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

FORM 10-K

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

For the fiscal year ended December 31, 2022

OR

☐ **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 001-41599

GENELUX CORPORATION
(Exact name of registrant as specified in its charter)

Delaware	**77-0583529**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

2625 Townsgate Road Suite 230
Westlake Village CA 91361
(Address of principal executive offices)
(Zip Code)

(805) 267-9889
(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, par value $0.001 per share	**GNLX**	**The Nasdaq Stock Market LLC (Nasdaq Capital Market)**

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

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

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

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

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

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

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

Emerging growth company ☒

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

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

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 Common Stock held by non-affiliates of the registrant was approximately $505.1 million, based on the closing price of the registrant's Common Stock on March 27, 2023.

There were 24,553,470 shares of Common Stock outstanding as of March 27, 2023.

DOCUMENTS INCORPORATED BY REFERENCE

Part III of this Annual Report on Form 10-K incorporates by reference certain information from the registrant's definitive Proxy Statement for its 2023 annual meeting of stockholders, which the registrant intends to file pursuant to Regulation 14A within 120 days of the end of the fiscal year ended December 31, 2022 (the 2023 Proxy Statement). Except with respect to information specifically incorporated by reference in this Form 10-K, the 2023 Proxy Statement is not deemed to be filed as part of this Form 10-K.

GENELUX CORPORATION
ANNUAL REPORT ON FORM 10-K
For the Year Ended December 31, 2022

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (this Annual Report) contains forward-looking statements within the meaning of the federal securities laws made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical facts contained in this Annual Report, including statements regarding our future results of operations and financial position, business strategy, research and development costs; the anticipated timing, costs and conduct of our clinical trials for our only product candidate, Olvi-Vec; the timing and likelihood of regulatory filings and approvals for Olvi-Vec; our ability to commercialize Olvi-Vec, if approved; the pricing and reimbursement of Olvi-Vec, if approved; the potential benefits of strategic collaborations and our ability to enter into strategic arrangements; the timing and likelihood of success, plans and objectives of management for future operations; future results of anticipated product development efforts; and our expected future financing needs, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplates,” “believes,” “estimates,” “predicts,” “potential” or “continue” or the negative of these terms or other similar expressions. The forward-looking statements in this Annual Report are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Annual Report and are subject to a number of risks, uncertainties and assumptions described under the sections titled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this Annual Report. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. Except as required by applicable law, we undertake no obligation to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. You should, however, review the factors and risks we describe in the reports we will file from time to time with the Securities and Exchange Commission (the SEC) after the date of this Annual Report.

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based on information available to us as of the date of this Annual Report, and while we believe such information provides a reasonable basis for these statements, such information may be limited or incomplete. Our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and you are cautioned not to unduly rely on these statements.

SUMMARY OF RISKS ASSOCIATED WITH OUR BUSINESS

We face risks and uncertainties associated with our business, many of which are beyond our control. Some of the material risks associated with our business include the following:

- We have incurred significant losses since our inception and anticipate that we will incur significant and increasing losses for the foreseeable future and we may never achieve or maintain profitability.
- We will require substantial additional financing to advance the development of our product candidates, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital could force us to delay, limit, reduce or terminate our product development programs, potential commercialization efforts or other operations.
- Our product candidates are in preclinical and clinical stages of development, are not approved for commercial sale and might never receive regulatory approval or become commercially viable.
- Our product candidates are based on a novel approach to the treatment of cancer, which makes it difficult to predict the time and cost of product candidate development.

- We currently have only one product candidate, Olvi-Vec, in clinical development. A failure of this product candidate in clinical development would adversely affect our business and may require us to discontinue development of other product candidates based on the same therapeutic approach.
- Preclinical and clinical development involve a lengthy and expensive process with an uncertain outcome and stringent regulations, and delays can occur for a variety of reasons.
- Changes in product candidate manufacturing or formulation may result in additional costs or delay.
- If we are unable to manufacture and release any product candidates in the volumes that we require on a timely basis, or fail to comply with stringent regulations applicable to biopharmaceutical manufacturers, we may face delays in the development and commercialization of, or be unable to meet demand for, any product candidates and may lose potential revenues.
- If we fail to comply with federal and state healthcare laws, including fraud and abuse laws, we could face substantial penalties and our business, financial condition, results of operations, stock price and prospects will be materially harmed.
- We are subject to stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse business consequences.
- If we are unable to obtain, maintain and protect our intellectual property rights for our technology and product candidates, or if our intellectual property rights are inadequate, our competitive position could be harmed.
- We are highly dependent on our key personnel, including our President, Chief Executive Officer and Chairman. If we are not successful in attracting, motivating and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.
- Unfavorable market and economic conditions may have serious adverse consequences on our business, financial condition, results of operations, stock price and prospects.
- Public health crises such as pandemics, including the COVID-19 pandemic, or similar outbreaks could materially and adversely affect our preclinical studies and clinical trials, business, financial condition and results of operations.
- The market price of our common stock has been extremely volatile and may continue to be volatile due to numerous circumstances beyond our control, which could result in substantial losses for our stockholders.

PART I

Item 1. Business

Overview

Genelux is a late clinical-stage biopharmaceutical company focused on developing a pipeline of next-generation oncolytic viral immunotherapies for patients suffering from aggressive and/or difficult-to-treat solid tumor types. Our most advanced product candidate, Olvi-Vec (olvimulogene nanivacirepvec), is a proprietary, modified strain of the vaccinia virus (VACV), a stable DNA virus with a large engineering capacity. We have met the preestablished endpoint for our Phase 2 clinical trial of Olvi-Vec in platinum resistant/refractory ovarian cancer (PRROC). Employing our proprietary selection technology and discovery and development platform (CHOICE), we have developed an extensive library of isolated and engineered oncolytic VACV immunotherapeutic product candidates. These provide potential utility in multiple tumor types in both the monotherapy and combination therapy settings, via physician- preferred administration techniques, including regional (e.g., intraperitoneal), local and systemic (e.g., intravenous) delivery routes. Informed by our CHOICE platform and supported by extensive clinical and preclinical data, we believe we have the capacity to develop a pipeline of treatment options to address high unmet medical needs for those patients with insignificant or unsatisfactory responses to standard- of-care therapies, including chemotherapies. From this library, we selected Olvi-Vec, which we believe has the potential to exhibit anti-tumor properties, including potent oncolytic properties (tumor cell lysis), and to activate both the innate and adaptive arms of the immune system, to produce favorable changes within the tumor microenvironment. The personalized and multi-modal immune activation generated by Olvi-Vec is designed with the goal to yield clinically-meaningful anti-tumor responses to virus treatment alone and in combination with other existing treatment modalities. We believe Olvi-Vec currently represents the most advanced clinical development program throughout the oncolytic treatment landscape involving the non-local administration (i.e., non-intratumorally) of viral immunotherapies.

In September 2019, we completed enrollment of a single-arm, open-label Phase 1b/2 clinical trial of Olvi-Vec in heavily pre-treated patients with PRROC. To date, the data from this trial suggests systemic anti- tumor responses to monotherapy and documented clinical responses to subsequent chemotherapy. Furthermore, no dose-limiting toxicity (DLT) or maximum tolerated dose (MTD) were reached and the most common observed adverse events were flu-like symptoms and abdominal pain. In November 2015, we completed an open- label Phase 1 clinical trial of Olvi-Vec in patients with documented progressive disease (PD) (i.e., Stage IV cancers). Our data from this study indicate changes in tumor growth rate post-Olvi-Vec treatment and that Olvi-Vec may have utility against a variety of cancers, particularly those diagnosed with lung diseases, including non-small-cell lung cancer (NSCLC). Furthermore, no MTD was reached and the intravenous administration of Olvi-Vec appeared well tolerated. Additionally, we completed an open-label, non-randomized Phase 1 clinical trial of Olvi-Vec in patients with solid organ cancers. Our data from this study indicated high and condensed intravenous doses of Olvi-Vec resulted in endured viral pharmacokinetics (PK) in the blood, and led to infection of and immune cell infiltration into tumor tissues.

Based on our clinical trial results and discussions with the U.S. Food and Drug Administration (FDA), we formally submitted our protocol to our Phase 3 registration clinical trial of Olvi-Vec in PRROC in January 2022 and made minor clarifying revisions in a protocol amendment in May 2022. We also submitted two amendments to our Investigational New Drug (IND) application in 2021 for our new in-house manufacturing process seeking to demonstrate comparability of product manufactured under our new in-house process to product used in our Phase 2 clinical trial of Olvi-Vec in PRROC. We responded to FDA comments regarding the manufacturing amendment in December 2021 and in February 2022. In July 2022, we received and responded to additional FDA comments regarding an assay used in our clinical trial. Our Phase 3 registration clinical trial of Olvi-Vec in PRROC initiated enrollment in the third quarter of 2022.

In September 2021, we entered into a License Agreement (the Newsoara License) with Newsoara BioPharma Co. Ltd. (Newsoara) pursuant to which we granted Newsoara an exclusive license to research, develop, commercialize or exploit Olvi-Vec in China, which includes mainland China, Taiwan, Hong Kong and

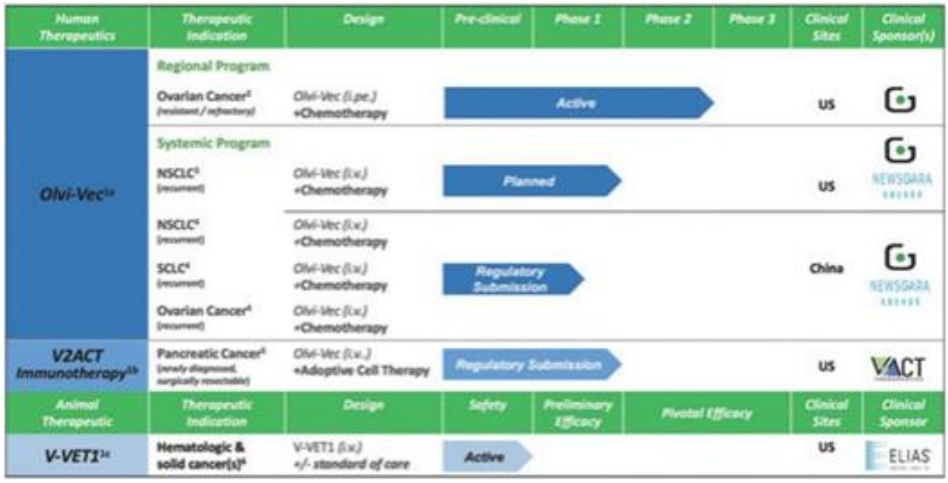
Macau, for all human diagnostic, prophylactic and therapeutic uses (Newsoara field). Under the Newsoara License, Newsoara also granted to us an exclusive and royalty bearing license to develop, commercialize and exploit outside the territory any derived products developed by Newsoara. Additionally, Newsoara is required to use commercially reasonable efforts to research, develop, manufacture and commercialize the licensed products in the territory in the applicable Newsoara field and is solely responsible for all costs and expenses incurred in connection with such activities. Subject to FDA authorization, we anticipate beginning regulatory study start-up of a Phase 2, open-label, randomized, and controlled clinical trial designed to evaluate the efficacy and safety of intravenously delivered Olvi-Vec oncolytic VACV followed by treatment as per the National Comprehensive Cancer Network (NCCN) Guidelines for patients with recurrent NSCLC in the United States in the first half of 2023, which will be funded in its entirety by Newsoara. We plan to conduct this trial under our current open IND and, subject to regulatory authorization, potentially launch a multi-regional clinical trial with Newsoara in the United States and China. We further anticipate Newsoara will initiate a Phase 1 clinical trial of Olvi-Vec in patients with recurrent SCLC in the first half of 2023, and thereafter initiate trials in recurrent NSCLC and recurrent ovarian cancer in China.

Through our CHOICE discovery platform, we have developed an extensive library of potential product candidates and plan to pursue additional oncolytic immunotherapy product(s) for human and animal health applications, either internally or through partnerships and collaborations. Importantly, our oncolytic immunotherapy product candidates are “off-the-shelf” personalized immunotherapies. In other words, while we administer the same virus product to different patients, the cellular immune response generated is specific to the unique neoantigens in that patient. For example, in addition to Olvi-Vec, other product candidates developed from our library include V2ACT Immunotherapy and V-VET1. We formed V2ACT Therapeutics, LLC (V2ACT), a joint venture with TVAX Biomedical Inc. (TVAX), for the purpose of V2ACT developing and commercializing a product candidate, V2ACT Immunotherapy, that combines an oncolytic virus (e.g., Olvi-Vec) and neoantigen-primed adoptive cell therapy (NACT) for cancer.

We believe that V2ACT Immunotherapy may offer significant advantages over other approaches to anti- cancer immune activation, such as targeted therapies that interdict a single cellular pathway or vaccines that rely upon a single antigen or a small collection of neoantigens, because the use of redundant biological pathways may overcome the therapeutic inhibition of such approaches and lead to clinical relapse. We also believe our manufacturing capacity is more cost-effective and efficient as compared to some other “personalized” immunotherapies that require individual product preparations at high costs for each patient. In October 2020, V2ACT filed an IND application and received authorization from the FDA for the initiation of a Phase 1b/2a clinical trial to study V2ACT Immunotherapy as a treatment for newly-diagnosed, surgically-resectable pancreatic cancer. This clinical trial is not yet scheduled to be initiated.

In November 2021, as amended in February 2022 and April 2022, we entered into a License Agreement (ELIAS License) with ELIAS Animal Health LLC (ELIAS) pursuant to which we granted ELIAS the exclusive, worldwide and royalty bearing license to research, develop, use, sell, offer for sale, have sold, import and otherwise commercialize any and all veterinary products that contain the oncolytic virus known as V-VET1 in the diagnosis, prevention and treatment of cancer in non-human animals (the ELIAS field). Under the ELIAS License, ELIAS also granted to us an exclusive, fully paid and royalty free license to use the data and results developed by ELIAS to develop, commercialize and exploit any therapeutic virus outside the ELIAS field. Additionally, ELIAS is required to use commercially reasonable efforts to research, develop, and commercialize the licensed products, and is solely responsible for all costs and expenses incurred in connection with such activities, including all studies and clinical trials necessary to obtain regulatory approval for the licensed products in the ELIAS field.

The following table summarizes our clinical development pipeline:



1 Commercial Rights
1a Genelux: Worldwide (excluding Greater China); Newsoara (Greater China)
1b V2ACT Immunotherapy: Worldwide (excluding Greater China)
1c ELIAS: Worldwide

2 We enrolled the first patient in our Phase 3 clinical trial.

3 Based on the results of our previously completed Phase 1 clinical trials of Olvi-Vec administered intravenously to patients with solid tumors, we are planning to initiate a Phase 2 clinical trial of Olvi-Vec in recurrent NSCLC.

4 Newsoara has submitted an IND and protocols to the Chinese National Medical Products Association.

5 V2ACT has an active IND for this product candidate. The Phase 1b/2a clinical trial is not yet scheduled to be initiated.

6 ELIAS is developing an efficacy trial.

We were founded in 2001 by an academic team from Loma Linda University, led by Aladar A. Szalay, Ph.D., an internationally recognized leader in the monitoring of gene regulation and in whole cell and live organism imaging using light-emitting proteins or protein fusions. We have assembled a seasoned business leadership team with extensive experience involving oncology therapies, including advancing product candidates from preclinical research through clinical development and commercialization. Thomas D. Zindrick, J.D., President, Chief Executive Officer and Chairman, previously held the position of President and Chief Executive Officer and Director, of Amitech Therapeutic Solutions, Inc. and held various executive management positions at Amgen Inc., including Associate Vice President, General Counsel and Chief Compliance Officer, and held legal positions of increasing responsibility in The Dow Chemical Company. James L. Tyree, our Lead Independent Director, previously held numerous executive positions at Abbott Laboratories, including Executive Vice President Global Pharmaceuticals, held the position of President of SUGEN, Inc., and held management positions in Bristol-Myers Squibb Company (BMS) and Pfizer, Inc. (Pfizer).

Our Strategy

Our strategy is to leverage our deep internal capabilities in the clinical development of oncolytic viruses to create a leading immunotherapy company, discovering, developing and commercializing next-generation products for the treatment of a broad range of cancers, including solid tumors, many of which are among the most difficult cancers to treat. We are focused on the execution and success of our clinical programs and, over time, on building our organization into a fully-integrated therapeutics company. Key elements of our strategy include:

- ***Advance our lead product candidate, Olvi-Vec, through clinical development and seek regulatory approval.*** We formally submitted our protocol to the FDA for our randomized, controlled Phase 3 registration clinical trial involving the intraperitoneal delivery of Olvi-Vec in approximately 186 patients with PRROC in January 2022 and made minor clarifying revisions in a protocol amendment in May 2022. Our Phase 3 registration trial of Olvi-Vec in PRROC initiated enrollment in the third quarter of 2022.
- ***Broaden and strengthen our internal manufacturing capabilities, utilizing our in-house manufacturing facility.*** We have strong in-house pharmaceutical development and manufacturing capabilities and have established, equipped and are operating our own cGMP manufacturing facility in San Diego, California for multi-product cGMP manufacturing. Our facility is producing cGMP material that we intend to use in our subsequent clinical trials of Olvi-Vec and for the initial commercial launch of Olvi-Vec, if approved. We plan to continue to invest in growing our manufacturing capabilities.
- ***Support the clinical and commercial development of Olvi-Vec with our strategic partner, Newsoara, advise and coordinate the design and initiation of clinical trials in China and provide product supply and technology transfer.*** Subject to FDA authorization, we anticipate beginning regulatory study start-up of a Phase 2, open-label, randomized, and controlled clinical trial designed to evaluate the efficacy and safety of intravenously delivered Olvi-Vec oncolytic VACV followed by treatment as per the NCCN Guidelines for patients with recurrent NSCLC in the United States in the first half of 2023, which will be funded in its entirety by Newsoara. We plan to conduct this trial under our current open IND and, subject to regulatory authorization, potentially launch a multi-regional clinical trial with Newsoara in the United States and China. We further anticipate Newsoara will initiate a Phase 1 clinical trial of Olvi-Vec in patients with recurrent SCLC in the first half of 2023, and thereafter initiate trials in recurrent NSCLC and recurrent ovarian cancer in China. Newsoara is funding all of these trials in their entirety.
- ***Seek additional development and commercial collaborations for Olvi-Vec and our other human therapeutic product candidates, while retaining significant economic and commercial rights in key geographic areas.*** We intend to retain rights in the United States for our product candidates and to develop an oncology-focused commercial organization of internal and/or contract resources. When economically attractive, we intend to accelerate development and commercialization of, and patient access to, our product candidates by pursuing strategic partnerships with leading biopharmaceutical companies in those geographic areas where we are unlikely to pursue development and commercialization on our own.
- ***Leverage our CHOICE discovery platform to build a portfolio of oncology product candidates that target a range of immune mechanisms and progress these product candidates into clinical development.*** We plan to continue to strengthen our leading position in the oncolytic viral immunotherapy field through ongoing product development and investments in VACV product candidates generated by our CHOICE platform. We plan to introduce into the clinic at least one next-generation oncolytic virus, aimed at further optimizing delivery and activating multiple immune mechanisms for the treatment of a broad range of cancers.
- ***Support our joint venture, V2ACT, in the clinical and commercial development of V2ACT Immunotherapy, advise and coordinate the design and initiation of clinical trial(s) and provide technology transfer and optional contracted support services.*** V2ACT holds an active IND for the clinical investigation of V2ACT Immunotherapy in a Phase 1/2a trial for the treatment of newly diagnosed surgically-respectable pancreatic cancer. This clinical trial is not yet scheduled to be initiated. We and TVAX intend to utilize our respective clinical, regulatory and manufacturing capabilities to efficiently further the development of this program and thereby strategically build upon our novel immunotherapy platform to a robust pipeline.
- ***Support ELIAS developing and commercializing V-VET1, advise and coordinate the design and initiation of clinical trials and provide technology transfer and optional contract manufacturing.*** We granted ELIAS the exclusive worldwide license to our V-VET1 clinical program in November 2021. At this time, we are completing the technology transfer of V-VET1 to ELIAS.

Immuno-oncology Background and Limitations of Existing Therapies

Cancer is a broad group of diseases in which normal cells are transformed into a state of rapid and uncontrolled cell division, typically resulting in tumors. Cancer originates from a particular tissue in the body, such as the lung or ovary, and often spreads, or metastasizes, as the disease progresses and, if uncontrolled, can lead to death. Tumors are comprised of multiple cell types, including cancerous cells and the body's own immune cells. The composition and the type of tumor dictate the aggressiveness of a particular cancer, its susceptibility to treatment, and ultimately, patient outcome.

Historically, cancer treatment has been limited to surgical removal, cytotoxic chemotherapy and/or radiation. However, those treatments are not long-term solutions, as not all cancer cells may be killed or removed from the patient and those which remain may become resistant to standard-of-care treatment over time.

Another potential approach to cancer treatment is to activate the immune system by targeting specific genetic changes in individual tumors and redirecting the patient's immune system to eliminate tumors.

The immune system contains many different cell types that fall into two general categories—cells of the innate immune system and cells of the adaptive immune system. The innate immune system is a first-line, ubiquitous, non-specific defense mechanism and involves a diverse set of cells, which generate a rapid response to any foreign body, particularly microbial pathogens and parasites, as well as tumor cells. The adaptive immune system is a second line of defense that is specific to particular foreign or mutated proteins, known as antigens, and is triggered when the innate immune system releases signals to activate and recruit cells from the adaptive immune system. The adaptive immune system is composed of T cells and B cells which can form immunologic memory and therefore be activated upon reintroduction of the initial antigens. Activation of both the innate and adaptive components of the immune system is believed to be essential for the induction of an effective anti-cancer immune response by the body.

Immuno-oncology therapies have been developed recently to activate or modulate the anti-cancer immune responses in some patients. Unfortunately, most patients either are not eligible for or do not respond to these therapies. For example, only about 15–60% of patients respond to immune checkpoint inhibitors (ICIs) in general, with a response rate that is lower than ten percent for certain cancer types, such as recurrent ovarian cancer or cancers with negative programmed death-ligand. While these therapies have advanced the treatment of cancer for some patients, many are still underserved.

Tumors have many defense mechanisms against anti-cancer therapies, which is why cancer patients often respond to initial treatment but then relapse when the tumors regrow. To overcome these defense mechanisms, it is commonly believed that multiple mechanisms of action will be required to unlock the full potential of available therapies. Given the limitations of current standards of care, whether traditional cancer therapy or newer immune-oncology therapies, there remains an urgent need for new therapeutic options that offer improved clinical outcomes for cancer patients.

We see a vast opportunity for therapies that stimulate robust anti-tumor responses by activating both the innate and adaptive immune systems and modifying the immunosuppressive tumor microenvironment by making cancer cells more receptive to subsequent treatments. This includes sensitizing cancer cells that are otherwise resistant to standard-of-care therapies.

Oncolytic immunotherapy is the treatment of cancer with viruses that selectively replicate in tumors but not in normal tissues. Viral immunotherapies cause immunogenic tumor cell death by way of viral oncolysis, which has the therapeutic benefit of exposing all the tumor's neoantigens to the immune system. Tumor neoantigens are uniquely present in tumors, as compared to normal tissue, because they result from the genetic changes that occur as cancer develops. Immunogenic tumor cell death triggers both innate and adaptive immune responses and the establishment of lasting antitumor immunity, resulting in the further destruction of existing tumors and those that may form later. We believe that viral immunotherapies are the most promising modality available today to activate multiple arms of the immune system and improve outcomes for cancer patients.

Cancer is the second most common cause of death in the United States and worldwide, exceeded only by cardiovascular disease. The American Cancer Society (ACS) estimates that 1.9 million new cancer cases are expected to be diagnosed in 2022 and approximately 609,000 Americans are expected to die of cancer in 2022. This estimate excludes basal cell and squamous cell skin cancers, which are not required to be reported to cancer registries, and carcinoma in situ (noninvasive cancer) except for urinary bladder cancer. According to estimates from the International Agency for Research on Cancer (IARC), in 2020, there were approximately 19.3 million new cancer cases worldwide with a corresponding estimated number of cancer deaths of 10.0 million.

The death rate is expected to continue to increase despite introduction of scores of new treatments. Curative treatment requires elimination of all cancer cells, including cancer stem cells, an objective that current systemic treatments achieve only infrequently. For most patients, current systemic treatments provide incremental benefit with substantial toxic side effects. There is a significant unmet medical need for safer and more effective treatments for a wide array of human cancers.

