 10-K SUMMARY

None.

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SIGNATURES

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

GREENWICH LIFESCIENCES, INC.

/s/ Snehal Patel

April 15, 2025 — Chief Executive Officer (Principal Executive Officer and Principal Accounting and Financial Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Snehal Patel as his or her attorney-in-fact, with full power of substitution and resubstitution, for him or her in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact, or his 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, this Report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

SIGNATURE	TITLE	DATE
/s/ Snehal Patel Snehal Patel	Chief Executive Officer and Director (Principal Executive Officer and Principal Accounting and Financial Officer)	April 15, 2025
/s/ F. Joseph Daugherty F. Joseph Daugherty	Chief Medical Officer and Director	April 15, 2025
/s/ David McWilliams David McWilliams	Director	April 15, 2025
/s/ Eric Rothe Eric Rothe	Director	April 15, 2025
/s/ Kenneth Hallock Kenneth Hallock	Director	April 15, 2025

GREENWICH LIFESCIENCES, INC.

Index to Financial Statements

Texas Office:

7915 FM 1960 West
Suite 220
Houston, TX 77070

www.rbsmllp.com

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors of
Greenwich LifeSciences, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Greenwich LifeSciences, Inc. (the "Company") as of December 31, 2024 and 2023, and the related statements of operations, stockholders' equity and cash flows for the years then ended, 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 as of December 31, 2024 and 2023, and the results of its operations and its cash flows for the years then ended December 31, 2024 and 2023, in conformity with accounting principles generally accepted in the United States of America.

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 recurring losses from operations, limited cash flow, and an accumulated deficit. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustment that might result from the outcome of this uncertainty. Our opinion is not modified with respect to this matter.

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 audit. 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 audit, 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 audit 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 audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ RBSM LLP

We have served as the Company's auditor since 2024.

Houston, Texas
April 15, 2025
PCAOB ID: 587

GREENWICH LIFESCIENCES, INC.
BALANCE SHEETS
AS OF DECEMBER 31, 2024 AND 2023

	2024	2023
Assets		
Current assets		
Cash	$ 4,091,990	$ 6,989,424
Acquired patents, net	1,779	5,391
Total assets	$ 4,093,769	$ 6,994,815
Liabilities and stockholders' deficit		
Current liabilities		
Accounts payable & accrued interest	$ 1,177,536	$ 256,317
Deferred compensation	306,281	
Unreimbursed expenses	75,916	38,089
Total current liabilities	1,559,733	294,406
Total liabilities	1,559,733	294,406
Stockholders' equity		
Common stock, $0.001 par value; 100,000,000 shares authorized; 13,152,729 and 12,848,165 shares issued and outstanding as of December 31, 2024 and December 31, 2023, respectively	13,153	12,848
Additional paid-in capital	68,674,261	57,052,130
Accumulated deficit	(66,153,378)	(50,364,569)
Total stockholders' equity	2,534,036	6,700,409
Total liabilities and stockholders' equity	$ 4,093,769	$ 6,994,815

See accompanying notes to financial statements.

GREENWICH LIFESCIENCES, INC.
STATEMENTS OF OPERATIONS
FOR THE YEARS ENDED DECEMBER 31, 2024 AND 2023

	2024	2023
Revenue	$ —	$ —
Operating expenses		
Research and development	12,952,029	7,698,622
General and administrative	3,059,788	1,629,244
Total operating expenses	16,011,817	9,327,866
Loss from operations	(16,011,817)	(9,327,866)
Interest income	223,008	436,063
Net loss	$ (15,788,809)	$ (8,891,803)
Per share information:		
Net loss per common share, basic and diluted	$ (1.21)	$ (0.69)
Weighted average common shares outstanding, basic and diluted	13,014,585	12,848,165

See accompanying notes to financial statements.