The Genelux Approach

Oncolytic VACV

We utilize VACV as the backbone of our therapeutics and diagnostics platform. VACV is a member of the Orthopoxvirus genus and contains a single linear DNA genome. Like other large DNA viruses, VACV exhibits greater complexity and depends less on its host for replication than other viruses. The DNA genome of a number of strains of VACV has been sequenced and found to encode approximately 150–200 proteins. VACV particles include a large number of viral enzymes and related factors that allow the virus to produce functional messenger ribonucleic acid (RNA) within the host cell cytoplasm. Therefore, VACV has a high level of independence from host cell functions with its genome encoding most of the proteins required for the production of virions, the infectious form of the virus.

Our approach is based on the mechanism of action of VACV, which has the following characteristics we consider desirable in an oncolytic virus for clinical applications:

- Not dependent on any known receptor and can infect nearly any type of cancer cells;
- Large insertion capacity (> 25 kb) for the expression of multiple exogenous genes;
- High genetic stability;
- Lack of a known natural host;
- Not associated with naturally-occurring disease in humans;
- Remains in the cytoplasm (mitigating its potential for mutagenesis by incorporation into the host genome);
- Short, well-characterized life cycle;
- Robust lytic capabilities, high replication and proliferation;
- Upregulates a unique profile of pro-inflammatory chemokines/cytokines and other apoptotic/cytotoxic factors;
- Induces a Th1-type immune (cellular) response, which is an optimal immune response for cancer killing;
- Well-tolerated with low incidence of side effects when previously administered as the backbone of the vaccination campaign that eradicated smallpox;
- Limited pre-existing immunity (waning over time as immunizations ended in the general population in the 1970s); and
- Amenable to large scale production of high levels of active virus.

Mechanism of Action

Oncolytic vaccinia viral immunotherapies, such as Olvi-Vec, have multiple properties that differentiate them from other anti-tumor therapies, including the ability to transform so-called immunologically "cold" tumors into "hot" tumors:

Viral Infection of Tumor Cells – VACV has shown a natural tropism, or an ability to productively infect a particular cell through mechanisms that are believed to contribute to the selective "targeting" of tumor cells as compared to normal cells.

- *Cellular tropism* refers to the observation that virus replication can be permissive, semi-permissive or abortive in cultured cells of different lineages or species. The binding and entry of poxviruses into mammalian cells is an efficient process. The intracellular events of the infected cell that affect replication efficiency of the virus include cell-cycle status, lineage and differentiation state, the availability of trans-acting transcription factors from the host, and its intrinsic antiviral state. There is evidence that mitogenically stimulated quiescent cells favor viral replication; therefore, it is expected that VACV may replicate more effectively in proliferating cells, such as tumor cells.
- *Tissue tropism* refers to the frequently observed increased levels of virus replication in specific host organs or tissues, which can be influenced by factors that mediate cellular tropism as well as by tissue- specific antiviral responses. VACV are relatively large particles (350 nm in diameter) that require leaky vasculature (fenestrations) for transfer of the virus out of the circulation. The aberrant angiogenic signaling in tumors results in a vasculature that is leaky and tortuous. Therefore, after a systemic delivery, VACV is preferentially delivered or "targeted" to tumors.

Amplification and Oncolysis – Once inside the tumor cells, VACV particles replicate rapidly in the cells' cytoplasm. Reasons for such amplification include:

- *Compromised immunosurveillance* refers to the impairment of the immune processes, such as a downregulated interferon pathway, by which cells of the immune system look for and recognize foreign pathogens, such as bacteria and viruses, or pre-cancerous and cancerous cells. The immunosuppressive nature of tumor tissues creates a virtual "safe haven" favoring the survival of VACV in the tumor tissues without immune system interference. In addition, with such defects in cellular anti-viral pathways, cancerous cells are also intrinsically susceptible to viral infection. In fact, specific defects in interferon pathway was noted as potential biomarkers for sensitivity towards oncolytic virotherapy.
- *Genetic modifications* refer to inactivation of one or more genes of the virus genome to further enhance the favoring of VACV replication in tumor tissues over normal ones. For example, inactivation of the thymidine kinase (TK) gene forces the virus to be dependent on host cell nucleotides, which are more available in rapidly dividing tumor cells as compared to resting normal cells.

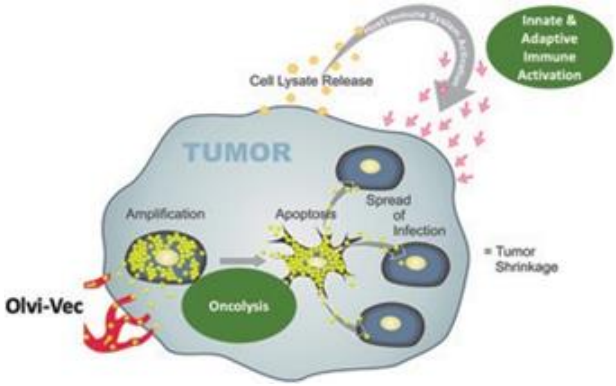
Viral replication ultimately causes tumor cell necrosis (oncolysis) and release of mature viral particles into the tumor. These newly released viral particles repeat the process by infecting and killing neighboring tumor cells. The oncolytic process can also cause bystander cell killing and viral-changes in tumor-associated vasculature.

Viral Particle and Tumor Antigen Release – The oncolytic process also harnesses the body's immune system to fight the cancer. As viral particles begin destroying tumor cells, tumors release tumor antigens and tumor cell debris, including neoantigens specific to the patient, which could otherwise be hidden from the immune system. This process of necrotic cell death releases intra-cellular markers of "danger," the danger associated molecular patterns (DAMPs), while the virus produces pathogen associated molecular patterns (PAMPs).

Immune Stimulation – The release of DAMPs and PAMPs activates the innate immune system through multiple pattern recognition receptors, each resulting in the production of interferon which activates natural killer cells. Innate immune activation also helps to trigger adaptive anti-cancer immunity, in which antigen presenting cells (APCs) are attracted to the infected tumor. APCs internalize cancer antigens, including neoantigens, and traffic back to the draining lymph nodes where they present the antigens to T cells.

Tumor Regression – The T cells are then primed to proliferate and disperse systemically to seek cancer cells with the same antigen profile throughout the body and destroy distant tumor deposits, with enhanced tumor infiltrating lymphocytes (TILs) correlated with improved survival in many solid tumor cancers. As such, while oncolysis is an important step, once anti-tumor immune stimulation and immune cell memory are developed, ongoing oncolysis (i.e., continued virus presence) is not necessary. The inflammatory cascade within the tumor microenvironment also can initiate or enhance an anti-tumor response upon subsequent administration of chemotherapies or targeted therapies.

The following graphic demonstrates the expected mechanism of action of Olvi-Vec based on the factors described above:



Given its paradigm-shifting biology, we believe that VACV has the potential to unlock the full power of viral immunotherapies and to fundamentally change the way cancer is treated.

Development Program

We are developing a pipeline of oncolytic immunotherapy clinical and preclinical product candidates with the potential to address many significant unmet medical needs in oncology. Specifically, our clinical and preclinical product candidates are intended to selectively kill tumor cells and induce a robust immune response against a patient's tumor neoantigens.

Importantly, our oncolytic immunotherapy product candidates are "off-the-shelf" personalized immunotherapies. In other words, while we administer the same virus product to different patients, the cellular immune response generated is expected to be specific to the unique neoantigens in that patient.

We believe that our approach may offer significant advantages over other approaches to anti-cancer immune activation, such as targeted therapies that interdict a single cellular pathway or vaccines that rely upon single antigen or a small collection of neoantigens, because the use of redundant biological pathways may overcome the therapeutic inhibition of such approaches and lead to clinical relapse. We also believe our manufacturing capacity is more cost-effective and efficient as compared to some other "personalized" immunotherapies that require individual product preparations at high costs for each patient.

Our technology is broadly based on the use of genetically-engineered organisms, such as viruses, bacteria, and mammalian cells (e.g., stem cells), that deliver therapeutic and diagnostic constructs to tumors. This depth and breadth of approach allows for a deeper scientific understanding of the biological mechanisms of tumor biology and potentially allows for future discoveries and expansion of our clinical pipeline.

Lead Product Candidate: Olvi-Vec

Our current development focus is on our lead product candidate, Olvi-Vec (USAN: olvimulogene nanivacirepvec; laboratory name: GLV-1h68; previously known as GL-ONC1), a genetically stable, attenuated Lister-Institute of Viral Preparations (LIVP) strain of VACV.

We modified the LIVP strain by integrating three foreign gene expression cassettes—*Ruc-GFP* (a fusion gene of *Renilla* luciferase and green fluorescent protein); *LacZ* (ß-galactosidase gene from *E. coli*); and *gusA* (ß- glucuronidase from *E. coli*)—to selectively disrupt non-essential vaccinia genes (*F14.5L*, thymidine kinase (*TK*), and hemagglutinin (*HA*) loci, respectively). The following table sets forth a description of the genomic modifications made to the LIVP strain.

Loci	Change	Gene	Rationale
F14.5L	inactivation	5.5k hypothetical protein F14.5L	Higher tumor selectivity
	insertion	Renilla luciferase-Aequorea green fluorescent protein (RUC-GFP)	Visual detection of infection Cytotoxicity High immune response
J2R	inactivation	thymidine kinase	Tumor selectivity
	insertion	Ò-galactosidase (*E. coli*)	High immune response; potential for enzyme-prodrug therapy
A56R	inactivation	hemagglutinin	Reducing infectivity
	insertion	Ò-glucuronidase (*E. coli*)	High immune response; potential for enzyme-prodrug therapy

Clinical Development of Olvi-Vec

We are developing Olvi-Vec for the treatment of multiple cancers based on the results of preclinical studies that suggest Olvi-Vec has the potential to infect and directly kill a wide range of tumor cell types *in vitro* and *in vivo* and produce an anti-tumor immune response. To date, Olvi-Vec has been studied in multiple early- and mid-phase clinical trials via regional, local and systemic deliveries, as a monotherapy and in combination with other therapies, in approximately 150 patients with a variety of cancer types. All of our clinical trials have yielded data that has informed our future clinical strategy and trial design involving multiple indications and methods of delivery.

In all of our clinical trials, irrespective of the route of administration, dosing regimen or cancer type, Olvi-Vec was:

- Observed to be well tolerated, and whether administered in a single dose or multiple doses per cycle, no MTD was reached in any of the trials and there were no significant issues with virus shedding into the environment;
- Shown to infect and selectively kill tumor cells, initiate an anti-tumoral response and modulate the tumor microenvironment, including re-sensitizing certain tumors to chemotherapy;
- Observed to have a virus-dose dependent benefit on disease control (including tumor growth reduction), progression-free survival (PFS), overall survival (OS) and other clinical benefits in a monotherapy setting; and
- Shown to enhance chemotherapeutic activities in a combination therapy setting.
- In addition, in clinical trials in which Olvi-Vec was systemically administered, Olvi-Vec was:
- Shown to likely overcome pre-existing anti-vaccinia antibody levels by high and condensed dosing;
- Detectable in the active state as live virus in blood circulation even at two hours after infusion, which we believe is ample time for the virus to reach distal metastases; and
- Could infect tumor tissues and reduce circulating tumor cells.

The following table summarizes the clinical trials in which Olvi-Vec has been administered in approximately 150 patients to date.

Clinical Trial Summary

Protocol Number	Trial Dates	Indication	Modality & Route	Dose & Regimen	# of Patients	Treatment Related SAEs (Grades 3-5)	Phase 1 Objectives/ Phase 2 Endpoints	Results
GL-ONC1-002/MA (United Kingdom: Phase 1 - NCT00794131)	11/19/08 to 11/14/15	Advanced solid tumors	Monotherapy as intravenous infusion	**Phase 1: Cohorts 1 to 5b:** Single Dose/ Cycle 28-day cycle Dose: 1×10^5 pfu up to 3×10^9 pfu Cohorts 6 & ^ Multiple Dose/ Cycle 28-day cycle Dose: 1.667×10^7 pfu to 1.667×10^8 pfu × 3 consecutive days/ cycle **Phase 1b:** Multiple/Single Dose/Cycle 28, 14 or 7 day/ cycle Cycle 1 Dose: 1.667×10^9 pfu × 3 consecutive days Cycles 2-6 Dosing: Single dose at either 3×10^9 pfu or 5×10^9 pfu/cycle	43	**Phase 1:** Three treatment-related serious adverse effects (SAEs) in one (1) patient in Cohort 5 (1×10^9 pfu): Grade 3 Pain in leg Grade 3 Left leg stiffness Grade 3 Arterial embolism One treatment-related SAE in one (1) patient in Cohort 5a (3×10^9 pfu): Grade 3 aspartate aminotransferase (liver enzyme) levels **Phase Ib:** One treatment-related SAE in one (1) patient in Cohort 8c treated (Cycle 1: 3 doses @ 1.667×10^9 pfu each; 10^9 pfu each): Grade 3 airway obstruction-trachea	Primary Objective: To assess safety and tolerability Secondary Objectives: To assess anti-tumor activity, infection and replication in the primary tumor and metastatic disease; and anti-vaccinia virus immune response	Well-tolerated and MTD not reached. Multiple high doses of virus delivered by intravenous route: (A) demonstrated to be feasible: (i) extended PK (overcoming neutralizing antibodies), (ii) confirmed viral infection, replication at tumor sites distal to site of administration and in circulating tumor cells, (iii) induction of proinflammatory response and triggering activation of adaptive immunity (B) demonstrated to generate anti-tumor activity and clinical benefits, including a virus- dose- dependent overall survival benefit, especially in patients with primary lung cancer or other tumor types with lung metastases. Of the 22 evaluable patients with such lung disease, 11 patients who received the lower cumulative dose had a mOS of 4.6 months vs. a mOS of 16.8 months for the 11 patients who received the higher cumulative dose ($p = 0.026$); when further extending the analysis, the five patients cumulative dose had a mOS of 4.6 months vs a mOS of 20.9 months for the 11 patients who received the highest cumulative dose ($p = 0.002$).

Clinical Trial Summary

Protocol Number	Trial Dates	Indication	Modality & Route	Dose & Regimen	# of Patients	Treatment Related SAEs (Grades 3-5)	Phase 1 Objectives/ Phase 2 Endpoints	Results
GL-ONC1-003/MSK (United States: Phase 1 (Investigator Sponsored) - NCT01766739)	01/11/13 to 01/20/21	Malignant pleural effusion related either to malignant pleural mesothelioma or metastatic disease	Monotherapy as intrapleural catheter delivery	Single dose, 3 consecutive done Dose: 1×10^7 pfu to 6×10^9 pfu (multiple dose cohort)	18	No treatment-related SAEs (Grades 3-5) reported	Primary Objective: To determine the recommended Phase II dose Secondary Objectives: To assess safety and tolerability of intrapleural delivery; tumor infection and replication; immune response; and possible therapeutic efficacy	Well-tolerated, no dose- limiting toxicities, and MTD not reached No virus shedding detected Confirmed viral availability and PK in pleural fluid after multiple high doses of virus delivered by intravenous route: Confirmed viral infection and replication in tumor tissues Confirmed trend of survival advantage for patients with epithelioid subtype of mesothelioma when compared to well-documented historical data. The median overall survival (mOS) was 22.3 months vs. historical 14 months in all epithelioid subtype patients: for those who did not have subsequent surgery, the mOS was 23.4 months vs. historical 10 months; and for those who had subsequent surgery, the mOS was 22.3 months vs. historical 19 months.

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Clinical Trial Summary

Protocol Number	Trial Dates	Indication	Modality & Route	Dose & Regimen	# of Patients	Treatment Related SAEs (Grades 3-5)	Ph1 Objectives/ Ph2 Endpoints	Results
GL- ONC1-004/TUE (Germany: Phase 1 - NCT01443260)	11/29/11 to 03/10/15	Peritoneal carcinomatosis	Monotherapy as intraperitoneal catheter delivery	Treatment once per cycle (every 28 days) for up to 4 cycles Dose: 1×10^7 pfu up to 1×10^9 pfu/ cycle	9	1 treatment-related SAE in one (1) patient in Cohort 1 (1×10^7 pfu): Grade 3 Fatigue	Primary Objective: To determine the maximum tolerated Secondary Objectives: To determine recommended dose/ schedule for Phase 2; anti- tumor activity, assess tumor infection and replication; evaluate anti-vaccinia virus immune response	Well-tolerated, and no dose- limiting toxicities, and MTD not reached Confirmed viral infection and replication in tumor tissues and oncolysis of tumor cells; and induction of proinflammatory response and anti-tumor immune response Confirmed anti-tumor activity: Of the 6 patients receiving more than one dose, 67% exhibited SD by RECIST 1.1 (with one exhibiting PR by CHOI criteria).
GL-ONC1-005/UCSD (United States: Phase 1 - NCT01584284)	09/05/11 to 03/10/15	Newly diagnosed head and neck cancer	Combination therapy with intravenous or bolus injection with cisplatin and radiotherapy	Dose: 3×10^8 pfu up to 3×10^9 pfu	19	No treatment-related SAEs (Grades 3-5) reported	Primary Objective: To assess safety and tolerability Secondary: Objectives: To assess viral shedding To assess tumor infection and replication, and therapeutic outcomes.	Well tolerated and no MTD reached. No virus shedding detected Confirmed (i) viral infection and replication of tumor tissues and (ii) induction of proinflammatory response and T-cell activation pathways Confirmed 90% (17/19) ORR [77% (13/17) with CR], compared to historical of 64% ORR. Favorable PFS and OS as compared to well-documented historical data: The 1-year progression-free survival (PFS) rate was 66%, and 1-year overall survival (OS) rate was 86% in HPV-negative Stage IV patients, relative to historical data, including both Stage III & Stage IV patients, of 1-year PFS at 60%, and 1-year OS at 70%.

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Clinical Trial Summary

Protocol Number	Trial Dates	Indication	Modality & Route	Dose & Regimen	# of Patients	Treatment Related SAEs (Grades 3-5)	Ph1 Objectives/ Ph2 Endpoints	Results
GL-ONC1-011/UCSD (United States: Phase 1 (Investigator Sponsored) -	03/21/16 to 03/25/20	Solid Organ Cancer	Neoadjuvant monotherapy as intravenous	3 or 5 daily treatment during Week 1	5	No treatment-related SAEs (Grades 3-5)	Primary Objective: To assess safety and tolerability in patients	Well tolerated and no dose- limiting toxicities and MTD not reached
NCT02714374)			bolus infusion followed by surgical resection of tumor	Dose: 2 × 10^9 pfu × 5 daily doses or 2,3,5 × 10^9 pfu		reported	undergoing surgery Secondary Objectives: To assess tumor infection and replication To evaluate anti-vaccinia and anti-tumor immune responses	Confirmed feasibility of systemic route of delivery: (i) live virus detected in blood circulation hours after completion of virus infusion; (ii) viral infection and replication in tumor tissues and (iii) induction of increased tumor-infiltrating lymphocytes into virus-infected tumor tissues
GL- ONC1-021/AHCI (United States: EAP - NCT03420430)	02/05/18 - present	Advanced cancers (solid	Monotherapy as intravenous bolus infusion	3 or 5 daily treatment during Week 1	8	No treatment-related SAEs (Grades 3-5)	Primary Objective: To assess safety and tolerability	Well tolerated and no dose- limiting toxicities and MTD not reached
		tumors & blood cancer)		Dose: 2 × 10^9 pfu × 5 daily doses or 2,3,5 × 10^9 pfu		reported	Secondary Objectives: To assess clinical benefit	Confirmed objective response and clinical benefit of monotherapy and immunochemotherapy. Clinically-significant anti-tumor effects were documented in two of three solid tumor patients who received Olvi-Vec-primed immunochemotherapy.

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Clinical Trial Summary

Protocol Number	Trial Dates	Indication	Modality & Route	Dose & Regimen	# of Patients	Treatment Related SAEs (Grades 3-5)	Ph1 Objectives/ Ph2 Endpoints	Results
GL—ONC1-015/AHCI (United States: Phase 1b/2 - NCT02759588)	05/03/16 -present	Platinum resistant/ refractory ovarian cancer, fallopian cancer or primary peritoneal carcinomatosis	IP Infusion as Monotherapy or as combination therapy with carboplatin doublet chemotherapy ± bevacizumab	3×10^9 pfu × 2 consecutive days 1×10^{10} pfu × 2 consecutive days $2.5 \times 10^{10} \times 2$ consecutive days	46	Seven treatment-related SAEs occurred in six (6) patients: Two (2) patients in Cohort 1 (3×10^9 pfu × 2 infusions): Grade 3 Vomiting Dehydration Three (3) patients in Cohort A (3×10^9 pfu × 2 infusions): Grade 3 Vomiting × 2 patients Grade 3 Abdominal pain Grade 3 Anorexia One (1) patient in Cohort C (3×10^9 pfu × 2 infusions): Grade 3 Fatigue	Primary Endpoints: Phase 1b: To assess safety and tolerability Phase 2 Cohorts A& B: To assess progression-free survival Phase 2 Cohorts C & D: To assess overall response rate by RECIST 1.1 and Exploratory Objectives: All Cohorts: Infection, replication and cancer cell killing; and anti-tumor immune response; confirm presence of Olvi-Vec in tumor tissue by VPA, immunohistochemistry & qPCR; determine prognostic value of circulating tumor cells	Primary endpoints met Well tolerated and no dose-limiting toxicities and MTD not reached Confirmed trend of favorable PFS, ORR and OS. The median PFS (mPFS) was 11.0 months, ORR was 54%, and OS was 15.7 months as compared to well-documented historical data <4 months, <20%, < 12 months, to a mPFS of 4.5 months on the patients' immediate prior line of therapy (historically, mPFS generally decreases with each subsequent line of therapy. Exploratory Objectives: Demonstrated viral infection and replication in tumor tissues, and oncolysis of tumor cells Demonstrated virus-mediated modulation of tumor immune microenvironment; induction of anti-tumor immune response

Clinical Program Development Strategy

The previously conducted intraperitoneal study (NCT01443260) was a Phase 1 trial designed to test various dosing regimens and, primarily, to assess safety and tolerability and translational anti-tumor effects in a variety of solid tumors. We believed the results of the study supported advancement into our Phase 1b/2 study (NCT02759588) in resistant/refractory ovarian cancer, the results of which we believe support advancement into a Phase 3 registration clinical trial.

The previously conducted intravenous studies (NCT00794131; NCT01584284; NCT02714374; NCT03420430) were all Phase 1 trials designed to test various dosing regimens and, primarily, to assess safety and tolerability and translational anti-tumor effects in a variety of solid tumors. We believe the results of the studies support advancement of intravenous systemic administration of Olvi-Vec in multiple solid tumor types. Subject to FDA authorization, we anticipate beginning regulatory study start-up of a Phase 2, open-label, randomized, and controlled clinical trial designed to evaluate the efficacy and safety of intravenously delivered Olvi-Vec oncolytic VACV followed by treatment as per the NCCN Guidelines for patients with recurrent NSCLC in the United States in the first half of 2023, which will be funded in its entirety by Newsoara. We plan to conduct this trial under our current open IND and, subject to regulatory authorization, potentially launch a multi-regional clinical trial with Newsoara in the United States and China. We further anticipate Newsoara will initiate a Phase 1 clinical trial of Olvi-Vec in patients with recurrent SCLC in the first half of 2023, and thereafter initiate trials in recurrent NSCLC and recurrent ovarian cancer in China.

The estimated enrollments of the planned systemic administration trials are set forth below.

Sponsor	Trial Sites	Indication	Clinical Stage	Patients (est.)	Randomization
	US	Recurrent NSCLC	Phase II	~138	2:1
		Recurrent OC	Phase I/II	~150	2:1
	China	Recurrent NSCLC	Phase I/II	~150	2:1
		Recurrent SCLC	Phase I/II	~150	Single arm

The previously conducted intrapleural study (NCT01766739) was a Phase 1 Investigator-initiated trial designed to test various dosing regimens and, primarily, to assess safety and tolerability and translational anti- tumor effects in a variety of solid tumors. While we believe the trial results warrant further study of the intrapleural systemic administration of Olvi-Vec, particularly in malignant pleural mesothelioma, at the present time we have determined to commit our resources to our other clinical development programs described above.

Ovarian Cancer Program

The Surveillance, Epidemiology, and End Results Program (SEER) database estimates ovarian cancer is the fifth most common cause of cancer death in women in the United States. According to GLOBOCAN 2020 (produced by the IARC), worldwide, there were 313,959 cases of ovarian cancer and 207,252 deaths in 2020 and worldwide, in 2018, almost 600,000 women were living within five years of an ovarian cancer diagnosis (five-year prevalence). It also predicted that by 2035 there will be a worldwide increase of annual incidence to 371,000, and an increase in deaths to 254,000. The ACS estimates in 2022 there will be approximately 19,880 new cases of ovarian cancer and approximately 12,810 deaths from the disease in the United States. The SEER database estimates in 2019 there were an estimated 233,565 women living with ovarian cancer in the United States (including those who had been cured of the disease). A majority (~80%) who respond to treatment will relapse. Median overall survival following recurrence of disease is 12 months or less with single-agent chemotherapy.

According to GlobalData (2019), the ovarian cancer market was valued at $1.8 billion in 2018 across the seven major markets – U.S., EU5 (UK, Germany, France, Italy, Spain) and Japan, and it is expected to grow to $6.7 billion in the following ten years with a compound annual growth rate (CAGR) of 14.4%. North America dominates the global market for ovarian cancer diagnostics and therapeutics, and Europe is the second largest market. Asia-Pacific is expected to show high growth rates in the next few years due to the large aging population, with China and India the fastest growing markets.

Based on internal research and analysis, we estimate the U.S. market potential of our existing products in our initial label indication resulting from the Phase 3 registration clinical trial of Olvi-Vec in patients with PRROC to reach sales of approximately $250.0 million, at five years from marketing approval (2029). In order to estimate this initial market opportunity in ovarian cancer, which does not include the potential treatment of earlier-line patients or re- treated patients, we reviewed publicly-available data sources (e.g., SEER, Datamonitor) and identified the number of Olvi-Vec treated patients by multiplying the relevant ovarian cancer patient population (from both the annual incidences and prevalent pool) and the ovarian cancer market share for each specific year. We estimate the annual population of addressable PRROC patients in the United States to be approximately 10,000 patients. The material market assumptions for Olvi-Vec initially assume an addressable population of PRROC patients who would be eligible for treatment consistent with the expected product label resulting from our Phase 3 registration clinical trial, if successful, and who otherwise would receive platinum under current standard of care treatment. Using those assumptions, we estimate approximately 1,250 patients per year will be treated with Olvi-Vec, which will be priced at $200,000 per patient per year based on the estimates of similar products in development for this indication. With the introduction of Olvi-Vec and the anticipated re-sensitization of tumors that otherwise would not be considered eligible for platinum, we expect a change in practice and an increase in the number of addressable PRROC patients; however, our current Olvi-Vec market share assumptions do not take this into consideration. Our projections are subject to a number of assumptions, risks and uncertainties that could cause them to be smaller than we currently estimate.

In the United States, patients diagnosed with ovarian cancer across all stages are generally treated with surgery followed by combination platinum-based chemotherapy (platinum). The majority of newly-diagnosed patients respond to platinum (so called platinum-sensitive) and many platinum-sensitive patients are eligible to receive maintenance poly-ADP ribose polymerase therapy. Unfortunately, most patients who initially respond to platinum will relapse and become resistant to further platinum therapy. Standard treatment of PRROC is largely palliative, relying on single agent non-platinum chemotherapies with or without the addition of bevacizumab. In platinum-resistant ovarian cancer, single agent therapies generally result in a 10 to 15% overall response rate (ORR), with three to four months PFS and approximately 12 months of OS. In a study of Avastin (bevacizumab) added to single agent non-platinum chemotherapy in patients with platinum-resistant ovarian cancer, sponsored by Hoffmann-La Roche, the addition of bevacizumab approximately doubles PFS; however, the 3.3 month improvement in OS (13.3 vs 16.6 months) did not reach statistical significance. The combination of non-platinum single agent therapies with bevacizumab have shown a significant increase of PFS.

Despite optimization of surgical and chemotherapy protocols, and initiation of clinical trials incorporating targeted therapy, the majority of patients with advanced-stage PRROC unfortunately relapse and eventually develop chemotherapy resistance. Also, importantly, common treatments continue to be associated with decreased patient quality of life due to toxicity. The treatment options for PRROC are very limited and only modest gains have been achieved in prolonging of survival of ovarian cancer. No approved therapy has been shown to significantly extend overall survival in patients with PRROC compared to standard chemotherapy. The five-year survival rate for women with Stage IV invasive epithelial ovarian cancer is only about 17%. Therefore, there is a critical unmet need to develop new therapeutic modalities that address intrinsic and acquired chemotherapy resistance in epithelial ovarian cancer.

A main manifestation of metastatic ovarian cancer is widespread peritoneal metastasis, which at late stage is often beyond the scope of surgery. We believe that peritoneal metastasis, because of its significant surface area and easy access in a limited space, is a potential ideal infection target for Olvi-Vec. We selected PRROC as our first registration-path indication because it represents a difficult-to-treat disease with significant unmet medical need, and intraperitoneal delivery allows for high and condensed dosing of Olvi-Vec.

Ovarian epithelial cancer, fallopian tube cancer and primary peritoneal cancer form in the same kind of tissue and are treated in the same way. These cancers are often advanced at diagnosis. Less common types of ovarian tumors include ovarian germ cell tumors and ovarian low malignant potential tumors. Epithelial ovarian cancer remains the most lethal gynecologic malignancy, owing to relatively late detection, intrinsic and acquired chemo-resistance, and relatively stable genomic makeup characterized by low mutation burden, microsatellite stable signature and infrequent PD-L1 staining.

Phase 1b/2 (GL-ONC1-015/AHCI Study)

We conducted a Phase 1b/2 clinical trial of Olvi-Vec, which was administered intraperitoneally at high doses in a single round of treatment consisting of a bolus infusion on two consecutive days. Patients enrolled into the trial were heavily pretreated (with a median of four prior lines of therapy), with PD at the time of enrollment, and had PRROC, with poor responses to conventional chemotherapies.

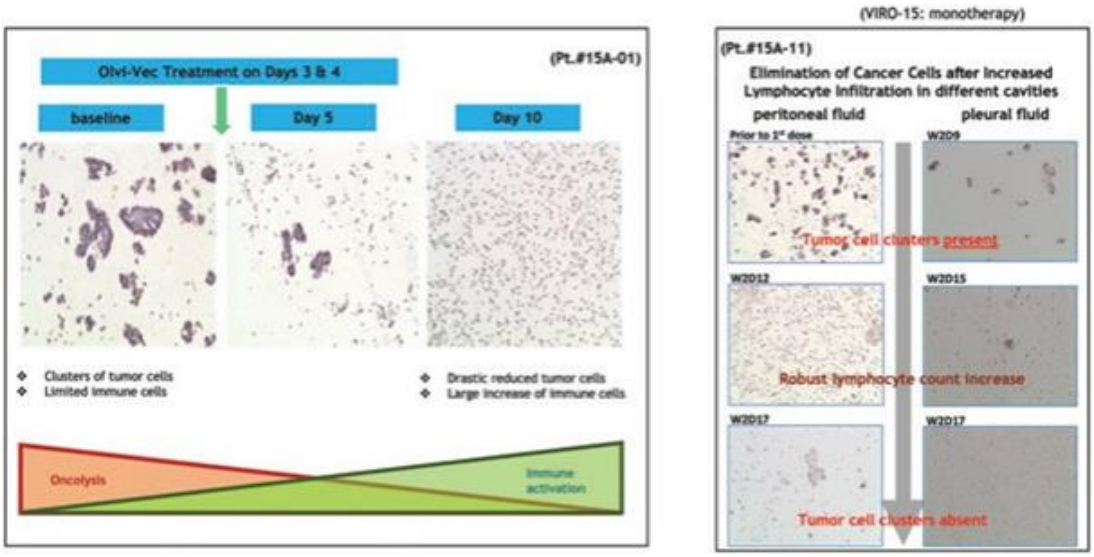
In the Phase 1b portion of the clinical trial, a total of 11 patients were treated in the first two dose escalation cohorts. Olvi-Vec was observed to be well tolerated with transient overnight flu-like symptoms. Daily intravenous hydration during the treatment process relieved the symptoms and prevented dehydration. No virus- related severe organ toxicity was observed by clinical or serologic parameters and an MTD was not reached.

In the Phase 2 portion of the clinical trial, we implemented a cohort designed to treat patients with Olvi-Vec, at the dose of the first cohort in the Phase 1b portion, and approximately six weeks thereafter, patients were administered a chemotherapy regimen consisting of a platinum-based doublet (+/- bevacizumab). Olvi-Vec treatment was observed to be well tolerated, consistent with the previous Phase 1b results.

Olvi-Vec Monotherapy

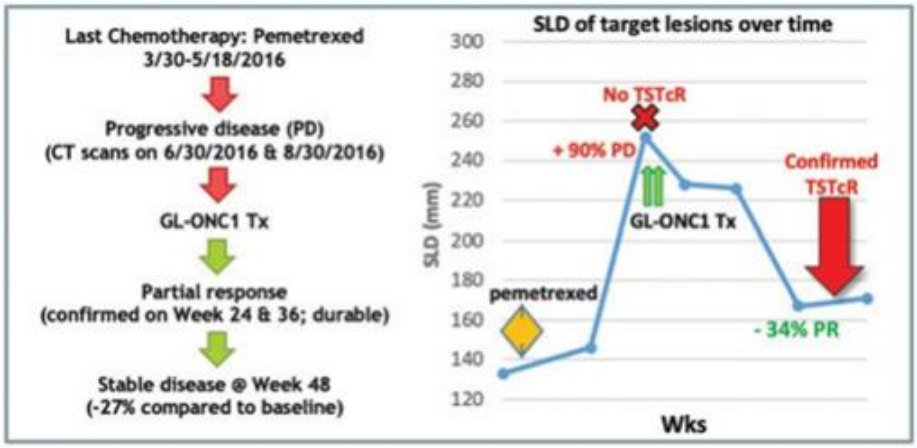
The following mechanisms of action were observed: (1) *Direct Lysis*—virus colonized and replicated in the tumor, killing of tumor cells in ascites, and reduced circulating tumor cells; and (2) *Immunotherapy*—virus- induced immune activation with enhanced tumor infiltration of CD8+ T cells and generation of tumor-specific T cell response (TSTcR). Killing and reduction of tumor cells, as well as a concurrent massive increase of immune cells, were confirmed by cytology analyses of ascites.

The following figure shows a typical tumor-cell and immune-cell dynamic observed across different patients (i.e., the tumor cell clusters in ascites fluid (abdomen) evident pre-treatment (W1D3) were cleared within days after virus infusion (W1D5, two days post-treatment), while at the same time, increasing infiltration of immune cells were observed after virotherapy (W2D10, seven days post-treatment)). This tumor-cell and immune-cell dynamic was not limited to the abdominal cavity.

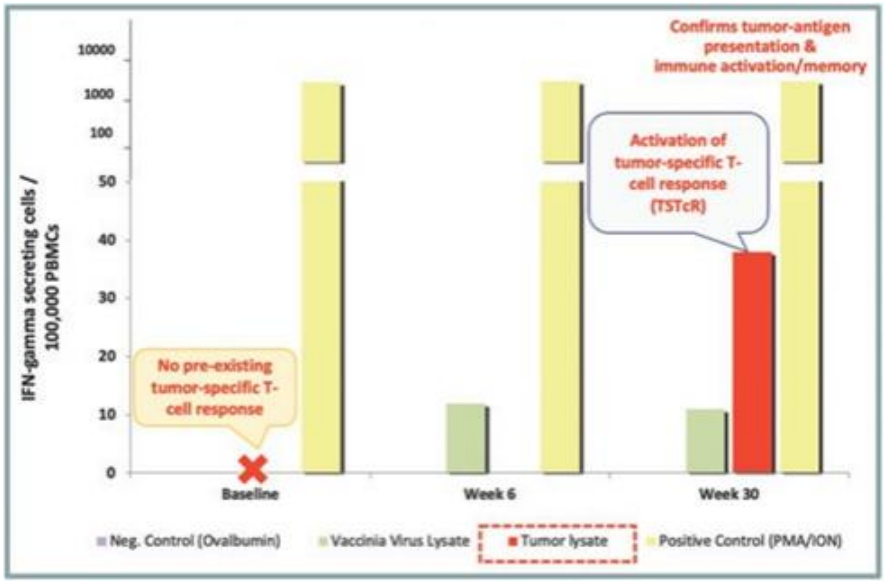


In an exemplary patient, a favorable and long-lasting TSTcR could still be detected at Week 30 after Olvi-Vec treatment alone as confirmed by interferon-g (IFN-g) ELISPOT assay. As shown in the following figure, this patient was heavily pretreated with nine prior lines of chemotherapy and failed the last line of pemetrexed treatment, with rapidly PD by CT scan at time of enrollment into our study. No TSTcR was detected in the patient's peripheral blood mononuclear cell sample at baseline. The patient subsequently achieved objective response as partial response (PR) per RECIST 1.1 criteria, measured by the significant reduction of sum of longest diameter (SLD) of the patient's tumor target lesions from the Olvi-Vec monotherapy. Response evaluation criteria in solid tumors (RECIST) 1.1 is the standard approach to objectively measure the response of a solid tumor to treatment in adult and pediatric cancer clinical trials. RECIST 1.1 defines a complete response (CR), PR, stable disease (SD) and PD as follows:

Category	Description
Complete Response	Disappearance of all tumor lesions
Partial Response	Reduction of >30% of the sum of target diameters
Stable Disease	Reduction of <30% or increase of <20% of the sum of target diameters
Progressive Disease	Increase of >20% of the sum of target diameters

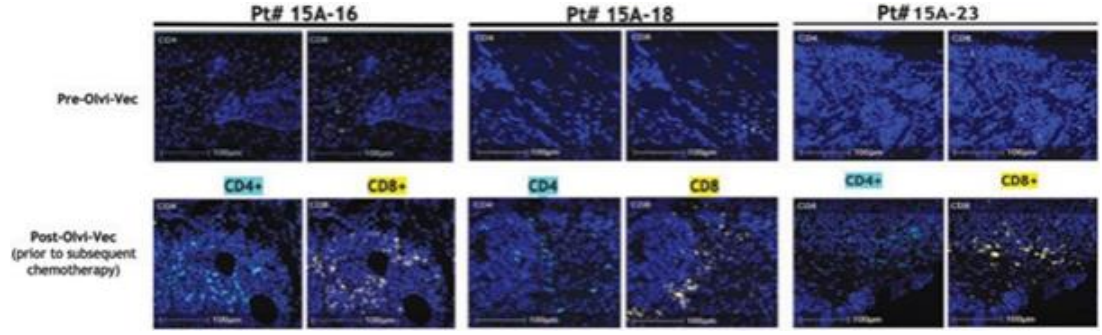


As shown in the following figure, more importantly, we confirmed the favorable and long-lasting TSTcR in the patient's blood by ELISPOT analysis coincided with the timing of objective response of PR by CT scan.

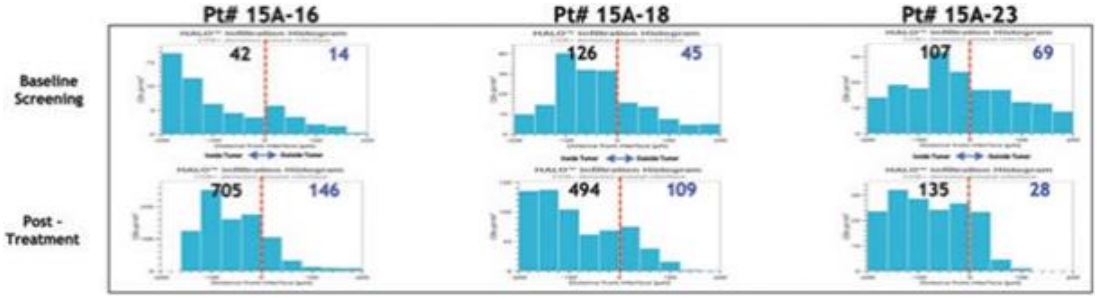


Enhanced tumor infiltration and/or activity of both cytotoxic T lymphocytes (CTLs) and CD4+ helper T cells has been a main aim of immunotherapy strategies and underlines the potent immune activation effect from virotherapy and its potential as an immunotherapy. In particular, the so-called immune-excluded phenotype, in which high levels of T cells and other immune cells accumulate at the tumor margin but cannot invade malignant cell nests, is generally linked to poor disease outcome, as compared to the "inflamed" or "hot" phenotype, in which intra-tumoral immune cells are abundant and get into direct apposition with neoplastic cells.

To investigate the influx of virus-induced CD8+ T cells into tumor tissues, multiplex immunohistochemistry analyses in paired tumor biopsies before and after virotherapy (prior to starting subsequent chemotherapy) were conducted. The following figure shows that the virus induced a large influx of CD4+ and CD8+ T cells into tumor tissues, in two representative patients. Both of these patients had recurrent cancer and achieved objective response by RECIST 1.1, with extended 11.4 and 13.0 months of PFS respectively, after subsequent platinum-based chemotherapy.

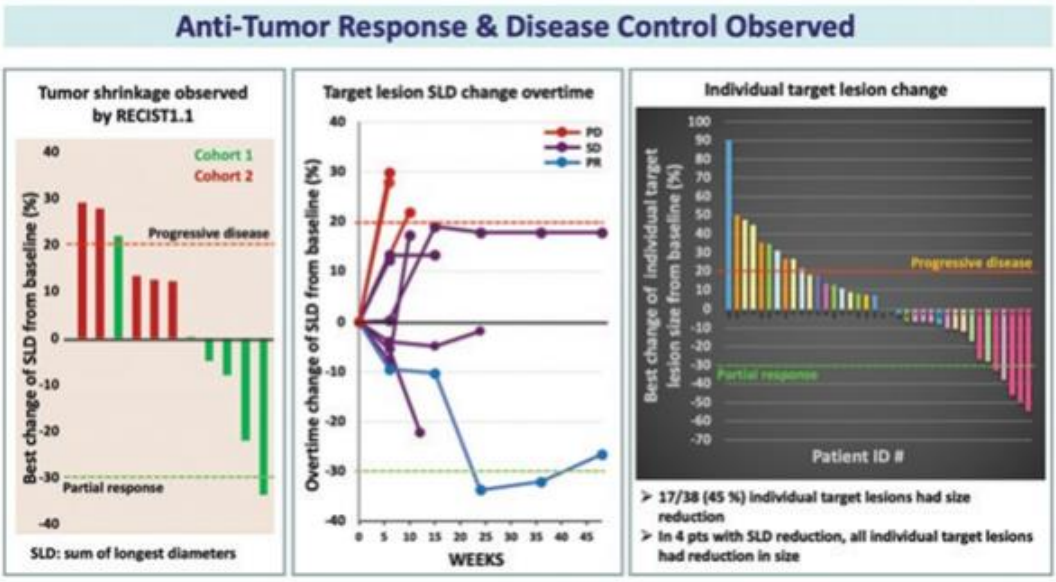


While studying CD4+ and CD8+ T cell infiltration in paired tumor biopsies by multiplex IHC, we also analyzed the number of T cells in distance relationship to the outlined tumor-stromal interface (set as '0' on the x axis) on a HALOTM infiltration histogram, with negative values of the x-axis to the left representing tumor region, and positive values to the right representing non-tumor stromal region. In five representative patients, a so-called "left-shift" of CD4+ and CD8+ T cells deeper into the tumor region occurred (i.e., away from stroma). The following figures show the CD8+ data described above.

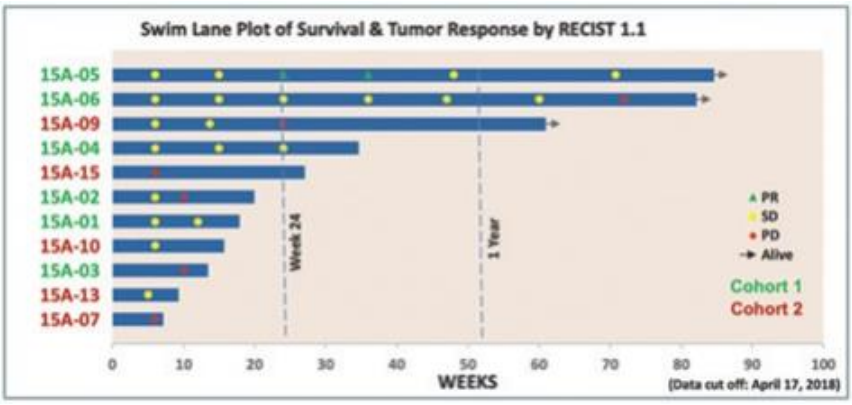


Clinically-significant anti-tumor effects of monotherapy were observed in both the Phase 1b and Phase portions of the trial.

As shown in the following figure, in the Phase 1b portion of the trial, the Clinical Benefit Rate (CR + PR + SD) was eight of 11 (73%); four out of 11 (36%) patients had a reduction in the SLD of target lesions, as confirmed by RECIST 1.1; and 17 of 38 (45%) of individual target lesions had a size reduction, with all target lesions reduced in size in the four patients with a reduction in SLD.



As shown in the following figure, SD of ≥15 weeks was 55% (six out of eleven patients); and an extended PFS also was documented with 23, 35, 59 (confirmed PR) and 71 weeks of PFS, respectively, in four out of eleven patients (three in Cohort 1 and one in Cohort 2). Additionally, four patients (two in Cohort 1 and two in Cohort 2) showed more than doubling of PFS compared to the patient's immediately-prior chemotherapy regimen.

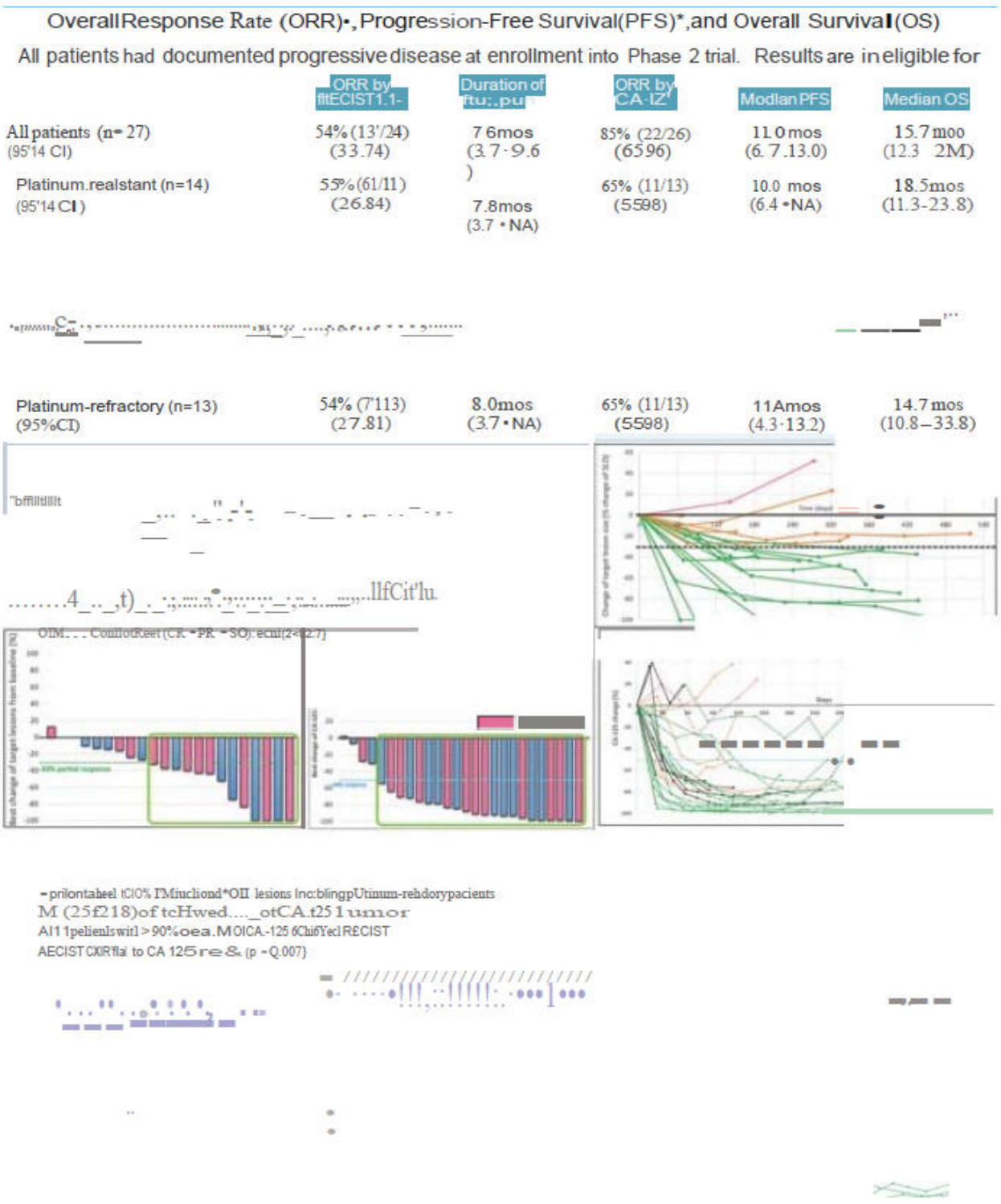


Olvi-Vec Primed Immunochemotherapy

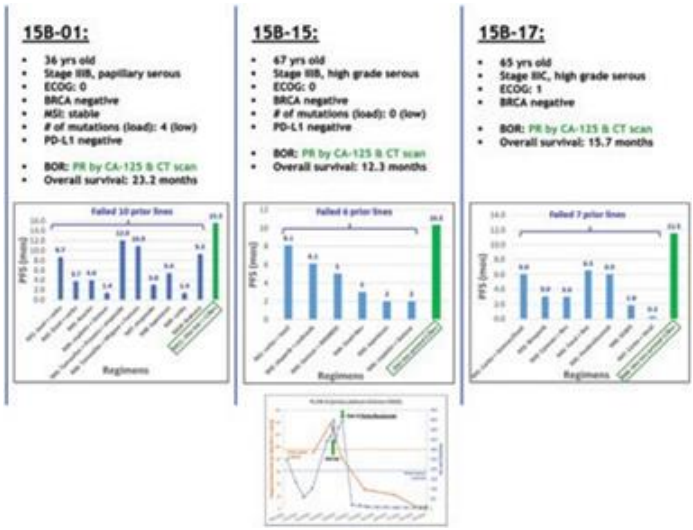
Patients who received Olvi-Vec-primed immunochemotherapy demonstrated responsiveness to platinum- based therapy, which they previously were deemed resistant or refractory. As shown in in the following figure, this was documented by multiple efficacy evaluation endpoints (based on pre-chemotherapy baseline), such as ORR, as determined by RECIST 1.1 Criteria by CT scans and GCIG CA-125 Response Criteria, and durability of responses as determined by duration of response, PFS and OS.