GREENWICH LIFESCIENCES, INC.
STATEMENTS OF STOCKHOLDERS' EQUITY
FOR THE YEARS ENDED DECEMBER 31, 2024 AND 2023

	Common Stock		Additional		Total
	Shares	Par Amount	Paid-in Capital	Accumulated Deficit	Stockholders' Equity
Balances, December 31, 2022	12,848,165	$ 12,848	$ 54,674,042	$ (41,472,766)	$ 13,214,124
Stock-based compensation	—	—	2,378,088	—	2,378,088
Net loss				(8,891,803)	(8,891,803)
Balances, December 31, 2023	12,848,165	$ 12,848	$ 57,052,130	$ (50,364,569)	$ 6,700,409
Stock-based compensation	—	—	7,253,327	—	7,253,327
Sale of common stock via ATM program, net of costs	129,739	130	1,868,981	—	1,869,111
Sale of common stock via Private Placement, net of costs	174,825	175	2,499,823	—	2,499,998
Net loss				(15,788,809)	(15,788,809)
Balances, December 31, 2024	13,152,729	$ 13,153	$ 68,674,261	$ (66,153,378)	$ 2,534,036

See accompanying notes to financial statements.

GREENWICH LIFESCIENCES, INC.
STATEMENTS OF CASH FLOWS
FOR THE YEARS ENDED DECEMBER 31, 2024 AND 2023

	2024	2023
Operating activities:		
Net loss	$ (15,788,809)	$ (8,891,803)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Amortization	3,612	3,612
Stock-based compensation	7,253,327	2,378,088
Changes in operating assets and liabilities:		
Accounts payable	921,219	35,472
Deferred compensation	306,281	
Unreimbursed expenses (accrued)	37,827	(3,971)
Net cash used in operating activities	(7,266,543)	(6,478,602)
Financing activities:		
Sale of common stock via ATM program, net of costs	1,869,111	
Sale of common stock via Private Placement, net of costs	2,499,998	—
Net cash provided by (used in) financing activities	4,369,109	—
Net increase (decrease) in cash	(2,897,434)	(6,478,602)
Cash, beginning of period	6,989,424	13,468,026
Cash, end of period	$ 4,091,990	$ 6,989,424

See accompanying notes to financial statements.

GREENWICH LIFESCIENCES, INC.
NOTES TO FINANCIAL STATEMENTS

1. Organization and Description of the Business

Greenwich LifeSciences, Inc. (the "Company") was incorporated in the state of Delaware in 2006 under the name Norwell, Inc. In March 2018, Norwell, Inc. changed its name to Greenwich LifeSciences, Inc. In February 2023, Greenwich LifeSciences Europe Limited was incorporated as a wholly owned subsidiary in Ireland. The Company is developing a breast cancer immunotherapy focused on preventing the recurrence of breast cancer following surgery.

2. Going Concern

The Company has prepared its financial statements on a going concern basis, which assumes that the Company will realize its assets and satisfy its liabilities in the normal course of business. However, the Company has incurred net losses since its inception and has negative operating cash flows. These circumstances raise substantial doubt about the Company's ability to continue as a going concern. The accompanying financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from the outcome of the uncertainty concerning the Company's ability to continue as a going concern.

As of December 31, 2024, the Company had cash of $4,091,990. For the foreseeable future, the Company's ability to continue its operations is dependent upon its ability to obtain additional capital.

3. Significant Accounting Policies

Basis of Presentation

The accompanying financial statements are presented in conformity with accounting principles generally accepted in the U.S. ("GAAP") and pursuant to the rules and regulations of US Securities and Exchange Commission ("SEC").

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in its financial statements and accompanying notes. On an ongoing basis, management evaluates these estimates and judgments, which are based on historical and anticipated results and trends and on various other assumptions that management believes to be reasonable under the circumstances. By their nature, estimates are subject to an inherent degree of uncertainty and, as such, actual results may differ from management's estimates.

Cash

Cash consists primarily of deposits with commercial banks and financial institutions. These cash deposits exceed the insured limits at individual banks and financial institutions.

Impairment of Long-Lived Assets

The Company reviews long-lived assets for impairment when events or changes in circumstances indicate the carrying value of the assets may not be recoverable. Recoverability is measured by comparison of the book values of the assets to future net undiscounted cash flows that the assets or the asset groups are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the book value of the assets exceed their fair value, which is measured based on the estimated discounted future net cash flows arising from the assets or asset groups. No impairment losses on long-lived assets have been recorded through December 31, 2024.