Importantly, relative to historical comparisons, patients receiving Olvi-Vec-primed immunochemotherapy generally showed marked clinical benefits, particularly with respect to ORR per RECIST 1.1 (54%) with durable response, median PFS (11.0 months) and median OS (15.7 months). Historically, the expected ORR per RECIST 1.1 would be < 20%, median PFS < 3 months, and median OS < 12 months. Of note, an ORR by RECIST 1.1 of 50%, median PFS (10.8 months) was achieved in patients with platinum-refractory disease versus the historically expected ORR per RECIST 1.1 would be < 20%, median PFS < 5 months; these patients progressed during, or within one month after, receiving their most recent prior platinum-based therapy.

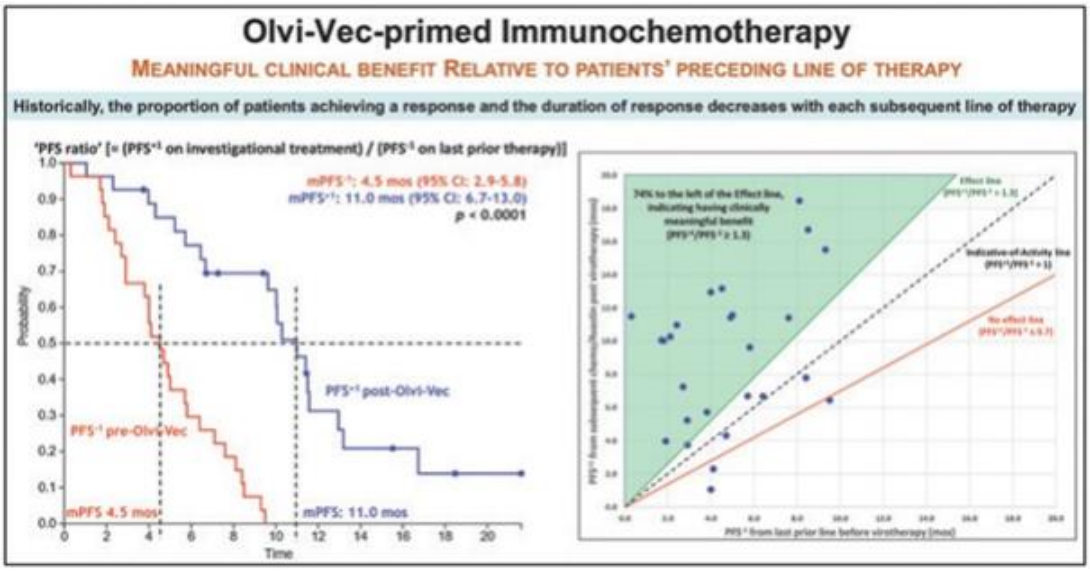
The trial results exceeded the pre-defined threshold of 13 or more of 28 evaluable patients (minimum 43%) demonstrating an objective response by RECIST 1.1; in total, and as shown in the figure below, 13 out of 2!1 patients (54%), evaluable by RECIST 1.1, demonstrated an objective response by RECIST 1.1.



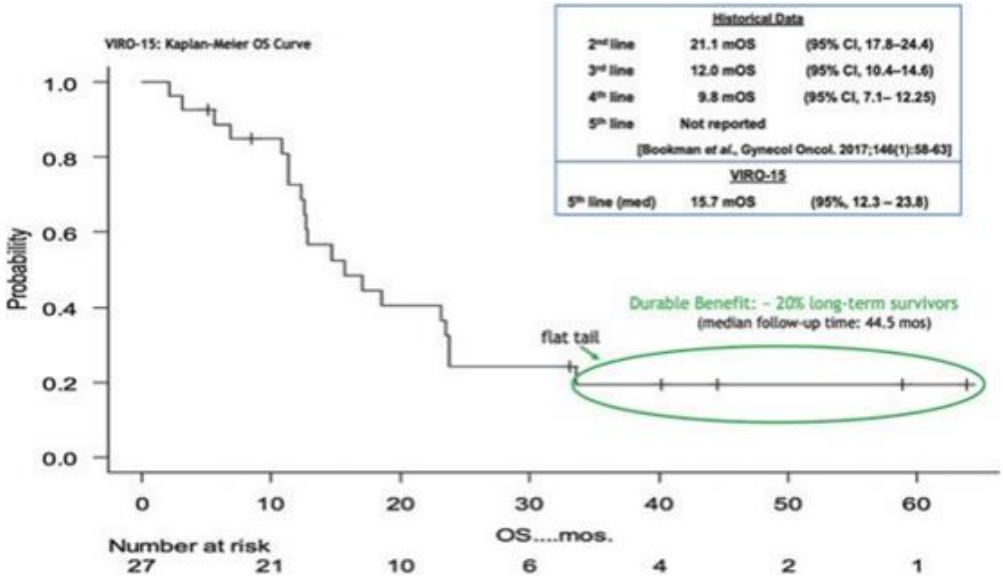
In the following graphic, we show the results of three exemplary heavily pre-treated platinum-refractory (i.e., progression while on last platinum), presenting at time of enrollment with progressive disease and projected short life expectancy. All achieved PFS exceeding any of their respective prior lines, and achieved objective partial response, suggesting meaningful clinical benefit from Olvi-Vec-primed immunochemotherapy.



The majority of patients treated with Olvi-Vec-primed immunochemotherapy showed clinical benefits exceeding their own last prior line of therapy (PFS of 11.0 months vs 4.5 months) with preserved or improved performance status. Historically, it is well known that patients with recurrent ovarian cancer suffer a decrease in PFS with each subsequent line of therapy. The effectiveness of subsequent lines of therapy have been described using the “PFS Ratio,” with any ratio greater than 1.3 considered clinically meaningful. The Kaplan-Meyer survival curves on the left show the median PFS was 4.5 months pre Olvi-Vec and 11.0 months post Olvi-Vec. The figure on the right shows that 74% of patients are on the left of the effect line, suggesting a clinically meaningful benefit following Olvi-Vec primed immunochemotherapy relative to prior lines of therapy.



Importantly, the median overall survival of patients exceeded the historical survival rates of earlier lines of therapy. Additionally, 20% of patients were long-term survivors, which is generally regarded as a hallmark of clinically beneficial immunotherapies.



Potential Mechanism of Action of Olvi-Vec-Primed Immunochemotherapy

We believe the high rate of responses and significantly prolonged PFS, in such a heavily-pretreated population with platinum-resistant/refractory disease, may be the result of mutual sensitization mechanisms between oncolytic VACV and chemotherapy/bevacizumab.

One such possible mechanism is so-called “prime & boost,” wherein Olvi-Vec may prime immune activation against tumor (neo)antigens, which is further boosted by immunogenic cell death by cytotoxic chemotherapies.

Combining Olvi-Vec-based immunotherapy with chemotherapy may have a particular clinical benefit against established tumors by increasing the tumor antigen-specific CD8+ T cell immune response through “cross-presentation” of the apoptotic tumor by subsequent cytotoxic chemotherapy, which is originally primed by virus-mediated vaccination.

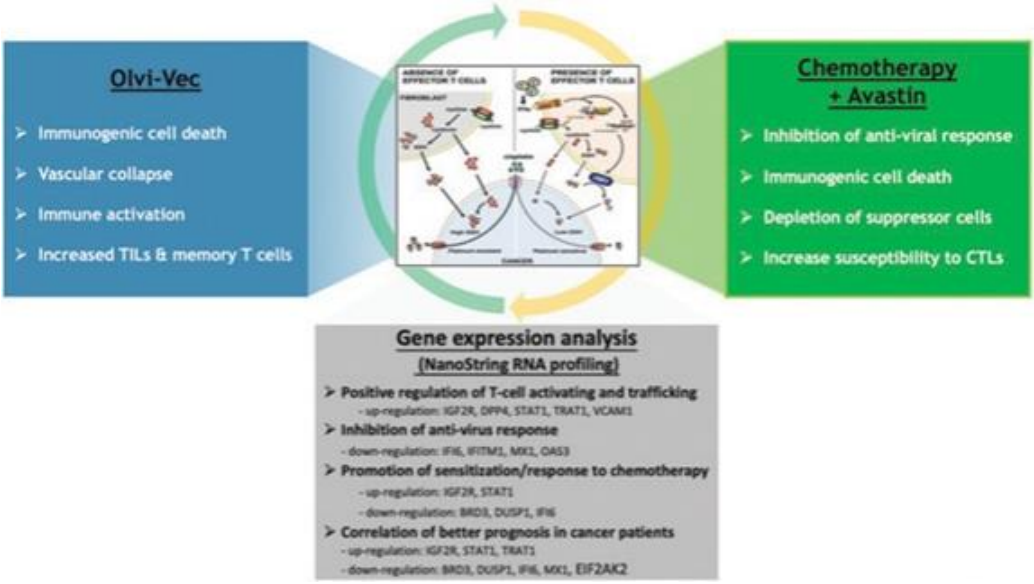
Carboplatin/paclitaxel/gemcitabine are also known to decrease tumor-induced immune suppression by abrogating MDSC and T-reg activities. Together the immunogenic cell death and abrogation of inhibitory signals by chemotherapy deliver a strong boost to the viral primed antitumor immunity and provide a sound rationale for the clinical application of the combination regimen as virus-primed immunochemotherapy.

We believe the combination treatment regimen established an efficient and robust mechanism, which resulted in the observed clinical results. Specifically, the oncolytic activity of Olvi-Vec primed anti-tumor immunity by the release and immunogenic presentation of tumor antigens (including neoantigens), and of virus- encoded foreign antigens (including vaccinia viral proteins and virus-encoded transgene products) which served as functional adjuvants. Subsequent cycles of cytotoxic chemotherapeutic drugs further generated immunogenic cell death and abrogated inhibitory signals, to deliver a strong boost to the viral-primed antitumor immunity. We believe that together, the virus-primed immunochemotherapy can potentially generate powerful and durable clinical benefits in otherwise difficult-to-treat cancer indications.

Another such possible mechanism is STAT1 upregulation, wherein Olvi-Vec-mediated upregulation of STAT1 may re-sensitize resistant tumors to chemotherapy. High STAT1 protein levels, along with STAT1-induced chemokines and intra-epithelial CD8+ T cell infiltration correlate with improved chemotherapy response and better PFS in ovarian cancer.

We believe Olvi-Vec plays a crucial role in this process by activation of CD8+ T cells and intra-tumoral infiltration, which modifies the tumor microenvironment through both immune priming and changes of gene expression profile. CD8+ effector T cells play a key role, via activated STAT1 signaling, in abrogating stroma- mediated chemoresistance in ovarian cancer.

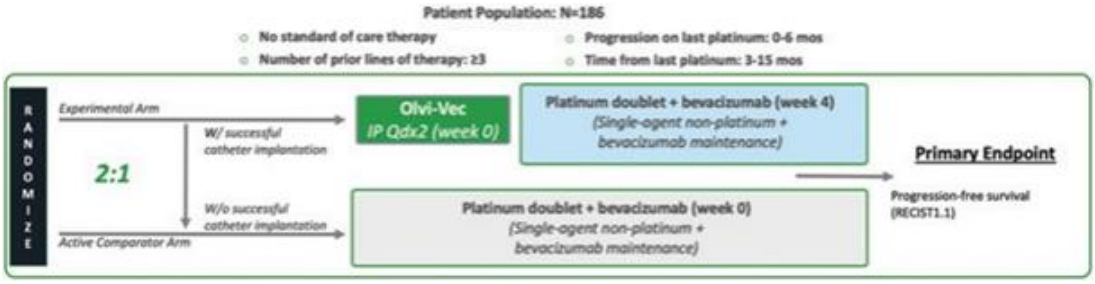
To characterize changes to the tumor microenvironment by Olvi-Vec treatment in patients, we conducted gene expression analysis by NanoString RNA profiling (PanCancer IO 360 Gene Expression Panel, including 770 genes that examine vital components involved in the complex interplay between the tumor, microenvironment and immune response in cancer) in paired (before and after virotherapy) tumor biopsies. Notably, gene expression generally associated with positive anti-tumor therapeutic effects was observed. For example, the gene expression of STAT1 of the IFN pathway was shown to be significantly upregulated ($p = 0.008$), which in combination with the observed virus-induced intra-tumoral influx of CD8+ T cells, together support the potential role of Olvi-Vec in abrogating platinum resistance in ovarian cancer.



PRROC Development Plan: Phase 3 Registration Trial

We envision that Olvi-Vec-primed immunochemotherapy may overcome chemotherapy for patients with end-stage ovarian cancer that would otherwise consider palliative care or use of drugs with historically poor response rates. After an End-of-Phase 2 meeting held with the FDA in March 2021 during which we discussed the potential of our planned Phase 3 clinical trial serving as a registrational trial, we initiated a Phase 3 registration trial in PRROC. The trial is an open-label, randomized control design (2:1 randomization), enrolling patients who received their last platinum within six months from enrollment (i.e., patients who would not be responsive to platinum re-challenge). The Experimental Arm patients will receive a single cycle (two doses) of Olvi-Vec administered intraperitoneally and, approximately four weeks later, a regimen of a platinum-based doublet plus bevacizumab followed by maintenance therapy. The Active Comparator Arm patients will receive a regimen of platinum-based doublet plus bevacizumab followed by maintenance therapy. The enrollment will be approximately 186 patients.

The following graphic summarizes the study design for the Phase 3 registration trial.



We formally submitted our protocol to the FDA for our Phase 3 registration clinical trial of Olvi-Vec in PRROC in January 2022 and made minor clarifying revisions in a protocol amendment in May 2022. In December 2021 and February 2022, we responded to FDA comments on our IND amendments for our new in-house manufacturing process seeking to demonstrate comparability of product manufactured under our new in-house process to product used in our Phase 2 clinical trial of Olvi-Vec in PRROC. In July 2022, we responded to FDA comments regarding an assay used in our clinical trial. Our Phase 3 registration clinical trial of Olvi-Vec in PRROC initiated enrollment in the third quarter of 2022.

Systemic Administration Program

The intravenous administration of viral immunotherapies is an attractive approach for potentially improving the standard of care for many oncology patients because it allows for all tumors in a patient to be treated, including micro-metastases that are often difficult to detect and treat. Historically, there have been several immunologic challenges and potential limitations to the intravenous use of oncolytic viruses in clinical practice. We have generated promising data in several clinical trials studying the intravenous administration of Olvi-Vec, including over multiple cycles as a monotherapy and in combination with chemotherapy.

Phase 1 Clinical Trial (GL-ONC1-002)/MA

We conducted an open-label, non-randomized Phase 1 clinical trial to evaluate the safety profile and clinical activities of Olvi-Vec when administered intravenously as monotherapy to patients with advanced solid tumors. Patients were enrolled in various cohorts with different dosing regimens and different total cumulative doses. A total of 43 patients were treated.

All patients entered the trial with documented PD. The majority of patients presented with Stage IV cancers, and a small fraction with Stage III cancers. These patients had failed previous treatment(s) with disease progression when entering the trial. Thirteen patients from early to later dose cohorts had radiographic evidence of SD by computerized tomography (CT) scans from 8, 12, 13, 24 weeks and up to 48 weeks as compared to baseline tumor imaging.

Clear changes in tumor growth rate post Olvi-Vec treatment were documented by CT scans. In such cases, patients failed previous therap(ies) with PDs, but experienced significant reduction in tumor growth after receiving Olvi-Vec treatment. OS was compared in patients with PD or with SD. A statistically significant difference ($p = 0.024$) was documented between the two groups, indicating a potential clinical benefit of Olvi-Vec therapy in the group of patients who entered the trial with PDs. The intravenous administration of Olvi-Vec was observed to be well tolerated and MTD was not reached in this trial.

Tumor colonization

Viral colonization in tumor biopsies were confirmed by immunohistochemistry.

Transient elevation of anti-tumor cytokines/chemokines and biomarkers

To elucidate immune stimulation from intravenous-delivered Olvi-Vec, we conducted immune analyses of cytokine levels at Day 8 after treatment compared to baseline levels. Overall, the data from this trial showed a profile of proinflammatory response.

There was an elevated level of various proteins involved in inflammation and Th-1 type related immune response, including acute-phase reactants, cytokines, and chemokines. Several IFN-g or interleukin-1 (IL-1)- induced proteins were significantly increased after virus treatment, including IP-10, ITAC, MCP-2 or MCP-4 (induced by IL-1 and TNF*a*), in addition to an increase in the interferon gamma-inducing factor, IL-18, all indirectly indicating an elevation in IFN gamma and IL-1 levels after virus treatment.

Increase of CD4+ and CD8+ cell populations

We investigated the potential impact of a peripheral blood mononuclear cells immune cell response on the therapeutic responses to Olvi-Vec. We included only the evaluable patients in the analysis, by looking at the relationship between the change from baseline for each peripheral blood mononuclear cell subset population and the responses to the Olvi-Vec treatment. Six of the seven patients with SD showed an increase in the CD4+CD69+ cell population (newly activated CD4+ cells) on Day 8 after Olvi-Vec treatment, whereas patients with PD did not show a major difference in concentration of these cells between baseline and Day 8 ($p = 0.028$). Similarly, there was a trend ($p = 0.13$) in elevated CD8+CD3+CD69+ cells (newly activated CTLs) in patients with SD compared to patients with PD. Interestingly, a drop in CD19+ cell population (B-lymphocytes) was observed in six out of seven SD patients, while out of ten patients with PD, five showed reduced B lymphocyte levels, two did not have any changes and three showed increased levels of this cell type.

Infection of Circulating Tumor Cells

We used the CellSearch system to analyze the blood of selected patients after Olvi-Vec administration, allowing detection by GFP fluorescence of circulating tumor cells which were infected with Olvi-Vec.

Clinical benefit in patients with pre-existing anti-vaccinia virus antibody titers

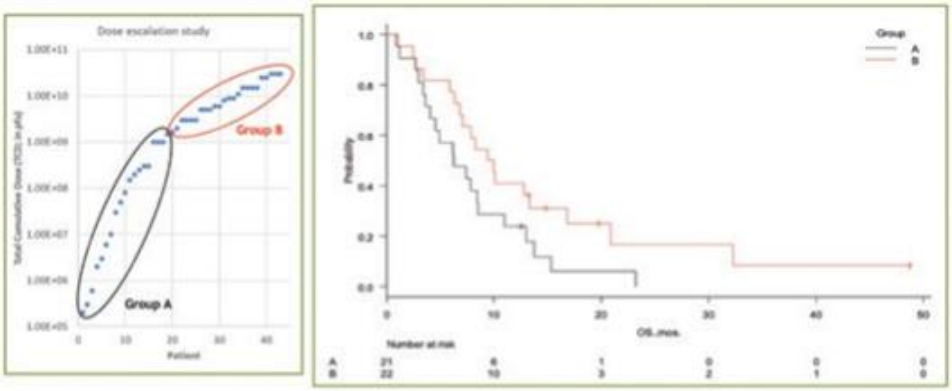
We examined the possible relationship of the baseline value of anti-vaccinia virus antibody titer and the anti- tumor activity of Olvi-Vec. Patients enrolled into this trial had failed previous line(s) of treatment with PD. Twenty seven of the 43 patients treated were evaluable by CT, and 13 of them showed SD for at least 12 to 24 weeks post treatment. The other 14 patients had PD by Week 12. We grouped these patients into those that received low, mid and high doses of virus, and examined how baseline anti-vaccinia titer (NAb) may or may not have affected their SD or PD status post treatment. We found that the anti-vaccinia virus titer does not plateau until around eight days after the first virus dose and does not continue to increase after repeated virus injections.

Only at the mid-dose level did we find that there was a statistically significant difference on baseline Nab between patients with SD or PD, which indicates that the baseline NAb affected the outcome of viral therapy. At the mid-dose level, patients with low to nonexistent baseline NAb tended to have SD, and patients with high baseline NAb tended to have PD ($p = 0.007$). At low-dose levels, lower baseline NAb titer does not significantly correlate to SD status and higher baseline NAb does not signal PD status ($p = 0.18$). This is understandable because such low doses are most likely sub-therapeutic. When high doses of virus were given, there was no statistical difference ($p = 0.74$). This tells us that high doses of virus may effectively ‘neutralize’ the NAb, regardless of the pre-existing baseline NAb level, and therefore the existence of baseline NAb titer does not pose significant inhibition to viral therapy or forecast poor response.

Dose-dependent clinical benefit

Olvi-Vec, intravenously administered over months of time, as a monotherapy in patients with advanced solid tumors, with no standard of care option, showed a virus-dose-dependent clinical benefit on OS from multiple intravenous cycles. For purposes of the analyses below, virus dose is expressed in total cumulative dose received in all cycles in each patient. As stated above, 43 patients with advanced solid tumors were treated in this study.

In the following figure, we show that, of the 43 patients, the 21 who received the lowest cumulative dose had a median OS of 6.2 months and the 23 who received the highest cumulative dose had median OS of 9.7 months. The results show a trend of OS favoring the higher-dose group.

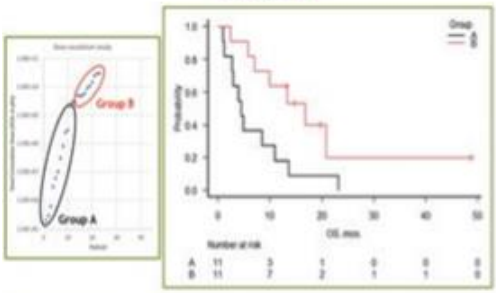


Group A: (n=21; **lower-dose group** patients with TCD ranging from 2×10^5 pfu - 2×10^9 pfu)
Group B : (n=22; **higher-dose group** patients with TCD ranging from 3×10^9 pfu - 3×10^{10} pfu)

Groups A vs B: median OS at **6.2 months** (95% CI: 3.6 – 8.5) vs **9.7 months** (95% CI: 6.3 – 16.8); $p = 0.067$; with a trend favoring the higher dose group.

In the following figure, we further show the results of the 22 evaluable patients within the total treated population, with intractable primary lung cancers and/or lung metastases of other tumor types. In Graph 1, we show that, of the 22 patients, the 11 patients who received the lowest cumulative dose had a median OS of 4.6 months and the other 11 patients who received the highest cumulative dose had median OS of 16.8 months. The results show a statistically significant OS benefit favoring the higher-dose group (p = 0.026). In Graph 2, when we further extend the analysis, of the 22 patients, the five patients who received the lowest cumulative dose had a median OS of 4.6 months and the 11 who received the highest cumulative dose had median OS of 20.9 months. The results show a statistically significant OS benefit favoring the higher-dose group (p = 0.002).

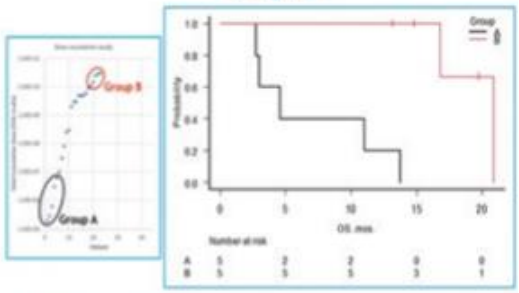
Graph 1



Group A : (n=11; **lower-dose group** with TCD ranging from $2\cdot10^5$ pfu - $2\cdot10^9$ pfu)
Group B : (n=11; higher-dose group with TCD ranging from $3\cdot10^9$ pfu - $3\cdot10^{10}$ pfu)

Groups lower vs higher TCD:
median Overall Survival at **4.6 months** (95% CI: 1.3 – 11.0) vs 16.8 months (95% CI: 5.9 – NA);
$p = 0.026$; a statistically significant clinical benefit favoring the higher dose group.

Graph 2



Group A : (n=5; **lowest-dose group** with TCD ranging from $2\cdot10^5$ pfu - $1\cdot10^9$ pfu)
Group B : (n=5; highest-dose group with TCD ranging from $1\cdot10^{10}$ pfu - $3\cdot10^{10}$ pfu)

Groups lowest vs highest TCD:
median Overall Survival at **4.6 months** (95% CI: 2.7 – NA) vs 20.9 months (95% CI: 16.8 – NA);
$p = 0.002$; a statistically significant clinical benefit favoring the highest dose group.

Data from this study suggest that Olvi-Vec may have activity against a variety of cancers, particularly with lung disease from either primary lung cancer or lung metastases from other cancer types, when intravenously administered initially prior to immune activation and potentially thereafter for multiple cycles.

Phase 1 Clinical Trial (GL-ONC1-011/UCSD)

We conducted an open-label, non-randomized Phase 1 clinical trial, which administered Olvi-Vec intravenously on multiple consecutive-days in a single cycle, as neoadjuvant treatment to patients with solid organ cancers prior to undergoing surgery. The objective of this study was to test a more aggressive dosing protocol in solid tumor patients by intravenously delivering high doses of virus on consecutive days in a single cycle from one week to one month prior to surgery. The intent was to obtain and analyze biological samples from the patients. As the surgeries were for curative intent, anti-tumor activity data was not obtained. The IV treatment was shown to be well tolerated and no DLTs were reported.

Neutralizing antibody dynamics suggest optimum dosing regimen

Anti-vaccinia antibody (NAb) levels were measured in blood before and after Olvi-Vec treatments. Substantial levels of NAb were detected by Day 8 in three out of five patients (NAb were low at Day 5 in two of these three patients), and were not reached in the other two patients at that time point. Therefore, these data indicate that there may be a window of opportunity for at least five days to allow condensed intravenous delivery of virus (e.g., consecutive days; even multiple doses per day) without significant neutralization effect from anti- vaccinia NAb. In one patient where long-term follow-up data was available, the Nab level dropped back to a low, near-baseline, level by six months post treatment. This data suggests that repeat dosing over extended time periods is possible. Overall, we believe the data described above indicates that a four-consecutive-day treatment schedule may balance efficiency of virus delivery and convenience of scheduling at the clinic.

Since patients received virus under neoadjuvant setting prior to surgery, primarily for curative intent, we were not able to determine therapeutic responses to Olvi-Vec among these patients. Nevertheless, data from this study suggest that high and condensed (up to five consecutive days) intravenous doses of Olvi-Vec result in endured viral pharmacokinetics in the blood and lead to infection of and immune cell infiltration into tumor tissues.

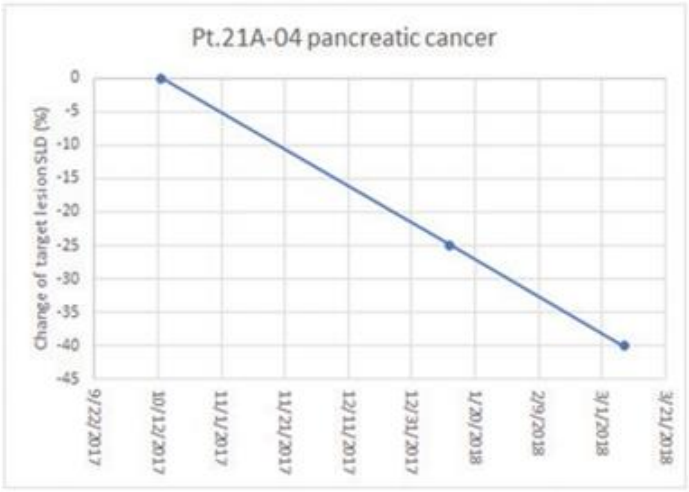
Expanded Access Program (GL-ONC1-021/AHCI)

We conducted an open-label, non-randomized expanded access study at Advent Health Cancer Institute, during which Olvi-Vec was administered on multiple consecutive-day intravenous doses in a single cycle to patients with advanced cancers and no standard of care or eligibility for other clinical trials and who otherwise would be provided hospice care.

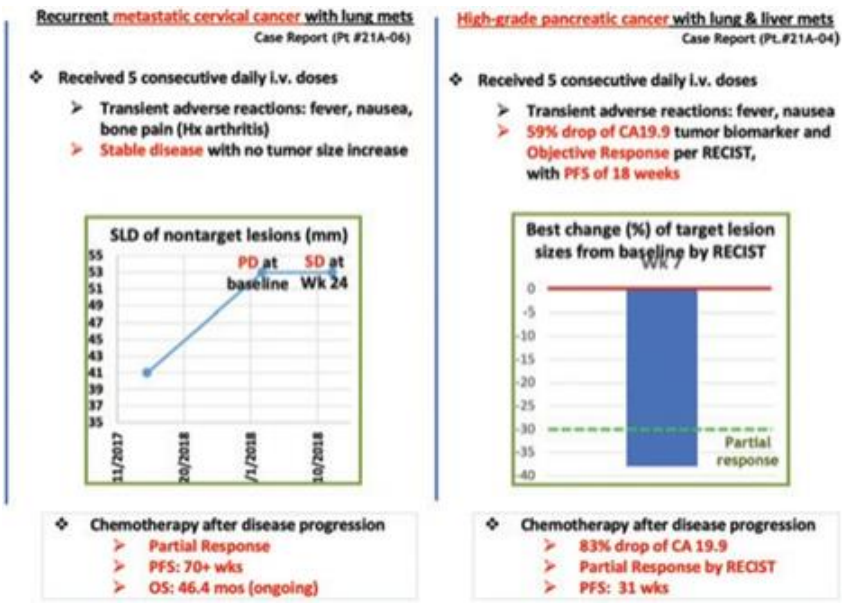
The intravenous treatment was shown to be well tolerated. Since patients received virus under an expanded access protocol, biological sampling was limited, and tumor biopsy materials were not collected.

Clinically-significant anti-tumor effects were observed in two of three solid tumor patients who received Olvi-Vec-primed immunochemotherapy, with results pending for a fourth patient currently undergoing treatment. Case reports for the two patients who had clinically-significant results are set forth below.

- Case Report Patient #21A-04: A high-grade pancreatic cancer patient with lung and liver metastases received five consecutive daily intravenous doses of Olvi-Vec. The patient achieved a 59% drop of the cancer biomarker CA19.9 and an objective PR (38% target lesion size reduction from pre-Olvi-Vec baseline) per RECIST 1.1 documented by CT scans from intravenous Olvi-Vec monotherapy, as depicted in the figure below, with a PFS of 18 weeks. After subsequent disease progression, the patient then received subsequent chemotherapy and again achieved a PR (-30% target lesion size reduction from pre-chemo baseline) by RECIST 1.1, with 83% drop of CA 19.9, and PFS of 31 weeks.



- Case Report Patient #21A-06: A patient with terminal recurrent metastatic cervical cancer with metastases in the lung also received five consecutive daily intravenous doses of Olvi-Vec. The patient had disease progression with multiple bilateral pulmonary tumor nodules increased in size compared with the prior exam at time of enrollment. Following Olvi-Vec treatment, the first CT scan at six weeks after treatment revealed growth arrest of her tumor lesions; her disease was stable for 24 weeks. The patient then went on to receive platinum doublet and bevacizumab after virotherapy and was assessed by the investigator to have had a PR to treatment. PFS for this patient was for 70 weeks, and her ongoing OS is at 36+ months with excellent performance status. Her current treating medical oncologist has recommended to again consider Olvi-Vec virotherapy when needed.



Data from this trial suggest that Olvi-Vec-primed immunochemotherapy may have utility when administered intravenously in cancers beyond ovarian and in combination with therapies beyond platinum-based regimens.

Olvi-Vec-Primed Immunochemotherapy for the Treatment of Recurrent Non-Small-Cell Lung Cancer (NSCLC)

The first indication we intend to pursue through intravenous administration is recurrent NSCLC. NSCLC is the most common type of lung cancer, accounting for 80-85% of all lung cancer diagnoses. The most common types of NSCLC are squamous cell carcinoma, large cell carcinoma, and adenocarcinoma. Metastatic NSCLC has a poor prognosis. For example, the five-year OS rate for Stage IV NSCLC patients is less than five percent. Survival was similar in the recurrent diseases regardless of stage at diagnosis, with median OS of 6.6 months for Stage I, 6.7 months for Stage II, and 6.9 months for those with initial Stage III disease. Patients with de novo or recurrent Stage IV disease have median OS of 4.9 months.

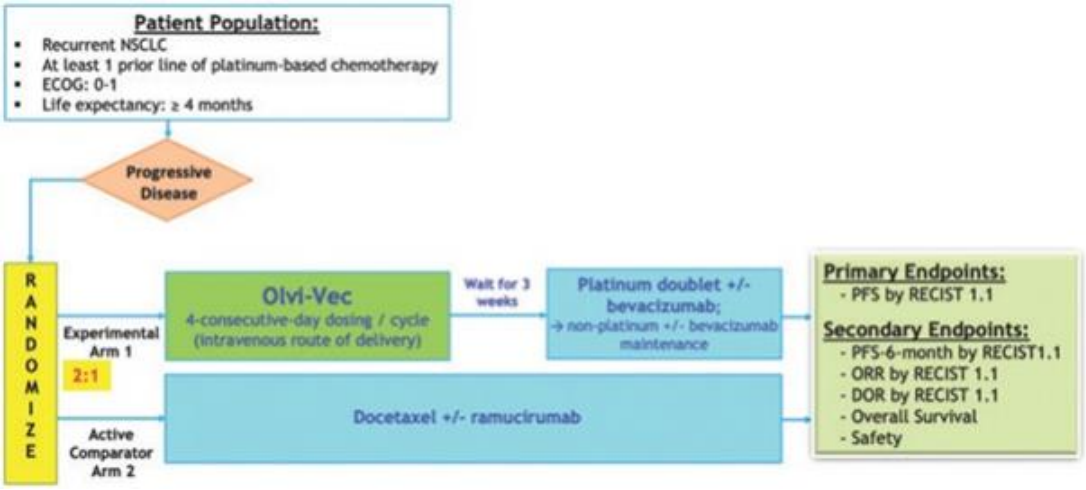
Patients experiencing a recurrence of, or with advanced NSCLC, have few treatment options and are treated with chemotherapy or precision cancer medicines. The most commonly used regimens include either cisplatin or carboplatin; combined with one of several other drugs approved for the treatment of NSCLC; pemetrexed, paclitaxel, docetaxel, gemcitabine, irinotecan, or vinorelbine. Bevacizumab or ramucirumab in combination with the chemotherapy drugs paclitaxel and carboplatin, is FDA-approved for the first-line treatment of advanced, non-squamous NSCLC.

Despite advances in treatment and management of recurrent advanced NSCLC, NSCLC represents a high unmet medical need and novel therapies are needed to improve therapeutic outcomes, especially in patients who do not have driver mutations for targeted therapies and/or immunotherapy, or who have developed resistance to their previous treatment(s). According to Datamonitor (2021), the market for NSCLC is expected to reach $39.0 billion by 2029 in the seven major markets (U.S., EU5 and Japan). The growth of the NSCLC market will be driven partly by increasing incident cases, as the population ages. In addition, premium-priced immuno- oncology and targeted pipeline agents are expected to drive the uptake of new therapies and prolong the duration of treatment in the first-line and beyond. Based on our internal research and analysis of publicly-available data sources, we estimate the U.S. market potential of our existing products, with a label expansion in recurrent NSCLC, to at least $1.0 billion in 2029. Our projections are subject to a number of assumptions, risks and uncertainties that could cause them to be smaller than we currently estimate.

Recurrent NSCLC Development Plan: Phase 2 Clinical Trial

We selected recurrent NSCLC as our first registration-path indication for intravenous delivery of Olvi-Vec-primed immunochemotherapy because of the promising data generated in patients with lung disease (primary or metastatic) in our GL-ONC1-002/MA and GL-ONC1-021/AHCI clinical trials. We believe intravenous delivery of Olvi-Vec to the lung, unlike other viruses that are administered intra-tumorally and that are less amenable to repeat injections, is particularly compelling because of the ‘first pass effect’ (i.e., after administration the virus reaches the heart and is then first transported to the lungs). In preclinical studies, we have repeatedly observed the eradication of distal pulmonary metastases from multiple tumor types by intravenously administered Olvi-Vec virus.

Subject to FDA authorization, we anticipate beginning regulatory study start-up of a Phase 2, open-label, randomized, and controlled clinical trial designed to evaluate the efficacy and safety of intravenously delivered Olvi-Vec oncolytic VACV followed by treatment as per the NCCN Guidelines for patients with recurrent NSCLC in the United States in the first half of 2023, which will be funded in its entirety by Newsoara. We plan to conduct this trial under our current open IND and, subject to regulatory authorization, potentially launch a multi-regional clinical trial with Newsoara in the United States and China. We further anticipate Newsoara will initiate a Phase 1 study of Olvi-Vec in patients with recurrent SCLC in the first half of 2023, and thereafter initiate trials in recurrent NSCLC and recurrent ovarian cancer in China.



Additional Potential Indications for Olvi-Vec

We believe our preclinical and clinical data support the broad development of Olvi-Vec in patients with liquid or (metastatic) solid tumors, as a monotherapy or in combination with other therapies. Our current plan is to expand our clinical development program by pursuing additional indications via intravenous delivery. Other indications will be selected from the balance of more than 20 major human cancers against which Olvi-Vec has shown activity in preclinical studies, including blood (other leukemia/lymphoma), breast, colon, kidney, lung, prostate and skin (melanoma) cancers.

For example, one program expansion may be to conduct a basket trial of Olvi-Vec in patients who are either refractory and/or intolerant to standard of care and who have primary lung cancer or who have lung tumors metastatic from other primary tumors such as breast cancer, colon cancer, prostate cancer, sarcoma, bladder cancer, neuroblastoma and Wilm's tumor.

A second program expansion may include clinical trials to assess the potential therapeutic benefit of Olvi-Vec in frontline settings, such as in ovarian cancer. In that regard, we have observed the potential benefits of combining Olvi-Vec with platinum compounds in preclinical studies, and in a completed Phase 1 clinical trial combining Olvi-Vec with cisplatin and radiation as front-line therapy in newly diagnosed head and neck cancer patients. Olvi-Vec was well tolerated and demonstrated favorable trends in PFS and OS.

We believe that the potential to induce immune responses may represent an important mechanism to control tumor growth, prevent the spread of tumors, improve the ability to surgically remove tumors and perhaps reduce the need for surgery, and reduce or delay the onset of relapse.

We may also pursue additional indications via regional delivery. Potential indications include appendiceal, colorectal and gastric cancers, other gynecologic malignancies, and peritoneal mesothelioma.

License Agreement with Newsoara

In September 2021, we entered into a License Agreement (the Newsoara License) with Newsoara BioPharma Co. Ltd. (Newsoara) pursuant to which we granted Newsoara an exclusive license to research, develop, commercialize or exploit (i) any and all oncolytic viruses that are controlled by us, including Olvi-Vec but excluding V-VET1 (licensed viruses); (ii) any pharmaceutical product in final form that is comprised of or

contains the licensed viruses as an active ingredient (licensed products); (iii) any virus developed by or behalf of Newsoara that (a) has a vaccinia virus backbone; (b) is not disclosed or covered by any of our patents; and (c) includes modifications (as compared to the licensed viruses) of a gene function with therapeutic intent (derived molecules); and (iv) any pharmaceutical product in final form that is comprised of or contains derived molecule as an active ingredient (derived products), in each case in China (the territory, which includes mainland China, Taiwan, Hong Kong and Macau) for all human diagnostic, prophylactic and therapeutic uses (the Newsoara field). The license granted to Newsoara is royalty bearing for licensed products and royalty free for derived products. Under the Newsoara License, Newsoara also granted to us an exclusive and royalty bearing license to develop, commercialize and exploit outside the territory any derived products developed by Newsoara.

Under the terms of the Newsoara License and to date, we have received from Newsoara an aggregate of $5.0 million as an upfront payment. Newsoara paid an additional $6.0 million milestone upon the FDA's authorization of our Phase 3 clinical trial for ovarian cancer. Additionally, Newsoara is obligated to pay us additional development and commercial milestone payments up to $160.5 million in the aggregate upon the occurrence of certain development, regulatory and commercial milestones by the licensed products, and royalties on net sales of the licensed products in the mid-single-digit to mid-teens percentage range (the Newsoara Royalty). The Newsoara Royalty term, with respect to a licensed product and each region in the territory, is the period beginning on the date of first commercial sale of such licensed product in such region and ending on the last to occur of: (a) the expiration of the last to expire patent controlled by us (including any applicable patent term extension) in such region that contains either (i) an issued valid claim that covers the licensed product (including the licensed virus contained therein, and including the composition of matter and method of making and using thereof) or (ii) a pending valid claim that covers the sequence of the licensed virus contained therein; (b) the tenth anniversary of the first commercial sale of such licensed product in such region; and (c) the expiration of all regulatory exclusivity for such licensed product in such region.

If we, at our discretion, elect to develop and commercialize outside the territory any derived product developed by Newsoara, we are required to make certain milestone and royalty payments to Newsoara.

The partnership is managed by a four-member management committee that has equal representation from us and Newsoara. In the event of a dispute at the management committee level, Newsoara will have the final decision- making authority with respect to all matters concerning the development, manufacture or commercialization of the products for the Newsoara field in the territory and we shall have the right to veto any decision by Newsoara that would result in a substantial adverse effect on the products outside the Newsoara field and/or territory.

Newsoara is required to use commercially reasonable efforts to research, develop, manufacture and commercialize the licensed products in the territory in the applicable Newsoara field and is solely responsible for all costs and expenses incurred in connection with such activities. In addition, Newsoara is required to use commercially reasonable efforts to conduct a multi-center Phase 2 clinical trial for Olvi-Vec in NSCLC using clinical sites in the United States and China and Newsoara will be responsible for the cost of such trial. Newsoara's development work will be initially focused on Olvi-Vec, and Newsoara may not develop any derived product in NSCLC or PRROC until either Olvi-Vec has been approved in such indication in the territory or the development of Olvi-Vec in such indication has been abandoned by the parties.

Unless terminated earlier, the Newsoara License will continue on a product-by-product and country-by-country basis until expiration of the Newsoara Royalty. Each party may terminate the Newsoara License for the uncured material breach of the other party or in the case of bankruptcy of the other party. In addition, we may terminate the Newsoara License if Newsoara challenges any of the licensed patents, and Newsoara may terminate the Newsoara License for convenience with a specified prior notice period.

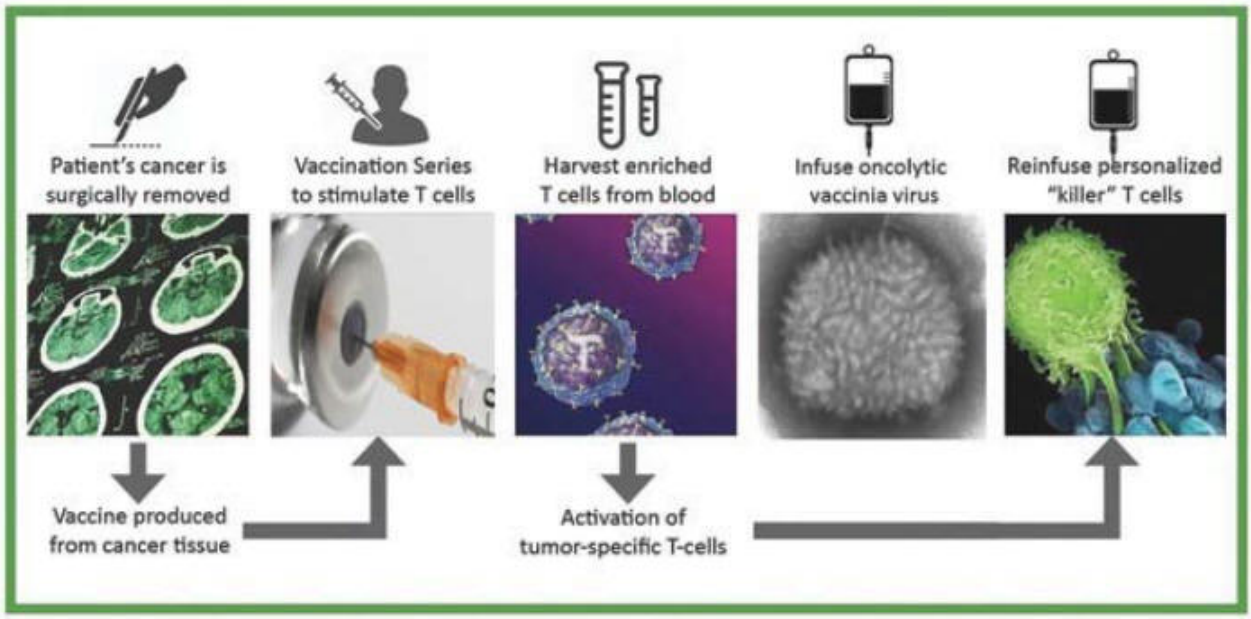
Virus and Neoantigen-primed Adoptive Cell Therapy (V2ACT Immunotherapy)

V2ACT Immunotherapy is a proprietary, indication-agnostic personalized immunotherapy designed to safely maximize the number and effect of cancer neoantigen-specific effector T cells within cancer tissues. It combines immunotherapeutic modalities, neoantigen-primed effector T cell immunotherapy (NACT) and oncolytic immunotherapy (initially, Olvi-Vec), each of which is supported by extensive preclinical and clinical proof-of-concept data, including Phase 1 and 2 clinical trials, in various cancer indications. V2ACT Immunotherapy will be developed by V2ACT, a joint venture with TVAX and us.

Immunotherapies can be subcategorized into 1) cytokines (e.g., Interleukin 2, Interferon beta); 2) vaccines (e.g., Bacillus Calmette-Guerin, Sipuleucel-T); 3) ICIs (e.g., ipilimumab, pembrolizumab, and nivolumab); 4) oncolytic viruses (e.g., T-Vec); and 5) adoptive CAR T cell transfer (e.g., Yescarta). Each has had significant therapeutic success in certain patient populations and the listed examples are FDA-approved products. It is generally believed that combinations of immunotherapies could broaden their applicability and increase overall efficacy.