Leases

In February 2016, the FASB issued Accounting Standards Update ("ASU") No. 2016-02-Leases (Topic 842), which significantly amends the way companies are required to account for leases. Under the updated leasing guidance, some leases that did not have to be reported previously are now required to be presented as an asset and liability on the balance sheet. In addition, for certain leases, what was previously classified as an operating expense must now be allocated between amortization expense and interest expense. The Company elected to adopt this update using the modified retrospective transition method and prior periods have not been restated. The current monthly rent is approximately $2,819. The month-to-month sub-lease is from a related party and the underlying lease expires in July of 2026. The Company has elected the practical expedient to not record right of use asset and lease obligation liability for leases with terms of less than 12 months.

Stock-Based Compensation

Compensation expense related to warrants and stock granted to employees and non-employees is measured at the grant date based on the estimated fair value of the award and is recognized on a straight-line basis over the requisite service period in the Company's statements of income. Forfeitures are recognized as a reduction of stock-based compensation expense as they occur. Accounting guidance requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The Company has limited historical experience with forfeitures and were based on management's estimates. Stock-based compensation expense for an award with a performance condition is recognized when the achievement of such performance condition is determined to be probable. If the outcome of such performance condition is not determined to be probable or is not met, no compensation expense is recognized and any previously recognized compensation expense is reversed.

GREENWICH LIFESCIENCES, INC.
NOTES TO FINANCIAL STATEMENTS

Research and Development Costs

Research and development expenses are charged to operations as incurred. Research and development expenses include, among other things, salaries, costs of outside collaborators and outside services, and supplies.

Income Taxes

The Company's income tax returns are based on calculations and assumptions that are subject to examination by the Internal Revenue Service and other tax authorities. In addition, the calculation of tax liabilities involves dealing with uncertainties in the application of complex tax regulations.

Basic and Diluted Loss per Share

The Company computes loss per share in accordance with Accounting Standards Codification ("ASC") 260 — Earnings per Share. ASC 260 requires presentation of both basic and diluted earnings per share ("EPS") on the face of the statements of operations. Basic EPS is computed by dividing net loss available to common shareholders (numerator) by the weighted average number of common shares outstanding (denominator) during the period. Diluted EPS gives effect to all dilutive potential common shares outstanding during the period using the treasury stock method and convertible notes payable using the if-converted method. Diluted EPS excludes all dilutive potential shares if their effect is antidilutive. During periods of net loss, all common stock equivalents are excluded from the diluted EPS calculation because they are antidilutive.

As of December 31, 2024 and 2023, the Company had common stock equivalents related to warrants outstanding to acquire 20,174 shares of the Company's common stock.

As of December 31, 2024 and 2023, the Company had common stock equivalents related to options outstanding to acquire 3,126,065 and 1,498,128 shares of the Company's common stock, respectively.

As of December 31, 2024 and 2023, the Company has no common stock equivalents related to convertible preferred stock issued and outstanding.

Convertible Debt and Convertible Preferred Stock

In January 2021, the Company early adopted ASU 2020-06 Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging — Contracts in Entity's Own Equity (Subtopic 815-40). ASU 2020-06 simplifies the accounting for convertible debt instruments and convertible preferred stock by reducing the number of accounting models and limiting the number of embedded conversion features separately recognized from the primary contract. The guidance also includes targeted improvements to the disclosures for convertible instruments and earnings per share. ASU 2020-06 is effective for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020. The adoption of ASU 2020-06 did not have a material impact on the Company's financial statements.

Recently Adopted Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13, Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments. The main objective of the standard is to provide financial statement users with more decision-useful information about the expected credit losses on financial instruments and other commitments to extend credit held by a reporting entity at each reporting date. To achieve this objective, the amendments in this standard replace the incurred loss impairment methodology in current GAAP with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. The update is effective for the Company beginning January 1, 2023 with early adoption permitted. The Company adopted the standard on January 1, 2023. The adoption of this standard did not have a material effect on the Company's audited consolidated financial statements and related disclosures.