V2ACT Immunotherapy is designed to combine the benefits of agents from four of the five subcategories. Neoantigen-specific adoptive T cell therapy and Olvi-Vec employ different and potentially synergistic mechanisms for cancer cell killing and prolonging patient survival. Adoptive transfer of cancer neoantigen- specific effector T cells has proven to be an effective treatment for multiple cancers. Reducing cancer tissue associated immunosuppression could increase the anti-cancer effects of adoptively transferred neoantigen- specific effector T cells. In addition to lysing cancer cells, Olvi-Vec induces an acute inflammatory response within cancer tissue that modulates the immune microenvironment in a way that would be anticipated to enhance the effects of adoptively transferred neoantigen-specific effector T cells.

The following diagram sets forth the potential synergistic use and mechanism of action of V2ACT Immunotherapy:



The scientific rationale for V2ACT Immunotherapy is as follows:

- *Patient's cancer is surgically removed*. Surgery performed for clinical benefit removes cancer tissue for manufacture of an attenuated autologous cancer cell vaccine.
- *Vaccination series to generate neoantigen-primed T cells.* Vaccination with the patient's own neoantigen-containing cancer cells combined with a powerful immunological adjuvant generates an immune response that produces high numbers of primed cancer neoantigen-specific effector T cell precursors in the patient's body.

- *Harvest enriched T cells from blood.* Immune cells obtained from a blood draw are stimulated with T cell activators ex vivo to convert neoantigen-specific effector T cell precursors into effector T cells and increases their numbers.
- *Infuse oncolytic VACV.* Olvi-Vec selectively enters cancer tissue and i) kills cancer cells; ii) generates an immunostimulatory acute inflammatory response, a "hot spot" that increases receptivity to the anti- cancer effects of adoptively transferred neoantigen-specific effector T cells; and iii) boosts anti-cancer immune responses.
- *Re-infuse personalized "killer" T cells*. Ex vivo-activated neoantigen-specific effector T cells are carried to cancer tissue throughout the body, enter cancer tissue and initiate a cascade of immunological events that produce cancer cell killing, which are propagated with a course of low-dose interleukin 2 to stimulate continued multiplication of the infused cancer neoantigen-specific effector T cells.

Neoantigen-primed Adoptive Cell Therapy (NACT)

In addition to Olvi-Vec, NACT is the other component of V2ACT Immunotherapy.

Following successful completion of preclinical studies, Phase 1/2a proof-of-concept studies of NACT were performed in humans. Those studies were conducted under an investigator-initiated, university-sponsored IND and an IND sponsored by TVAX.

Patients vaccinated with an attenuated autologous cancer cells and an immunological adjuvant generally produced a detectable immune response across a wide variety of cancer types in these studies. Specifically, 130 patients were vaccinated twice with 107 live attenuated autologous cancer cells and granulocyte macrophage colony-stimulating factor (GM-CSF). Patients were tested for generation of adaptive T cell-mediated immune responses using delayed-type hypersensitivity skin testing with attenuated autologous cancer cells. The average percent positivity was 89% + 3% (estimated mean ± standard error). The following table sets forth the results of this study:

Cancer Types	Subjects Tested	Immune Responses*
Brain	36	92%
Breast	20	90%
Colon	13	92%
Lung	**25**	**88%**
Kidney	17	88%
Melanoma	14	75%
Ovary	5	100%
Total	**130**	**89%**

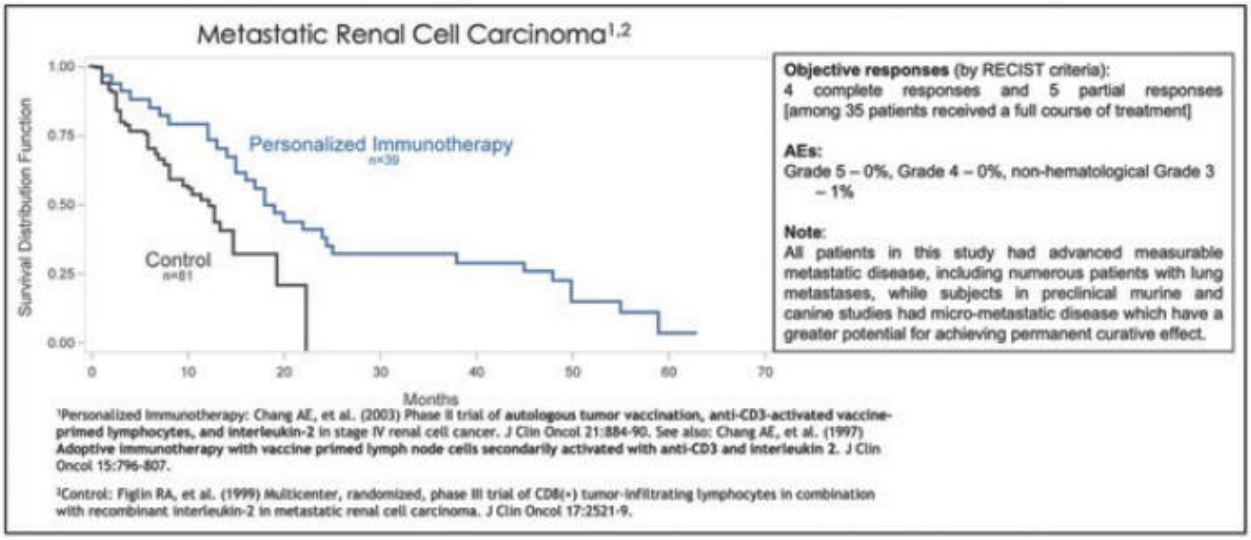
89% of patients across cancer types showed positive cancer - specific DTH skin test immune response

*% delayed type hypersensitivity (DTH) skin test positivity following a single vaccination; multiple vaccinations push percentage positivity to 100%. Multiple autologous cancer vaccine publications have confirmed these data and added positive data related to leukemia, pancreatic cancer, prostate cancer and sarcoma (list available)

Benefits of vaccination with neoantigen-expressing cancer cells:

1. Increases number of primed neoantigen-specific T cells in patient's body that can be used to manufacture cancer neoantigen-specific effector T cells for treatment
2. Increases number of primed neoantigen-specific T cells in cancer tissue that are available for subsequent stimulation *in situ*

In a single-arm Phase 2a clinical trial, metastatic renal cell cancer patients were treated with the combination of attenuated autologous cancer cell/immunological adjuvant vaccination and adoptive cell therapy of T cells activated ex vivo with anti-CD3 and a T cell proliferation-stimulating cytokine. The objective clinical response rate was 25% (5PR, 4CR) and all nine patients were long-term survivors. The following figure sets forth the results of this trial relative to historical control data.



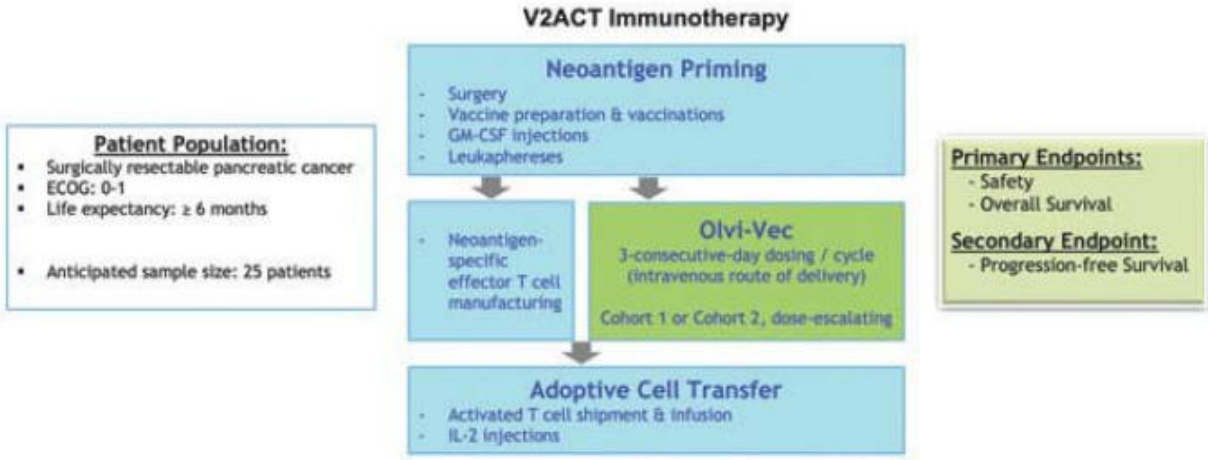
Pancreatic Cancer Development Plan: Phase 1/2a Trial

According to GlobalData (2021), pancreatic cancer has a global incidence of 495,773 cases annually, with 466,003 deaths attributable. From 2014 to 2018, the worldwide five-year survival rate for pancreatic cancer increased two percent to nine percent. The ACS estimates in 2022 there will be 62,210 new cases of pancreatic cancer and 49,830 will die from the disease in the United States. According to GLOBOCAN 2020, the market for pancreatic cancer in the eight major markets (U.S., EU5, Japan and urban China) is expected to increase to $4.1 billion in 2029 at a moderate compound annual growth rate (CAGR) of 8.2%.

Pancreatic cancer can develop from two kinds of cells in the pancreas: exocrine cells and neuroendocrine cells, such as islet cells. Survival is significantly better for patients with locally advanced disease (median survival 9–15 months) than for those with metastatic disease (three to six months). Unfortunately, pancreatic cancer often presents late and only a portion of patients with pancreatic cancer have disease at time of presentation that can be surgically resected with an expectation that surgery will generate clinical benefit.

Chemotherapy, primarily gemcitabine, is the mainstay of treatment for patients with advanced disease. Importantly, the targeted therapies and checkpoint inhibitor therapies that have demonstrated efficacy in some other forms of cancer have provided minimal benefit in pancreatic cancer. Despite advances in surgical and medical treatment of pancreatic cancer there has been a minimal improvement in the five-year survival rates.

In October 2020, V2ACT received an IND authorization from the FDA for the initiation of a Phase 1b/2a clinical trial to study V2ACT Immunotherapy as a treatment for newly diagnosed, surgically-resectable pancreatic cancer. This clinical trial is not yet scheduled to be initiated. The trial is designed to enroll 25 patients. All patients will have surgery to remove all or a portion of their primary cancer. The patients then will receive V2ACT Immunotherapy. This Phase 1/2a study is designed to obtain preliminary safety and efficacy data on this combination in order to design a larger Phase 2b clinical trial. The following graphic summarizes the study design for the planned Phase 1/2a clinical trial.



Joint Venture with TVAX Biomedical, Inc.

Limited Liability Company Agreement

In January 2019, we formed V2ACT as a joint venture with TVAX for the purpose of V2ACT developing and commercializing V2ACT Immunotherapy. The joint venture is governed by an Amended and Restated Limited Liability Company Agreement entered into in June 2021 (LLC Agreement) which provides each of us and TVAX with 50% ownership interests, identical voting and management rights and responsibilities, equal representation on the governing four-member management committee, and equal sharing of profits and losses of V2ACT. To date, V2ACT's expenses have been de minimis and have been funded through equal capital contributions made to V2ACT by us and TVAX, and we expect this to continue for the foreseeable future.

The LLC Agreement requires a majority vote by the management committee to approve general business matters and a supermajority vote of the members to approve specified major transactions, including a merger or consolidation of V2ACT and the sale, lease, exchange, or other disposition of all or substantially all of the assets of V2ACT. Cash available for distribution, if any, is determined by the management committee quarterly and distributed to the members on a pro rata basis. Transfers of a member's ownership interest require the other member's consent, other than transfers to affiliates or successors. The LLC Agreement provides for the dissolution of V2ACT upon a supermajority vote of the members, among other specified events.

License Agreement with V2ACT Therapeutics

In June 2021, we entered into a License Agreement with V2ACT (V2ACT License), pursuant to which we granted V2ACT a worldwide, non-exclusive, fully paid, royalty free license for our proprietary oncolytic virus (Licensed Virus(es)) to research, develop and commercialize any product, procedure or method for the treatment of cancer that combines (a) Licensed Virus(es), and (b) autologous or allogeneic cancer-specific T lymphocytes (T-Cell Therapeutic(s)) for the diagnosis, prevention and treatment of cancer in humans (Products). V2ACT is solely responsible, by itself or through its sublicensees, for all research, development, manufacturing and commercialization activities with respect to Products in the applicable field. V2ACT is required to use commercially reasonable efforts to research, develop, manufacture and commercialize Products in the applicable field and is solely responsible for all costs and expenses incurred in connection with such activities. We have the sole right and discretion to prepare, file, prosecute, maintain, enforce and defend the licensed patents at our cost and expense. On September 26, 2021, V2ACT and TVAX entered into a First Amendment to the License Agreement, whereby the Territory was defined as worldwide except for Greater China (i.e., Mainland China, Hong Kong, Macau and Taiwan).

Pursuant to the V2ACT License, unless V2ACT fails to initiate any human clinical trial of any Product within 18 months of the effective date of the V2ACT License, or fails to dose any subjects for a period of 18 months after the initiation of any such human clinical trial, we and our affiliates (other than an acquiror) may not directly or indirectly, engage in any development, commercialization, manufacturing, import and/or export activities, or enter into any collaboration or license agreement with any third party in connection with any such activities related to any Product. This non-compete does not limit or restrict our ability to develop, commercialize or exploit the Licensed Virus(es) as a stand-alone product or in combination with any product that is not a T-Cell Therapeutic(s).

Under the V2ACT License, V2ACT may request that we perform certain research, development and/or manufacturing services related to the Licensed Virus(es) in connection with the research, development and manufacture of Products in the applicable field.

Each party may terminate the V2ACT License for the uncured material breach of the other party or in the case of bankruptcy. In addition, we may terminate the V2ACT License if V2ACT challenges any of the licensed patents, and V2ACT may terminate the V2ACT License for convenience with a specified prior notice period.

License Agreement between V2ACT Therapeutics and TVAX

In June 2021, TVAX entered into a License Agreement with V2ACT (TVAX License), pursuant to which TVAX granted V2ACT a worldwide, non-exclusive, fully paid, royalty free license for its proprietary T-Cell Therapeutics (Licensed T-Cell Therapeutic(s)) to research, develop and commercialize any product, procedure or method for the treatment of cancer that combines (a) any virus-based cancer therapeutics, and (b) Licensed T-Cell Therapeutic(s) for the diagnosis, prevention and treatment of cancer in humans (Products). In addition, TVAX granted V2ACT an exclusive (even as to TVAX and its affiliates), a fully paid, royalty free license under certain patents related to the use of virus and cell therapies in combination to research, develop and commercialize Products in the applicable field. V2ACT is solely responsible, by itself or through its sublicensees, for all research, development, manufacturing and commercialization activities with respect to Products in the applicable field. V2ACT is required to use commercially reasonable efforts to research, develop, manufacture and commercialize Products in the applicable field and is solely responsible for all costs and expenses incurred in connection with such activities. On September 26, 2021, V2ACT and TVAX entered into a First Amendment to the License Agreement, whereby the Territory was defined as worldwide except for Greater China (i.e., Mainland China, Hong Kong, Macau and Taiwan).

TVAX has the sole right and discretion to prepare, file, prosecute, maintain, enforce and defend the licensed patents (other than the combination therapy patents) at its cost and expense. TVAX will continue to prosecute and maintain the combination therapy patents at its cost and expense but must transfer the patent prosecution of the combination therapy patents to V2ACT at the request of V2ACT.

Pursuant to the TVAX License, unless V2ACT fails to initiate any human clinical trial of any Product within 18 months of the effective date of the TVAX License, or fails to dose any subjects for a period of 18 months after the initiation of any such human clinical trial, TVAX and its affiliates (other than an acquiror) may not directly or indirectly, engage in any development, commercialization, manufacturing, import and/or export activities, or enter into any collaboration or license agreement with any third party in connection with any such activities related to any Product. This non-compete does not limit or restrict TVAX’s ability to develop, commercialize or exploit the Licensed T-Cell Therapeutic(s) as a stand-alone product or in combination with any product that is not a therapeutic virus.

Under the TVAX License, V2ACT may request that TVAX perform certain research, development and/or manufacture services related to the Licensed T-Cell Therapeutics in connection with the research, development and manufacture of Products in the applicable field.

Each party may terminate the TVAX License for the uncured material breach of the other party or in the case of bankruptcy. In addition, TVAX may terminate the TVAX License if V2ACT challenges any of the licensed patents, and V2ACT may terminate the TVAX License for convenience with a specified prior notice period.

Preclinical Studies of Olvi-Vec

Our preclinical studies demonstrate Olvi-Vec has the potential to infect and directly kill a wide range of tumor cell types *in vitro* and *in vivo* and produce an anti-tumor immune response. Our preclinical animal data show regression and elimination of the more than 20 major liquid and solid cancer types tested in preclinical models, including some of those deemed "very difficult to treat," such as having known chemo-resistance or radio-resistance. We have also demonstrated the combination of oncolytic immunotherapy and clinically used chemo-, immuno-, and radio-therapies have the potential to enhance outcomes.

In vitro Cytotoxicity Studies

In a preclinical study conducted with the National Institutes of Health, we demonstrated the virus can replicate in a large panel of cell lines of different cancer types. We also have shown in many *in vitro* cytotoxicity studies that Olvi-Vec can infect and replicate more efficiently in human tumor cells than in normal cells. For example, we conducted *in vitro* cell culture experiments to test the tumor-cell killing (plaque forming) efficiency of Olvi-Vec in a fibrosarcoma cell line compared to the plaque forming efficiency in primary dermal fibroblasts. We showed a preferential infection and killing of fibrosarcoma tumor cells as compared to the noncancerous primary dermal fibroblasts.

Preclinical Studies (GLV-1h68)

Based on preclinical studies of Olvi-Vec (Lab name: GLV-1h68), we believe Olvi-Vec not only has the potential to enhance the anti-tumor effect of chemotherapies and radiation therapies, but also immunotherapies such as cellular and targeted therapies (e.g., immune checkpoint inhibitors and co-stimulatory molecules).

Lymphoma: Effect of VACV with Immune-modulating Checkpoint Inhibitor Following Local Tumor Irradiation

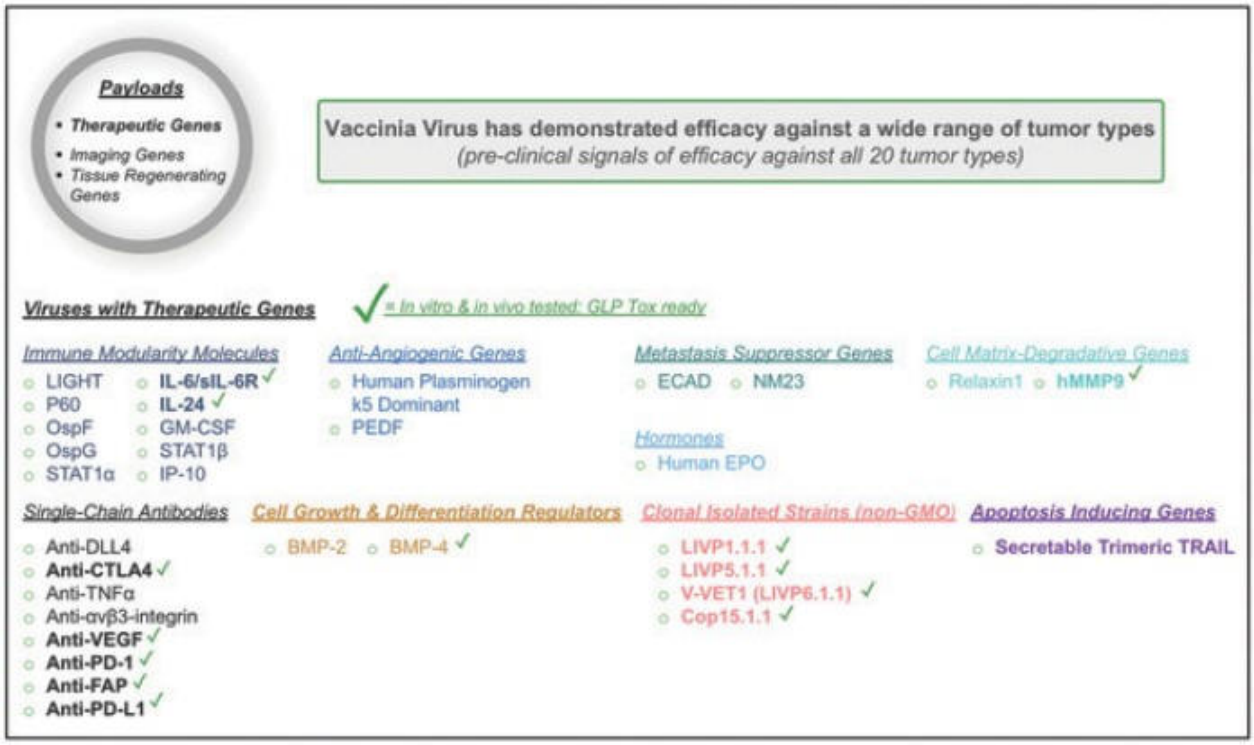
We examined the activity of a proprietary VACV (GLV-6b500), as both a single agent and as a combination agent with a checkpoint inhibitor and radiation, in a syngeneic animal model of hematologic malignancies to simulate advanced lymphoma. Murine lymphoma A20 cells were injected subcutaneously on bilateral flanks of BALB/c mice and treatment initiated on day 17 to only the right flank tumor with local irradiation, intra-tumoral VACV (Irr-VACV) and intra-tumoral anti-CTLA-4 monoclonal antibody (Irr-VACV-CTLA4). The Irr-VACV- CTLA4 regimen was most effective in eradicating or shrinking not only the treated tumor but also the non-treated tumor and extending survival, followed by the Irr-VACV regimen.

CHOICE Discovery Platform

Our proprietary CHOICE discovery platform is the foundation of our oncolytic immunotherapy product development program and is designed to allow us to develop new product candidates rapidly from conception through the initiation of clinical trials. The discovery platform is based on our collection of various strains of VACV based on multiple selection criteria, both in vitro (e.g., viral replication rate, plaque size, transgene expression efficiency, etc.) and in vivo (e.g., viral titer, antitumor activities, safety, etc.).

Through genetic engineering, recombinant strains have been generated to carry single or multiple exogenous therapeutic and/or diagnostic gene expression cassette(s) under different synthetic or natural promoters to regulate the timing and strength for transgene expression. We can generate custom-made viruses based on desired transgene(s) and specific parental viral strain, designed to optimize safety by reducing toxicity, tumor selectivity and desired diagnostic and/or therapeutic potential, e.g., to act at several key points in the pathways involved in the initiation of an immune response.

We have generated an extensive portfolio of oncolytic vaccinia immunotherapy clinical candidates. We have made over 500 different versions of the VACV armed with greater than 110 transgenes, having a variety of engineered attributes, including immune modulatory and cell killing properties. We intend to develop one or more therapies derived from this platform to address multiple types of tumors, utilizing transgenes such as those set forth in the following table:



Leveraging the knowledge and experience gained through the development of Olvi-Vec, we intend to nominate at least one additional product candidate after initiating and establishing our Phase 3 registration trial in ovarian cancer and our Phase 2 clinical trial in NSCLC, and to begin IND-enabling toxicology studies following nomination.

Selection criteria for nomination of next product candidate(s) will be based in part on our current and future preclinical and clinical experience with Olvi-Vec. We will evaluate our clinical candidates based on preclinical observations in animal model demonstrations that these viruses can more effectively lyse tumor cells, stimulate the immune system and/or enhance the ability to reach tumor sites after intravenous administration, including repeated dosing.

Our Animal Health Program

Cancer is the leading cause of death for dogs and the number one pet health concern for dog owners in the United States. In addition to surgery, currently available canine cancer treatment typically provides limited survival benefit.

The National Cancer Institute's Center for Cancer Research Comparative Oncology Program has reported that as many as six million pet dogs and six million pet cats are diagnosed with cancer annually in the United States. The veterinary oncology market is estimated to reach $909.4 million by 2026, with North America expected to hold a dominant position.

V-VET1 (Laboratory name: LIVP6.1.1), our lead animal health product candidate, is a genetically characterized, veterinary-grade replication-competent oncolytic VACV that is a naturally-attenuated isolate.

V-VET1-001/CVS (Canine Veterinary Oncology Study)

We conducted a canine cancer study in which V-VET1 was administered as a single intravenous dose in multiple cycles to a total of 11 canine patients.