Recently Issued Accounting Pronouncements Not Yet Adopted

In *July 2023,* the FASB issued ASU *No 2023-03,* "Presentation of Financial Statements (Topic *205*), Income Statement—Reporting Comprehensive Income (Topic *220*), Distinguishing Liabilities from Equity (Topic *480*), Equity (Topic *505*), and Compensation—Stock Compensation (Topic *718*)" pursuant to SEC Staff Accounting Bulletin *No. 120,* which adds interpretive guidance for public companies to consider when entering into share-based payment transactions while in possession of material non-public information. The effective date of this update is for fiscal years beginning after *December 15, 2023,* including interim periods within those fiscal years. The Company does *not* expect the adoption to have a material impact on our consolidated financial statements.

In October 2023, the FASB issued ASU 2023-06—Codification Amendments in Response to the SEC's Disclosure Update and Simplification Initiative. The main objective of the amendment is to modify the disclosure or presentation requirements of various Topics in the Codification. Certain amendments represent clarifications to or technical corrections of the current requirements. to eliminate disclosure requirements that were redundant, duplicative, overlapping, outdated, or superseded. The effective date for each amendment will be when the SEC's removal of that related disclosure from Regulation S-X or Regulation S-K becomes effective, with early adoption prohibited. The Company is still evaluating the impact of the adoption of this standard.

4. Related Party Transactions

Unreimbursed expenses have been accrued and incurred by management, which total $75,916 as of December 31, 2024 and $38,089 as of December 31, 2023.

Bonus compensation of $306,281 for senior management for services provided in 2024 has been deferred.

On June 13, 2024, the Company completed a private placement offering pursuant to which it issued and sold 174,825 shares of its common stock at a price of $14.30 per share to Snehal Patel, the Company's Chief Executive Officer and director, for net proceeds of $2,499,998. Mr. Patel agreed to a one year lock-up agreement with respect to his shares of common stock acquired in the offering.

GREENWICH LIFESCIENCES, INC.
NOTES TO FINANCIAL STATEMENTS

5. Income Taxes

Significant components of the Company's deferred tax assets and liabilities were as follows:

	December 31,	
	2024	**2023**
Deferred tax assets:		
Net operating loss carryforwards	6,297,696	4,505,244
Valuation allowance	(6,297,696)	(4,505,244)
Total deferred tax assets	—	—

The federal income tax rate used for 2024 and 2023 was 21%. At December 31, 2024, the Company had federal net operating loss ("NOL") carryforwards of approximately $30.0 million that will expire in tax years up through 2037. The NOLs generated in tax years 2018 and forward will carry forward indefinitely, but the deductibility of such federal net operating losses is limited. The NOL and tax credit carryforwards may be further subject to the application of Section 382 of the Internal Revenue Code of 1986, as amended (the "Code"), as discussed further below. The Company has provided a valuation allowance to offset the deferred tax assets due to the uncertainty of realizing the benefits of the net deferred tax asset.

The Company's issuances of common and preferred stock may have resulted in ownership changes as defined by Section 382 of the Code. The Company has not conducted a Section 382 study to date. It is possible that a future analysis may result in the conclusion that a portion of the Company's NOL carryforwards and R&D tax credit carryforwards will be limited due to Sections 382 and 383 of the Code.

The Company is subject to U.S. federal tax examinations by tax authorities for the years 2010 to 2009 due to the fact that NOL carryforwards exist going back to 2010 that may be utilized on a current or future year tax return.

6. Commitments and Contingencies

License Obligation, Legal Expenses, and Manufacturing Agreements

The Company entered into an exclusive license agreement with The Henry M. Jackson Foundation ("HJF") in April 2009, as amended, pursuant to which it acquired exclusive marketing rights to GP2, the Company's product candidate. In consideration for such licensed rights, the Company issued HJF 202,619 shares of the Company's common stock valued at $0.267 per share, which is amortized over 15 years at $3,607 per year. Pursuant to the exclusive license agreement, the Company is required to pay an annual maintenance fee, milestone payments and royalty payments based on sales of GP2 and to reimburse HJF for patent expenses related to GP2. The Company currently depends on third-party contract manufacturers for all required raw materials, active pharmaceutical ingredients, and finished product candidate for the Company's clinical trials.

Accounts payable includes accrued interest which totals $220,845 as of December 31, 2024 and 2023.