We did not observe any significant treatment related hematologic toxicities at any time. There was no report of skin rash from any dogs, and no report of horizontal transmission of virus. Samples were negative from canine patients who had nasal and lesion swabs taken post-virus administration and tested by viral plaque assay. One dog in the highest dose level cohort had oral swabs taken at ten minutes post-administration of virus injection and virus was detected on Cycle 1, Day 3 and Cycle 2, Day 1. No MTD was reached in this dose-escalation trial, even at the highest dose (3 × 109 pfu/25 kg body weight) out of four dose levels tested.

The following tables summarizes the individual best overall responses for the 11 evaluable canine patients.

Tumor Type	Total # of Dogs	Best Overall Response
Mast Cell Tumor	2	1 PR /1 SD
Osteosarcoma	2	2 SD
Soft Tissue Sarcoma	4	3 SD /1 PD
Anal Gland Carcinoma	2	2 SD
T Cell Lymphoma	1	1 PR
Overall Response	**11**	**2 PR /8 SD /1 PD**

PR = Partial Response / SD = Stable Disease / PD = Progressive Disease

Overall, evidence of antitumor responses and disease control was documented in patients with different tumor types. Two objective responses (PR) in lymphoma and mast cell tumor, respectively, were documented among these patients, with an ORR of 18% and disease control rate (CR+PR+SD) of 91% (ten out of 11).

License Agreement with ELIAS

In November 2021, as amended on February 2022 and April 2022, we entered into a License Agreement (ELIAS License) with ELIAS Animal Health LLC (ELIAS) pursuant to which we granted ELIAS the exclusive, worldwide and royalty bearing license to research, develop, use, sell, offer for sale, have sold, import and otherwise commercialize any and all veterinary products that contain the oncolytic virus known as V-VET1 in the diagnosis, prevention and treatment of cancer in non-human animals (the ELIAS field). Under the ELIAS License, ELIAS also granted to us an exclusive, fully paid and royalty free license to use the data and results developed by ELIAS to develop, commercialize and exploit any therapeutic virus outside the ELIAS field.

Under the terms of the ELIAS License, ELIAS is obligated to pay us certain development and sale milestones and to pay royalties in the mid single-digit percentage range on net sales of the licensed products (the ELIAS Royalty). The ELIAS Royalty term will continue, on a country-by-country basis, until the latest of: (i) the 10th anniversary of the first commercial sale of such product in such country; (ii) the expiration of the last-to-expire valid claim in the licensed patents in such country that covers such product (including the composition of matter, manufacture or use of such product or any component therein); and (iii) the expiration of all regulatory exclusivity for such product in such country.

ELIAS is required to use commercially reasonable efforts to research, develop, and commercialize the licensed products, and is solely responsible for all costs and expenses incurred in connection with such activities, including all studies and clinical trials necessary to obtain regulatory approval for the licensed products in the ELIAS field. We and ELIAS created a technology transfer plan to enable ELIAS to initiate the development and manufacturing of the licensed products in the ELIAS field. At this time, we are completing technology transfer of V-VET1 to ELIAS.

Unless earlier terminated, the ELIAS License shall remain in effect, on a country-by-country basis, until the expiration of the ELIAS Royalty. ELIAS has the right to terminate the ELIAS License for convenience with advance written notice. Each party has the right to terminate the ELIAS License for the uncured material breach of the other party or in the case of bankruptcy of the other party. In addition, we may terminate the ELIAS License immediately upon prior written notice to ELIAS, if they challenge any of the licensed patents.

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary rights. We face significant competition from many sources, including pharmaceutical, biopharmaceutical and biotechnology companies, as well as universities and private and public research institutions. Many of our potential competitors, alone or with their strategic partners, may have substantially greater financial, technical and other resources than we do, such as larger research and development, clinical, marketing and manufacturing organizations. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of competitors.

We are focused on developing next-generation viral immunotherapies for the treatment of cancer. Any viral immunotherapies that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

Competition in cancer therapeutics comes in many forms, where different technologies are employed against different molecular targets or biological systems. We are aware of other companies either marketing or focused on developing competing therapies for the treatment of cancer which generally fall into the following treatment groups:

- Oncolytic viral immunotherapies, including Amgen's IMLYGIC (talimogene laherparepvec), the only FDA-approved oncolytic immunotherapy, which is approved for the local treatment of unresectable cutaneous, subcutaneous, and nodal lesions in patients with melanoma recurrent after initial surgery and is in development for several other indications, and other oncolytic viruses in development by companies such as AstraZeneca plc (AstraZeneca), Boehringer Ingelheim, CG Oncology, Inc., Candel Therapeutics, Inc., Daiichi Sankyo Company, Limited, DNAtrix, Inc., Johnson & Johnson, Merck & Co., Inc. (Merck), Oncolytics Biotech, Inc., Oncorus, Otsuka Holdings Co. Ltd., PsiOxus Therapeutics, Ltd., Regeneron Pharmaceuticals, Inc. (Regeneron), Replimune Group, Inc., SillaJen, Inc. (SillaJen), Targovax USA, Transgene SA (Transgene), Turnstone Biologics Corp. (Turnstone Biologics) and Vyriad, Inc.;
- Approved immunotherapy antibodies and immunotherapy agents in clinical development, including antibody agents, bispecific T cell engagers, including those in development by Amgen, and immuno- oncology companies focused on IL-12, such as Ziopharm Oncology, Inc. (Ziopharm Oncology);
- Cancer vaccines, including personalized vaccines and those targeting tumor neoantigens, including neoantigen therapies in development by companies such as Advaxis Inc., Agenus, Inc., AstraZeneca, Bavarian Nordic A/S, BioNTech SE, Genocea Biosciences, Inc., Gritstone Oncology, Inc., Heat Biologics, Inc., ImmunityBio, Inc., Iovance Biotherapeutics, Inc. (Iovance), IMV, Inc., Moderna, Inc., SOTIO a.s., Transgene, Turnstone Biologics and VBI Vaccines, Inc.;
- Cell-based therapies, including TILs in development by Iovance and approved and in-development CAR T cell therapies, including those commercialized by BMS, Gilead Sciences, Inc. and Novartis AG (Novartis), T cell receptor and NK cell therapies;
- Therapies aimed at activating innate immunity such as those targeting stimulator of interferon genes protein (STING) and toll-like receptors (TLRs) including those in development by BMS, Checkmate Pharmaceuticals, Inc., Chinook Therapeutics, Inc., GlaxoSmithKline plc (GSK), Idera Pharmaceuticals, Inc., Merck, Mologen AG, Nektar Therapeutics, TriSalus Life Sciences, and UroGen Pharma, Inc.; and
- Traditional cancer therapies, including chemotherapy, surgery, radiation and targeted therapies.

These technologies and compounds can focus on very specific targets, such as up- and down-regulating genes, hyperactive protective factors, growth factors, and the immune system or broadly attack the cancer in the manner of conventional chemotherapy and radiation. We believe that our product candidates, if and when marketed, would largely complement rather than compete directly with these existing treatment options.

We are aware of several other companies developing therapies based on VACV. To our knowledge, the only clinical product based on VACV that has advanced beyond Phase 1 clinical development is Pexa-Vec, being jointly developed by SillaJen and Transgene. Pexa-Vec has a different product profile from Olvi-Vec, including a different strain of VACV and different transgenes. In August 2019, SillaJen announced the discontinuation of its Phase 3 PHOCUS trial of Pexa-Vec in advanced liver cancer for futility.

We are also aware of other companies either marketing or focused on developing competing therapies for the treatment of other cancers which generally fall into the following treatment groups:

NSCLC

- Chemotherapies which include carboplatin (manufactured by sixteen companies), vinorelbine tartrate (manufactured by six companies), paclitaxel (manufactured by seven companies), taxotere (manufactured by fifteen companies), doxorubicin hydrochloride (manufactured by thirteen companies) along with Celgene's Abraxane, Eli Lilly's Gemzar and Eli Lilly's Alimta.
- BRAF (v-Raf murine sarcoma viral oncogene homolog B) kinase inhibitors which include Novartis's Tafinlar and Novartis's Mekinist.
- ALK (anaplastic lymphoma kinase) inhibitors which include Pfizer's Xalkori, Novartis's Zykadia, Genentech's Alecensa, Takeda Pharmaceutical Company's Alunbrig and Pfizer's Lorbrena.
- EGFR (epidermal growth factor receptor) inhibitors which include AstraZeneca's Tagrisso, AstraZeneca/Teva Pharmaceutical Industries Ltd.'s Iressa, Astellas Pharma Inc./Chugai Pharmaceutical Inc./Roche/Genentech's Tarceva, Boehringer Ingelheim Pharmaceutical's Gilotrif, Pfizer's Vizimpro and Eli Lilly's Portrazza.
- TRK (tropomyosin receptor kinase) inhibitors which include Genentech's Rozlytrek, Bayer AG's Vitrakvi and Novartis's Tabrecta.
- RET (rearranged during transfection) kinase inhibitors which include Eli Lilly's Retevmo and Blueprint Medicines/Roche's Gavreto.
- Anti-angiogenesis medications which include Genentech's Avastin and Amgen Inc.'s Mvasi (in combination with cisplatin and paclitaxel) and Eli Lilly's Cyramza (in combination with docetaxel and erlotinib).

Pancreatic Cancer

- Chemotherapies which include fluorouracil (manufactured by six companies), along with Genentech's Xeloda, Eli Lilly's Gemzar, Pfizer's Camptosar, GSK's Wellcovorin, Celgene's Abraxane, Ipsen Biopharm Ltd's Onivyde and Sanofi's Eloxatin.
- Targeted therapies which include AstraZeneca/Roche/Genentech's Tarceva, AstraZeneca's Lynparza and Loxo Oncology's Vitrakvi.
- Immunotherapy which includes Merck's Keytruda.

Ovarian Cancer

We are aware of other companies either marketing or focused on developing competing therapies for the treatment of ovarian cancer, including PRROC:

Currently marketed products for ovarian cancer, include generic products cisplatin (manufactured by 18 companies), carboplatin (manufactured by 22 companies) and paclitaxel (manufactured by 19 companies), along with Sanofi-Aventis's (Sanofi) Taxotere, Celgene Corp.'s (Celgene) Abraxane, Esai Inc.'s (Esai) Hexalen, Roche Holding AG's (Roche) Xeloda, Roche/Genentech, Inc.'s (Genentech) Avastin, Baxter Healthcare's Cytoxan and lfex, Etoposide (manufactured by ten companies), Eli Lilly and Company's (Eli Lilly) Gemzar and Alimta, Pfizer Inc.'s (Pfizer) Camtosar, Janssen Pharmaceutical's Doxil, GSK's Alkeran, Sandoz's Topotecan, Laboratoires Pierre Fabre's Navelbine, GSK's Zejula, AstraZeneca's Lynparza, and Clovis Oncology's Rubraca.

Product candidates in registration trials or later development for PRROC include:

- Mirvetuximab soravtansine, a folate receptor binding antibody drug conjugate by ImmunoGen, Inc.
- Nemvaleukin alfa, an engineered interleukin-2 by Alkermes Plc.
- Upifitamab rilsodotin, a sodium-dependent phosphate transport protein binding antibody drug conjugate by Mersana Therapeutics.

Manufacturing and Distribution

We have assembled a seasoned management team with extensive experience in developing and manufacturing biological, viral and gene therapies. We have strong in-house process development and manufacturing capabilities for VACV. Concurrent with the clinical development of Olvi-Vec, we have been developing a large-scale manufacturing process designed to optimize production of cGMP material that we expect will result in a high yield and lower overall cost of goods. We transitioned from using an external contract manufacturing organization for production of Olvi-Vec in chicken embryo fibroblasts, to establishing our in-house manufacturing facility for larger-scale manufacturing using a mammalian-cell production system. Product is harvested, purified and filled into vials and maintained at -70°C plus or minus 10°C.

We signed a long-term lease for a 7,569 square-foot building in San Diego, California and have established and equipped our own manufacturing facility in order to secure supplies for clinical trials and commercial launch. The facility includes laboratories, cleanrooms and vialing rooms, and installed equipment, to accept and prepare raw materials, and produce drug substance and drug product in accordance with cGMPs and all other applicable laws and regulations. This building has additional space for expansion.

We maintain agreements with our raw material and equipment suppliers, as well as with contract laboratories to provide services such as analytical development and validation, raw material testing, release testing of drug substance and drug product and stability testing. We also contract with a third party for the labeling, packaging and distribution of our clinical material and we expect to do so in the future for commercial Olvi-Vec product, assuming it receives regulatory approval. We do not have long-term supply arrangements in place with our raw material and equipment suppliers.

We continue to invest in our internal development capabilities to establish critical in-house manufacturing expertise to support our pipeline. We expect to continue to invest to improve our proprietary processes that will enable us to be at a competitive advantage when manufacturing product candidates for our VACV immunotherapy program.

Sales and Marketing

None of our product candidates has been approved for sale. If and when our product candidates receive marketing approval, we intend to commercialize them on our own, or jointly with a partner, in the United States and potentially with pharmaceutical or biotechnology partners in other geographies. We currently have no sales, marketing or commercialization capabilities and have no experience as a company performing such activities. However, we intend to build the necessary capabilities and infrastructure over time following the advancement of our product candidates through clinical development. Clinical data, the size of the opportunity and the size of the commercial infrastructure required will influence our commercialization plans and decision making.

Intellectual Property

Our success depends upon our protecting and enhancing the proprietary technologies, inventions and improvements that we believe are important to our business, and we strive to and intend to seek, maintain and defend intellectual property rights, whether developed internally or licensed from third parties. We rely on a combination of patent, trademark, copyright and trade secret laws in the United States and other jurisdictions as well as confidentiality procedures and contractual provisions to protect our proprietary technology and our brand. We also enter into confidentiality and invention assignment agreements with our employees and consultants and confidentiality agreements with other third parties, and we rigorously control access to proprietary technology.

We believe our rights under issued patents and patent applications, if granted, will provide a competitive advantage. As of December 31, 2022, our patent portfolio consisted of 19 issued U.S. patents, one pending U.S. patent application, 20 issued foreign patents, two pending foreign patent applications and one PCT application, which relate generally to the composition of our current and potential future products, and their methods of use.

As briefly summarized, below, the 4802 Series claims cover Olvi-Vec and our other technologies from different perspectives. Patent protection for Olvi-Vec in the United States from regulatory extension of issued claims may extend until 2031.

- “4802” Series – This series of patents includes claims directed to a recombinant vaccinia virus that contains modifications at three gene loci: the thymidine kinase (TK/J2R) gene, hemagglutinin (HA/ A56R) gene and F3 (also named F14.5L) gene loci. Granted claims in the 4802 series include claims directed to isolated cells containing the modified vaccinia virus, pharmaceutical products (including a vaccine) containing the modified vaccinia virus, combinations of the modified vaccinia virus with an anti-cancer agent and methods for eliminating cancerous cells by administering the modified vaccinia virus. There are issued patents in the United States, Australia, Canada, China, Europe (the United Kingdom, France, Germany, Italy), Japan and Mexico. The United States patents expire in 2026 and 2024; one U.S. patent expires on November 29, 2026 (U.S. Patent No. 7588767) and the other U.S. patents and patents outside the United States expire June 18, 2024, absent any regulatory extensions.
- “4816” Series – There are five issued U.S. patents directed to vaccinia viruses that encode a diagnostic or therapeutic protein, combinations of the virus and a chemotherapeutic compound, isolated cells that contain the virus, and methods of treatment by administering the virus. These patents expire in 2027 and 2028, absent any patent term adjustments or extensions.
- “4832” Series – There are pending applications and granted patents directed to clonal isolates of LIVP that demonstrate relatively low toxicity and/or high anti-tumor activity, and thus include possible next generation clinical candidates. These patents expire in April 2032, absent any patent term adjustment (in the United States) and/or regulatory extensions.
- “4847” Series – There is an issued U.S. patent directed to methods of increasing infectivity of an oncolytic virus. This patent expires in September 2035, absent any patent term adjustment (in the United States) and/or regulatory extensions.
- “4849” Series – There is an issued U.S. patent and a pending PCT application directed to methods for producing viruses that include culturing host cells in a bioreactor. The PCT application, filed upon allowance of the U.S. application, which did not publish, does not claim priority to the U.S. patent. The U.S. patent expires in 2038, and any patent that issues from the PCT application is expected to expire in 2040, absent any patent term adjustments or extensions.

The 4832, 4847 and 4849 Series include claims covering V-VET1 and associated other technologies from different perspectives. Patent protection for V-VET1 in the United States expires in April 2032, absent any patent term adjustment (in the United States) and/or regulatory extensions.

In addition to the foregoing, we own several other series of patent applications that we believe will add substantial value to our intellectual property, if issued.

In 2016, TVAX filed a PCT application covering V2ACT Immunotherapy. The application was nationalized and applications are pending in the United States, Europe and Japan. Patents in this family are expected to expire in 2037, absent any patent term adjustments or extensions.

Any future provisional patent applications will not be eligible to become issued patents until, among other things, we file a non-provisional patent application within 12 months of filing of one or more of our related provisional patent applications. If we do not timely file any non-provisional patent applications, we may lose our priority date with respect to our provisional patent applications and any patent protection on the inventions disclosed in our provisional patent applications.

Although we intend to timely file non-provisional patent applications relating to our provisional patent applications, we cannot predict whether any of our future patent applications will result in the issuance of patents that effectively protect our technology or our product candidates, or if any of our future issued patents will effectively prevent others from commercializing competitive products. We may be subject to a third-party pre-issuance submission of prior art to the USPTO. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or in some cases not at all until they are issued as a patent. Therefore, we cannot be certain that we were the first to make the inventions claimed in our pending patent applications, or that we were the first to file for patent protection of such inventions.

Furthermore, we rely upon trade secrets and know-how and continuing technological innovation and in-licensing opportunities to develop, strengthen and maintain our competitive position. We seek to protect our proprietary information, in part, using confidentiality agreements with our collaborators, employees and consultants and invention assignment agreements with our employees. We also have confidentiality agreements or invention assignment agreements with selected consultants. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed through a relationship with a third party. These agreements may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our collaborators, employees and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. We also protect our proprietary information by physical security of our premises and our information technology systems.

Our commercial success also will depend in part on not infringing upon the proprietary rights of third parties. It is uncertain whether the issuance of any third-party patent would require us to alter our development or commercial strategies, or our product candidates or processes, obtain licenses, or cease certain activities. Our breach of any license agreements or failure to obtain a license to proprietary rights that we may require to develop or commercialize our future product candidates may have an adverse impact on us.

U.S. Patent Term Restoration and Marketing Exclusivity

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a non-provisional patent application. However, the actual protection afforded by a patent varies on a product-by-product basis, from country to country and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent.

Depending upon the timing, duration and specifics of FDA approval of product candidates, some of a sponsor’s U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and FDA regulatory review process.

However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period generally is one-half the time between the effective date of an IND and the submission date of a BLA plus the time between the submission date of a BLA and the approval of that application. Only one patent applicable to an approved biologic product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. Moreover, a given patent may only be extended once based on a single product. An application for patent extension must be filed within 60 days of FDA approval of the product. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

Patent term extension also may be available in other jurisdictions, including the European Union (EU), the United Kingdom, Japan and China.

The BPCIA creates an abbreviated approval pathway for biological products shown to be highly similar to or interchangeable with an FDA-licensed biological reference product. Biosimilarity sufficient to reference a prior FDA-approved product requires a high similarity to the reference product notwithstanding minor differences in clinically inactive components, and no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency. Biosimilarity must be shown through analytical studies, animal studies, and at least one clinical trial, absent a waiver by the FDA. There must be no difference between the reference product and a biosimilar in mechanism of action, conditions of use, route of administration, dosage form, and strength. A biosimilar product may be deemed interchangeable with a prior approved product if it meets the higher hurdle of demonstrating that it can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the biosimilar and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

A reference biologic is granted 12 years of exclusivity from the time of first licensure of the reference product, and no application for a biosimilar can be submitted for four years from the date of licensure of the reference product. However, certain changes and supplements to an approved BLA, and subsequent applications filed by the same sponsor, manufacturer, licensor, predecessor in interest, or other related entity do not qualify for the twelve-year exclusivity period. The Public Health Service Act (PHSA) also includes provisions to protect reference products that have patent protection. The biosimilar product sponsor and reference product sponsor may exchange certain patent and product information for the purpose of determining whether there should be a legal patent challenge. Based on the outcome of negotiations surrounding the exchanged information, the reference product sponsor may bring a patent infringement suit and injunction proceedings against the biosimilar product sponsor. The biosimilar applicant may also be able to bring an action for declaratory judgment concerning the patent.

Biosimilar protection may be available in other jurisdictions, including the EU, United Kingdom and Japan.

Also, certain indications, such as pancreatic cancer, for which we plan to develop our products may qualify as an Orphan, or Rare, Disease. A product qualifying for Orphan Drug status is eligible for 7 years of exclusivity following FDA marketing approval. A Rare Disease is defined as affecting fewer than 200,000 persons in the United States; a sponsor may request Orphan Drug status for a drug for only a subset of persons with a particular disease or condition that otherwise affects 200,000 or more people if the sponsor demonstrates that, due to one or more properties of the drug, the remaining persons with such disease would not be appropriate candidates for use of the drug. Orphan Drug status may also be available in other jurisdictions, including the EU, the United Kingdom and Japan.

Trademarks

We believe our rights under issued and pending trademarks are important and valuable and we strive to and intend to seek, maintain and defend our trademark rights.

"Genelux" is the subject of issued trademark registrations in the EU, the United Kingdom, China and in several other countries.

Our unregistered trademarks include “CHOICE”.

Government Regulation and Product Approval

In the United States, the FDA regulates biological products under the Federal Food, Drug, and Cosmetic Act (FDCA), the PHSA, and regulations and guidance documents implementing these laws. The FDCA, PHSA and their corresponding regulations govern, among other things, the testing, manufacturing, safety, purity, potency, labeling, packaging, storage, record keeping, distribution, reporting, advertising and other promotional practices involving biological products. Consent from the FDA is required before conducting human clinical testing of biological products. FDA licensure also must be obtained before marketing of biological products. 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.

U.S. Biological Products Development Process

Any biologic product must be licensed by the FDA before it may be legally marketed in the United States. The process required by the FDA before a biologic product candidate may be marketed in the United States generally involves the following:

- Completion of preclinical laboratory tests and in vivo studies in accordance with the FDA’s Good Laboratory Practice (GLP) regulations and applicable requirements for the humane use of laboratory animals or other applicable regulations;
- Submission to the FDA of an investigational new drug (IND) application, which allows human clinical trials to begin unless FDA objects within 30 calendar days;
- Approval by an independent institutional review board (IRB), reviewing each clinical site before each clinical trial may be initiated;
- Performance of adequate and well-controlled human clinical trials according to the FDA’s Good Clinical Practice (GCP) regulations, and any additional requirements for the protection of human research subjects and their health information, to establish the safety, purity and potency of the proposed biologic product candidate for its intended use;
- Preparation and submission to the FDA of a biological products license application (BLA) for marketing approval that includes substantial evidence of safety, purity and potency from results of nonclinical testing and clinical trials;
- Review of the product by an FDA advisory committee, if applicable;
- Satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the biologic product candidate is produced to assess compliance with current Good Manufacturing Practice (cGMP) requirements and to assure that the facilities, methods and controls are adequate to preserve the biologic product candidate’s identity, safety, strength, quality, potency and purity;
- Potential FDA audit of the nonclinical and clinical trial sites that generated the data in support of the BLA; and
- Payment of user fees and FDA review and approval, or licensure, of the BLA.

The testing and approval process of product candidates requires substantial time, effort, and financial resources. Satisfaction of the FDA’s pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity, and novelty of the product or disease. Before testing any biologic product candidate in humans, the product candidate must undergo preclinical testing. Preclinical tests, also referred to as nonclinical studies, include laboratory evaluations of product chemistry, toxicity and formulation, as well as in vivo studies to assess the potential safety and activity of the product candidate and to establish a rationale for therapeutic use. The conduct of the preclinical tests must comply with federal regulations and requirements including GLPs.

Concurrent with clinical trials, companies usually must complete some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the drug 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, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug product. 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.

A clinical trial sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 calendar days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to a proposed clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks, and places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA also may impose partial or full clinical holds on a biologic product candidate at any time before or during clinical trials due to safety concerns or non-compliance. If the FDA imposes a clinical hold, trials may not recommence without FDA authorization and then only under terms authorized by the FDA. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that partially or fully suspend or terminate such studies.