GREENWICH LIFESCIENCES, INC.
NOTES TO FINANCIAL STATEMENTS

Deferred Compensation

Bonus compensation of $306,281 for senior management for services provided in 2024 has been deferred.

Legal Proceedings

From time to time, the Company may be involved in disputes, including litigation, relating to claims arising out of operations in the normal course of business. Any of these claims could subject the Company to costly legal expenses and, while management generally believes that there will be adequate insurance to cover different liabilities at such time the Company becomes a public company and commences clinical trials, the Company's future insurance carriers may deny coverage or policy limits may be inadequate to fully satisfy any damage awards or settlements. If this were to happen, the payment of any such awards could have a material adverse effect on the results of operations and financial position. Additionally, any such claims, whether or not successful, could damage the Company's reputation and business. The Company is currently not a party to any legal proceedings, the adverse outcome of which, in management's opinion, individually or in the aggregate, could have a material adverse effect on our results of operations or financial position.

7. Stockholders' Equity

On September 30, 2019, the board of directors and stockholders of the Company adopted the Greenwich LifeSciences, Inc. 2019 Equity Incentive Plan setting aside and reserving 1.5 million shares of common stock without any issuance of common stock or options under the plan. On December 19, 2024, the board of directors and stockholders of the Company amended the Greenwich LifeSciences, Inc. 2019 Equity Incentive Plan setting aside and reserving an additional 2.5 million shares of common stock for a total of 4 million shares of common stock (the "2024 Amended Equity Incentive Plan").

As of December 31, 2024 and 2023, 893,181 shares of the 908,362 shares of the common stock grant, which includes an additional grant of 120 shares issued during the vesting period due to rounding up of fractional shares, had vested at approximately $2,009,657 value and 15,181 shares remain unvested and unrecognized at approximately $34,157 value. In 2024 and 2023, no shares of common stock grant vested.

On January 23, 2022, the board of directors authorized the Company's management to implement a stock repurchase program for up to $10 million of the Company's common stock at any time. The term of the board of directors authorization of the repurchase program is until March 31, 2023. The repurchase program may be suspended or discontinued at any time and will be funded using the Company's working capital. As of December 31, 2023, approximately 519,828 shares of the Company's common stock has been repurchased and cancelled at an aggregate purchase price, including all transactions costs, of approximately $7,536,216.

On January 23, 2022, November 30, 2022, November 17, 2023, and March 12, 2024, the board of directors sequentially extended the lock-up of the shares owned by the Company's directors, officers, and existing pre-IPO investors to June 30, 2025 (approximately 57 months from date of the Company's IPO). During this period, current officers, directors and certain shareholders will not be able to sell their shares of the Company's common stock unless otherwise modified by the board of directors. After June 30, 2025, leak-out provisions will become effective unless otherwise modified by the board of directors.

Between January 1, 2024 and December 31, 2024, the Company sold shares of its common stock pursuant to its ATM agreement with Jefferies and H.C. Wainwright, in which it issued and sold a total of 129,739 shares of its common stock at an average offering price of $15.92 per share for gross proceeds of $2,065,366 and net proceeds of $1,869,111, after deducting underwriting discounts and commissions and offering expenses borne by the Company, which totaled $196,257.

On June 22, 2020, the Company filed an amendment to its Amended and Restated Certificate of Incorporation, as amended (the "Certificate of Incorporation"), to effectuate a 1-for-2.67 reverse stock split of the Company's issued and outstanding common and preferred stock. No fractional shares were issued and any fractional shares resulting from the stock split were rounded up to the nearest whole share. All common and preferred stock share and per-share data and conversion or exercise price data for applicable common stock equivalents included in these financial statements have been retroactively adjusted to reflect the reverse stock split.

GREENWICH LIFESCIENCES, INC.
NOTES TO FINANCIAL STATEMENTS

Initial Public Offering (IPO)

On September 25, 2020, the Company completed its initial public offering (the "IPO") pursuant to which it issued and sold 1,260,870 shares of its common stock at a public offering price of $5.75 per share for gross proceeds of $7,250,002 and net proceeds of $6,207,502, after deducting underwriting discounts and commissions and offering expenses borne by the Company, which totaled $1,042,500. In addition, the Company granted the underwriters a 45-day option to purchase up to 189,130 additional shares of common stock at the public offering price, less offering expenses, to cover over-allotments, if any.

On September 29, 2020, in connection with the completion of the IPO, the Company converted all of the outstanding shares of Series A Preferred Stock into an aggregate of 1,520,937 shares of common stock, all of the outstanding shares of Series B Preferred Stock into an aggregate of 129,267 shares of common stock, all of the outstanding shares of Series C Preferred Stock into an aggregate of 66,575 shares of common stock and all of the outstanding shares of Series D Preferred Stock into an aggregate of 305,990 shares of common stock upon the closing of the IPO, which included the issuance of an aggregate of 42,404 additional shares of common stock upon the issuance and conversion of an additional 42,404 shares of Series D Preferred Stock issuable in connection with the IPO as a result of the anti-dilution protection set forth in the Company's Certificate of Incorporation; based upon the IPO price of $5.75 per share.

On September 29, 2020, in connection with the completion of the IPO, the board and stockholders of the Company approved the Company's Second Amended and Restated Bylaws and the filing of the Company's Second Amended and Restated Certificate of Incorporation with the Delaware Secretary of State which authorizes the Company to issue 100,000,000 shares of common stock with a par value of $0.001 per share and 10,000,000 shares of preferred stock with a par value of $0.001 per share. In addition, on September 29, 2020, the Company entered into an employment agreement with Snehal Patel pursuant to which Mr. Patel will serve as the Company's Chief Executive Officer as described in the Company Current Report on Form 8-K filed with the SEC on October 1, 2020.

Follow-On Offering

On December 22, 2020, the Company completed a follow-on offering pursuant to which it issued and sold 660,000 shares of its common stock at a public offering price of $40.00 per share for gross proceeds of $26,400,000 and net proceeds of $23,959,000, after deducting underwriting discounts and commissions and offering expenses borne by the Company, which totaled $2,441,000. In addition, the Company granted the underwriters a 45-day option to purchase up to 99,000 additional shares of common stock at the public offering price, less offering expenses, to cover over-allotments, if any.

On January 29, 2021, the underwriter exercised its option to purchase 70,000 additional shares of common stock at the public offering price of $40.00 per share for gross proceeds of $2,800,000 and net proceeds of $2,548,000, after deducting underwriting discounts and commissions and offering expenses borne by the Company, which totaled $252,000.

GREENWICH LIFESCIENCES, INC.
NOTES TO FINANCIAL STATEMENTS

Warrants

Prior to the IPO, there were no outstanding warrants to purchase shares of common stock accounted for as equity or liabilities.

On September 25, 2020, in connection with the IPO, the underwriter, Aegis Capital Corp., was issued a warrant to purchase 100,870 shares of common stock, representing 8% of the number of shares sold in the IPO, excluding the over-allotment option. The warrants will be exercisable at any time and from time to time, in whole or in part, during a period commencing March 24, 2021 and expiring September 24, 2025. The warrants will be exercisable at a price equal to $7.1875 per share, which represents 125% of the public offering price per share of common stock sold in the IPO. In the event that a registration statement registering the common stock underlying the warrants is not effective, the warrants may be exercised on a cashless basis. If the warrants are exercised for cash within the first six months of the period in which they are exercisable, the exercise price will be equal to 97% of 125% of the public offering price or $6.9718 per share.

On October 19, 2021, the underwriter warrants were partially exercised resulting in the issuance of 80,696 shares of common stock and gross proceeds to the Company of $562,596.

At December 31, 2024, outstanding warrants to purchase shares of common stock accounted for as equity or liabilities were as follows with an aggregate intrinsic value as of December 31, 2024 of $81,553 based on the December 31, 2024 closing share price of $11.23:

Shares Underlying Outstanding Warrants	Exercise Price[1]	Expiration Date[1]
20,174	$ 7.1875	September 24, 2025
20,174		

(1) The warrants are exercisable at any time and from time to time, in whole or in part, during a period commencing March 24, 2021 and expiring September 24, 2025. The exercise price of the warrants is $7.1875 per share or $6.9718 per share if the warrants are exercised for cash within the first six months of the period in which they are exercisable.

Options

On June 22, 2022, prior to the close of the Nasdaq market, 1,498,128 shares of common stock were granted to employees, consultants, and directors issuable upon exercise of outstanding stock options under the Company's 2019 Equity Incentive Plan at an exercise price of $7.63 per share, which was the most recent prior closing share price on June 21, 2022. The options had a fair value on the grant date of $9,512,356, based on a risk-free rate of 3.2% and an annualized volatility of 106%, of which $6,004,672 was expensed through December 31, 2024 and $3,507,684 will be expensed in the future if and as vesting occurs. Vesting will be based on time of service over a four year period and certain additional performance milestones for senior management, primarily related to the Phase III clinical trial.

On December 24, 2024, prior to the close of the Nasdaq market, 1,627,937 shares of common stock were granted to employees, consultants, and directors issuable upon exercise of outstanding stock options under the Company's Amended 2024 Equity Incentive Plan at an exercise price of $12.16 per share, which was the most recent prior closing share price on December 23, 2024. The options had a fair value on the grant date of $16,190,565, based on a risk-free rate of 4.5% and an annualized volatility of 103%, of which $4,875,239 was expensed through December 31, 2024 and $11,315,326 will be expensed in the future if and as vesting occurs. Vesting will consist of 100,000 shares vesting upfront on December 24, 2024 and of the remaining shares, 25% vesting upfront on December 24, 2024 and 75% vesting based on time of service over a three year period with certain additional retention milestones for senior management.

Private Placement

On June 13, 2024, prior to the close of the Nasdaq market, the Company completed a private placement offering pursuant to which it issued and sold 174,825 shares of its common stock at a price of $14.30 per share, which was the most recent prior closing share price on June 12, 2024, to Snehal Patel, the Company's Chief Executive Officer and director, for net proceeds of $2,499,998. No investment banking fees were paid in connection with the offering. Mr. Patel agreed to a one year lock-up agreement with respect to his shares of common stock acquired in the offering.

8. 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 ("CODM") in deciding how to allocate resources and in assessing performance. The Company's CODM is the Chief Executive Officer. The Company views its operations and manages its business as one operating segment, which includes all activities related to its clinical development programs. The determination of a single reportable segment is consistent with the financial information provided to the CODM. The CODM views and manages the Company's clinical development programs as a single reportable segment for which all operations are centralized and does not evaluate any other discrete financial information. The accounting policies of the Company's single reportable segment are the same as those for the financial statements.

Segment loss is measured as the Company's net loss as reported on the statement of operations, which includes segment expenses such as research and development and general and administrative expenses and other segment items such as interest expense. As the Company does not currently generate revenues or profit, the CODM evaluates performance, makes decisions, allocates resources, and plans future activities through analysis of segment expense information. The CODM also monitors the Company's cash and cash equivalents and net cash used in operations as reported on the balance sheet and the statement of cash flows, respectively. The measure of total segment assets is reported on the balance sheet as total assets.

9. Subsequent Events

The Company has evaluated events through, April 15, 2025, the filing date of this Annual Report on Form 10-K, and determined that there have been no subsequent events that occurred that would require adjustments to our disclosures in the financial statements, other than the following:

Between January 1, 2025 and April 11, 2025, the Company completed At The Market ("ATM") offerings pursuant to its ATM agreement with H. C. Wainwright, in which it issued and sold a total of 120,810 shares of its common stock at an average offering price of $10.42 per share for gross proceeds of $1,259,198 and net proceeds of $1,232,026, after deducting underwriting discounts and commissions and offering expenses borne by the Company, which totaled $27,172.

On March 2, 2025, the board of directors further extended the lock-up of the shares owned by the Company's directors, officers, and existing pre-IPO investors to March 31, 2026 (approximately 66 months from date of the Company's IPO). During this period, current officers, directors and certain shareholders will not be able to sell their shares of the Company's common stock unless otherwise modified by the board of directors. After March 31, 2026, the quantity of these locked-up shares that can be sold daily and over various periods of time will be restricted unless otherwise modified by the board of directors.