Human Clinical Trials Under an IND

Clinical trials involve the administration of the investigational product to healthy volunteers or patients under the supervision of qualified investigators which generally are physicians not employed by, or under, the control of the trial sponsor. Clinical trials must be conducted under written study protocols detailing, among other things, the objectives of the trial, subject selection and exclusion, the trial procedures, the parameters to be used in monitoring safety, the effectiveness criteria to be evaluated, and a statistical analysis plan. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND.

Further, clinical trials must be conducted in accordance with federal regulations and GCP requirements, which include the requirements that all research subjects provide their informed consent in writing for their participation in any clinical trial, as well as review and approval by an IRB at each study site participating in the clinical trial or a central IRB. An IRB is charged with protecting the welfare and rights of trial participants and considers items such as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject, or their legal representative, reviews and approves the study protocol, and must monitor the clinical trial until completed.

Human clinical trials typically are conducted in three sequential phases that may overlap or be combined:

- *Phase 1*. The biologic product candidate initially is introduced into a small number of healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early understanding of its effectiveness. In the case of some product candidates for severe or life-threatening diseases, especially when the product candidate may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.
- *Phase 2*. The biologic product candidate is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product candidate for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.

- *Phase 3*. Phase 3 clinical trials are commonly referred to as “pivotal” or “registrational” studies, which typically denotes a study which presents the data that the FDA or other relevant regulatory agency will use to determine whether or not to approve a biologic product. In Phase 3 studies, the biologic product candidate is administered to an expanded patient population, generally at multiple geographically dispersed clinical trial sites in adequate and well-controlled clinical trials to generate sufficient data to statistically confirm the potency and safety of the product for approval. These clinical trials are intended to establish the overall risk/benefit ratio of the product candidate and provide an adequate basis for product labeling.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA.

Written IND safety reports must be promptly submitted to the FDA and the investigators for: serious and unexpected adverse events; any findings from other studies, in vivo laboratory tests or in vitro testing that suggest a significant risk for human subjects; or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor’s initial receipt of the information. Relevant additional information obtained by the sponsor that pertains to a previously submitted IND safety report must be submitted as a follow-up IND safety report. Such report should be submitted within 15 calendar days after the sponsor receives the information.

Information about certain clinical trials, including a description of the study and, in some cases, study results, must be submitted within specific timeframes to the National Institutes of Health (NIH) for public dissemination on their clinicaltrials.gov website. Manufacturers or distributors of investigational products for the diagnosis, monitoring, or treatment of one or more serious or life-threatening diseases or conditions where no other comparable or satisfactory therapeutic options exist must also have a publicly available policy on evaluating and responding to requests for expanded access, sometimes called “compassionate use,” requests.

Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor that regularly reviews accumulated data and advises the study sponsor regarding the continuing safety of the trial. This group may also review interim data to assess the continuing validity and scientific merit of the clinical trial. This group receives special access to unblinded data during the clinical trial and may advise the sponsor to halt the clinical trial if it determined there is an unacceptable safety risk for
subjects or on other grounds, such as no demonstration of efficacy.

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB’s requirements or if the trial poses an unexpected serious harm to subjects. The FDA or an IRB may also impose conditions on the conduct of a clinical trial. Clinical trial sponsors may also choose to discontinue clinical trials as a result of risks to subjects, a lack of favorable results, or changing business priorities.

Compliance with cGMP Requirements

Manufacturers of biological products must comply with applicable cGMP regulations, including quality control and quality assurance and maintenance of records and documentation. Manufacturers and others involved in the manufacture and distribution of such products also must register their establishments with the FDA and

certain state agencies. Both domestic and foreign manufacturing establishments must register and provide additional information to the FDA upon their initial participation in the manufacturing process. Establishments may be subject to periodic, unannounced inspections by government authorities to ensure compliance with cGMP requirements and other laws. Discovery of problems may result in a government entity placing restrictions on a product, manufacturer or holder of an approved BLA, and may extend to requiring withdrawal of the product from the market. The FDA will not approve a BLA 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 specification.

Concurrent with clinical trials, companies usually complete additional preclinical studies and must also develop additional information about the physical characteristics of the biologic product candidate as well as finalize a process for manufacturing the product candidate in commercial quantities in accordance with cGMP requirements. To help reduce the risk of the introduction of adventitious agents or of causing other adverse events with the use of biological products, the PHSA emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other requirements, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final biologic product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the biologic product candidate does not undergo unacceptable deterioration over its shelf life.

In relation to the clinical trials that may be conducted in other countries with a view to obtaining a marketing authorization, there are equivalent cGMP requirements and other regulatory rules that are implemented nationally.

U.S. FDA Review and Approval Process

Assuming successful completion of the required clinical and preclinical testing, the results of the preclinical tests and clinical trials together with detailed information relating to the product's CMC, including negative or ambiguous results as well as positive findings, and proposed labeling, among other things, are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications.

Under the Prescription Drug User Fee Act, as amended (PDUFA), each BLA must be accompanied by a significant user fee. The FDA adjusts the PDUFA user fees on an annual basis. The PDUFA also imposes an annual program fee for approved biological products. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on BLAs for product candidates designated as orphan drugs, unless the product candidate also includes a non-orphan indication.

In addition, under the Pediatric Research Equity Act (PREA), a BLA or supplement to a BLA for a new active ingredient, indication, dosage form, dosage regimen, or route of administration, must contain data that are adequate to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. Also, applications for product candidates intended for the treatment of adult cancer which are directed at molecular targets that the FDA determines to be substantially relevant to the growth or progression of pediatric cancer, in place of the PREA investigations, sponsors must submit, with the application, reports from molecularly targeted pediatric cancer investigations designed to yield clinically meaningful pediatric study data, using appropriate formulations, to inform potential pediatric labeling. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. Orphan products are also exempt from the PREA requirements.

The FDA reviews a BLA within 60 days of submission to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In that event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth, substantive review of the BLA.

The FDA reviews the BLA to determine, among other things, whether the proposed product candidate is safe and potent, or effective, for its intended use, has an acceptable purity profile and whether the product candidate is being manufactured in accordance with cGMP to assure and preserve the product candidate's identity, safety, strength, quality, potency and purity. The FDA may refer applications for novel biological products or biological products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. During the product approval process, the FDA also will determine whether a risk evaluation and mitigation strategy (REMS) is necessary to assure the safe use of the product candidate. REMS use risk minimization strategies beyond the professional labeling to ensure that the benefits of the product outweigh the potential risks. To determine whether a REMS is needed, the FDA will consider the size of the population likely to use the product, seriousness of the disease, expected benefit of the product, expected duration of treatment, seriousness of known or potential adverse events, and whether the product is a new molecular entity. A REMS could include medication guides, physician communication plans and elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS; the FDA will not approve the BLA without a REMS, if required.

Before approving a BLA, the FDA will inspect the facilities at which the product candidate is manufactured. The FDA will not approve the product candidate unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product candidate within required specifications. Additionally, before approving a BLA, the FDA typically will inspect one or more clinical sites to assure that the clinical trials were conducted in compliance with IND trial requirements and GCP requirements.

On the basis of the BLA and accompanying information, including the results of the inspection of the manufacturing facilities, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the biologic product with specific prescribing information for specific indications. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the BLA, the FDA will issue an approval letter.

If a product candidate receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing or dispensing in the form of a REMS, or otherwise limit the scope of any approval. The FDA may also require post-marketing clinical trials, sometimes referred to as Phase 4 clinical trials, designed to further assess a biologic product's safety and effectiveness, and testing and surveillance programs to monitor the safety of approved products that have been commercialized.

Every five years, the FDA agrees to specified performance goals in the review of BLAs under the PDUFA. One such current goal is to review standard BLAs in ten months after the FDA accepts the BLA for filing, and priority BLAs in six months, whereupon a review decision is to be made. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs and its review goals are subject to change from time to time. The review process and the PDUFA goal date may be extended by three months if the FDA requests or the BLA sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date.

Post-Approval Requirements

After approval, there also are continuing annual program user fee requirements for approved products, excluding, under certain circumstances, orphan products.

Rigorous and extensive FDA regulation of biological products continues after approval, particularly with respect to cGMP requirements. Manufacturers are required to comply with applicable requirements in the cGMP regulations, including quality control and quality assurance and maintenance of records and documentation. To help reduce the increased risk of the introduction of adventitious agents, the PHSA emphasizes the importance of manufacturing controls for products whose attributes cannot be precisely defined. The PHSA also provides authority to the FDA to immediately suspend licenses in situations where there exists a danger to public health, to prepare or procure products in the event of shortages and critical public health needs, and to authorize the creation and enforcement of regulations to prevent the introduction or spread of communicable diseases in the United States and between states.

Other post-approval requirements applicable to biological products include reporting of cGMP deviations that may affect the identity, potency, purity and overall safety of a distributed product, record-keeping requirements, reporting of adverse effects, reporting updated safety and efficacy information and complying with electronic record and signature requirements. After a BLA is approved, the product also may be subject to official lot release. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA, together with a release protocol, showing a summary of the history of manufacture of the lot and the results of all tests performed on the lot. The FDA also may perform certain confirmatory tests on lots of some products before releasing the lots for distribution. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency and effectiveness of biological products.

In addition, manufacturers and other entities involved in the manufacture and distribution of approved therapeutics are required to register their establishments with the FDA and certain state agencies, list their products, and are subject to periodic announced and unannounced inspections by the FDA and these state agencies for compliance with current cGMP and other requirements, which impose certain procedural and documentation requirements upon us and third-party manufacturers. Manufacturers must continue to expend time, money, and effort in the areas of production and quality-control to maintain compliance with current cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered. In addition, changes to the manufacturing process or facility generally require prior FDA approval or notification before being implemented, and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

Moreover, the Drug Quality and Security Act imposes obligations on manufacturers of biopharmaceutical products related to product tracking and tracing.

Adverse event reporting and submission of periodic reports, including annual reports and deviation reports, are required following FDA approval of a BLA. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in significant regulatory actions. Such actions may include refusal to approve pending applications, license suspension or revocation, imposition of a partial or full clinical hold or termination of clinical trials, warning letters, untitled letters, cyber letters, modification of promotional materials or labeling, provision of corrective information, imposition of post-market requirements including the need for additional testing, imposition of distribution or other restrictions under a REMS, product recalls, product seizures or detentions, refusal to allow imports or exports, total or partial suspension of production or distribution, FDA debarment, injunctions, fines, consent decrees, corporate integrity agreements, suspension and

debarment from government contracts, and refusal of orders under existing government contracts, exclusion from participation in federal and state healthcare programs, restitution, disgorgement, or civil or criminal penalties, including fines and imprisonment, and result in adverse publicity, among other adverse consequences.

A sponsor also must comply with the FDA's advertising and promotion requirements, such as the prohibition on promoting products for uses or in-patient populations that are not described in the product's approved labeling (known as "off-label use"). The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. Violations relating to the promotion of off-label uses may lead to investigations alleging violations of federal and state healthcare fraud and abuse and other laws, as well as state consumer protection laws. Companies, however, may generally share truthful and non-misleading information that is otherwise consistent with a product's FDA approved labeling. Discovery of previously unknown problems or the failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as possible civil or criminal sanctions.

Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant or manufacturer to administrative or judicial civil or criminal actions and adverse publicity. These actions could include refusal to approve pending applications or supplemental applications, withdrawal of an approval, clinical hold, suspension or termination of a clinical trial by an IRB, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines or other monetary penalties, refusals of government contracts, mandated corrective advertising or communications with healthcare providers, debarment, restitution, disgorgement of profits or other civil or criminal penalties.

Broadly equivalent requirements and controls typically apply in other countries to the submission of marketing authorization applications and, post-approval, to the holding of such marketing authorizations.

Other Healthcare Laws and Regulations

Our business activities, including but not limited to, research, sales, promotion, distribution, medical education, and other activities following product approval will be subject to regulation by numerous federal and state regulatory and law enforcement authorities in the United States in addition to the FDA, including potentially the Department of Justice, the Department of Health and Human Services (HHS) and its various divisions, including the Centers for Medicare & Medicaid Services (CMS) and the Health Resources and Services Administration, the Department of Veterans Affairs, the Department of Defense, and state and local governments. Healthcare providers and third-party payors play a primary role in the recommendation and use of pharmaceutical products that are granted marketing approval. Arrangements with third-party payors, existing or potential customers and referral sources, including healthcare providers, are subject to broadly applicable fraud and abuse laws and regulations, and these laws and regulations may constrain the business or financial arrangements and relationships through which manufacturers conduct clinical research, market, sell and distribute the products for which they obtain marketing approval. Such restrictions under applicable federal and state healthcare laws and regulations include the following:

- The federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or kind, in exchange for, or to induce, either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers, on the one hand, and prescribers, purchasers, formulary managers and other individuals and entities on the other. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the ACA) amended the intent requirement of the federal Anti-Kickback Statute such that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to commit a violation;

- The federal civil and criminal false claims, including the civil FCA, and Civil Monetary Penalties Laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payors that are false or fraudulent, or making a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government. Certain marketing practices, including off-label promotion, also may implicate the FCA. In addition, the ACA codified case law 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;
- The federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biological products and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services (the CMS) information related to payments and other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members;
- Health Insurance Portability and Accountability Act of 1996 (HIPAA) prohibits knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, a healthcare benefit program, regardless of whether the payor is public or private, in connection with the delivery or payment for health care benefits, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense and knowingly and willfully falsifying, concealing, or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items, or services relating to healthcare matters. Additionally, the ACA amended the intent requirement of certain of these criminal statutes under HIPAA so that a person or entity no longer needs to have actual knowledge of the statute, or the specific intent to violate it, to have committed a violation; and
- State and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers and drug pricing and/or marketing expenditures; and state and local laws requiring the registration of pharmaceutical sales representatives and state laws governing 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, thus complicating compliance efforts.

To the extent that any of our products are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

Violation of the laws described above or any other governmental laws and regulations may result in significant penalties, including administrative, civil and criminal penalties, damages, fines, the curtailment or restructuring of operations, the exclusion from participation in federal and state healthcare programs, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, imprisonment, and additional reporting requirements and oversight if a person becomes subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws. Furthermore, efforts to ensure that business activities and business arrangements comply with applicable healthcare laws and regulations can be costly for manufacturers of branded prescription products.

Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any products for which we may obtain regulatory approval. In the United States, sales of any product candidates for which regulatory approval for commercial sale is obtained will depend in part on the availability of coverage and adequate reimbursement from third-party payors. Third-party payors include government authorities and health programs in the United States such as Medicare and Medicaid, managed care providers, private health insurers and other organizations. These third-party payors are increasingly reducing reimbursements for medical products and services. The process for determining whether a payor will provide coverage for a drug product may be separate from the process for setting the reimbursement rate that the payor will pay for the drug product. Third-party payors may limit coverage to specific drug products on an approved list, or formulary, which might not include all of FDA-approved drugs for a particular indication. Additionally, the containment of healthcare costs has become a priority of federal and state governments, and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results.

A payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

Third-party payors are increasingly challenging the price and examining the medical necessity and cost- effectiveness of medical products and services, in addition to their safety and efficacy. New metrics frequently are used as the basis for reimbursement rates, such as average sales price, average manufacturer price and actual acquisition cost. In order to obtain coverage and reimbursement for any product that might be approved for sale, it may be necessary to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the products, in addition to the costs required to obtain regulatory approvals. If third-party payors do not consider a product to be cost-effective compared to other available therapies, they may not cover the product after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to sell its products at a profit.

The marketability of any product candidates for which we or our collaborators receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on pharmaceutical pricing. 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 or our collaborators receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. The cost containment measures that healthcare payors and providers are instituting and any healthcare reform could significantly reduce our revenues from the sale of any approved product candidates. We cannot provide any assurances that we will be able to obtain and maintain third-party coverage or adequate reimbursement for our product candidates in whole or in part.

In the EU, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies. EU member states may approve a specific price for a product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other member states allow companies to fix their own prices for products, but monitor and control company profits. The downward pressure on health care costs has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert competitive pressure that may reduce pricing within a country. Any country that has price controls or reimbursement limitations may not allow favorable reimbursement and pricing arrangements.

Health Reform

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

By way of example, in March 2010, the ACA was signed into law, intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose taxes and fees on the healthcare industry and impose additional health policy reforms. Among the provisions of the ACA of importance to our business are:

- An annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- An increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;

- A 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;
- Extension of a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- Expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- A Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for a manufacturer's outpatient drugs to be covered under Medicare Part D;
- Expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program; and
- A Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

There have been executive, judicial and Congressional challenges to certain aspects of the ACA. For example, on June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. In addition, in August 2022, President Biden signed the Inflation Reduction Act of 2022 (the IRA) into law, which among other things, extends enhanced subsidies for individuals purchasing coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost through a newly established manufacturer discount program.

Other legislative changes have been proposed and adopted in the United States since the ACA. For example, through the process created by the Budget Control Act of 2011, there are automatic reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect in April 2013 and, following passage of the BBA and the Infrastructure Investment and Jobs Act, will remain in effect until 2031 unless additional Congressional action is taken. Under current legislation the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester.

The heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics, also has resulted in executive orders, congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, President Trump used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders, and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that attempt to implement several of the administration's proposals. The FDA concurrently released a final rule and guidance in September 2020 implementing a portion of the importation executive order providing pathways for states to build and

submit importation plans for drugs from Canada. Further, on November 20, 2020, the HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. The implementation of the rule has been delayed until 2032. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. In addition, the IRA directs the Secretary of HHS to establish a Drug Price Negotiation Program (the Program) to lower prices for certain single-source prescription drugs and biologics covered under Medicare Parts B and D, based on criteria established under the IRA. Under the Program, the Secretary of HHS will publish a list of "selected drugs," and will then negotiate maximum fair prices (MFP) with their manufacturers. Beginning in 2026, the first year of the Program, the number will be limited to 10 Part D drugs and biologics. By 2029, and in subsequent years thereafter, the number will increase to 20 drugs and biologics covered under Part D and Part B. Agreements between HHS and manufacturers will remain in place until a drug or biologic is no longer considered a "selected drug" for negotiation purposes. Manufacturers who do not comply with the negotiated prices set under the Program will be subject to an excise tax based on a percentage of total sales of a "selected drug" up to 95% and the potential of civil monetary penalties. Further, the IRA imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. In addition, the Biden administration released an additional executive order on October 14, 2022, directing HHS to report on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries.

At the state level, individual states in the United States have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Some third-party payors also require pre-approval of coverage for new or innovative devices or therapies before they will reimburse healthcare providers that use such therapies.

We expect that these initiatives, as well as other healthcare reform measures that may be adopted in the future, as well as the trend toward managed healthcare and increasing influence of managed care organizations, may result in more rigorous coverage criteria and lower reimbursement, and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government- funded programs may result in a similar reduction in payments from private payors. The implementation of current and future cost containment measures or other healthcare reforms may adversely affect our operations and prevent us from being able to generate revenue, attain profitability or commercialize our product candidates.

Data Privacy and Security

In the ordinary course of our business, we collect, receive, process, generate, use, transfer, make accessible, protect, secure, dispose of, transmit and store (collectively, process) confidential and sensitive information, including personal information, intellectual property, trade secrets, and proprietary information owned or controlled by ourselves or other third parties. Accordingly, we may be subject to numerous data privacy and security obligations, including federal, state, local, and foreign laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements and other obligations related to data privacy and security. These frameworks are evolving and may impose potentially conflicting obligations. Such obligations may include, without limitation, the Federal Trade Commission Act, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020 (CPRA) (collectively, CCPA), the

European Union's General Data Protection Regulation 2016/679 (EU GDPR), the EU GDPR as it forms part of United Kingdom law by virtue of section 3 of the European Union (Withdrawal) Act 2018 (UK GDPR), the ePrivacy Directive, and wiretapping laws. Further, HIPAA, as amended by HITECH, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. In addition, several states within the United States, such as Virginia, Colorado, Connecticut, and Utah, have enacted comprehensive data privacy laws, and similar laws are being considered at the federal, state, and local levels.

The EU GDPR, UK GDPR, and CCPA are examples of the increasingly stringent and evolving regulatory frameworks related to personal information processing that may increase our compliance obligations and exposure for any noncompliance. European data privacy and security laws (including the EU GDPR and UK GDPR) impose significant and complex compliance obligations on companies that are subject to those laws, notably with respect to the processing of health-related data from European Economic Area (EEA) or United Kingdom-based individuals. Additionally, the CCPA applies to personal information of consumers, business representative, and employees who are California residents, imposes specific requirements on covered businesses, provides for administrative fines of up to $7,500 per violation and allows private litigants affected by certain data breaches to recover significant statutory damages. In addition, the CPRA expanded the CCPA's requirements. Furthermore, U.S. federal and state consumer protection laws may require us to publish statements that accurately and fairly describe how we handle personal information and choices individuals may have about the way we handle their personal information.

See the section titled "Risk Factors—We are subject to stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse business consequences" for additional information about the laws and regulations to which we are or may become subject and about the risks to our business associated with such laws and regulations.

Additional Regulation

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservation and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern the use, handling and disposal of various biologic, chemical and radioactive substances used in, and wastes generated by, operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. Equivalent laws have been adopted in other countries that impose similar obligations.

U.S. Foreign Corrupt Practices Act

The U.S. Foreign Corrupt Practices Act (FCPA) prohibits U.S. corporations and individuals from engaging in certain activities to obtain or retain business abroad or to influence a person working in an official capacity. It is illegal to pay, offer to pay or authorize the payment of anything of value, directly or indirectly, to any foreign government official, government staff member, official or employee of a public international organization, or a political party or political candidate for the purpose of influencing any act or decision of the foreign entity in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity. The scope of the FCPA includes interactions with healthcare professionals of foreign state-owned or affiliated hospitals, universities, or research institutions. The FCPA also obligates companies whose securities are listed in the United States to comply with 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. Activities that violate the FCPA, even if they occur wholly outside the United States, can result in criminal and civil fines, imprisonment, disgorgement, oversight, and suspension and debarment from government contracts, and refusal of orders under existing government contracts.

Equivalent laws have been adopted in other foreign countries that impose similar or arguably broader obligations.

Human Capital Resources

In order to achieve the goals and expectations of our company, it is crucial that we continue to attract and retain top talent. To facilitate talent attraction and retention, we strive to make our company a safe and rewarding workplace, with opportunities for our employees to grow and develop in their careers, supported by strong compensation, benefits and health and wellness programs, and by programs that build connections between our employees.

As of December 31, 2022, we had 15 full-time and part-time employees, including three who hold Ph.D. or M.D. degrees. Of these, eight employees were engaged in research and development and manufacturing; our remaining employees are management and administrative staff. None of our employees is subject to a collective bargaining agreement or represented by a trade or labor union. We consider our relationship with our employees to be good.

The success of our business is fundamentally connected to the well-being of our employees. Accordingly, we are committed to their health, safety and wellness. We provide our employees and their families with access to a variety of innovative, flexible and convenient health and wellness programs, including benefits that can provide peace of mind concerning events that may require time away from work or that support their physical and mental health by providing tools and resources to help them improve or maintain their health status and encourage engagement in healthy behaviors; and that offer choice where possible so they can customize their benefits to meet their needs and the needs of their families. In response to the COVID-19 pandemic, we implemented significant changes that we determined were in the best interest of our employees, as well as the communities in which we operate, and which comply with government regulations. This includes allowing our employees to work from home.

We provide compensation and benefits programs to help meet the needs of our employees. In addition to salaries, these programs include potential annual discretionary bonuses, stock awards, a 401(k) Plan, healthcare and insurance benefits, paid time off, family leave, and flexible work schedules, among others.

Corporate Information

We incorporated in Delaware in September 2001. Our principal executive offices are located at 2625 Townsgate Road, Suite 230, Westlake Village, California 91361, and our telephone number is (805) 267-9889. We completed our initial public offering (IPO) in January 2023 and our common stock is listed on the Nasdaq Capital Market under the symbol “GNLX.”

We are an “emerging growth company” as defined in the JOBS Act. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of our initial public offering (i.e. December 31, 2028), (b) in which we have total annual gross revenue of at least $1.235 billion or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

Available Information

We are subject to the informational requirements of the Securities Exchange Act of 1934, as amended, (the Exchange Act), and, accordingly, file Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, with the SEC. In addition, the SEC maintains a web site (http://www.sec.gov) that contains material regarding issuers that file electronically, such as ourselves, with the SEC.

We maintain a website at www.genelux.com, to which we regularly post copies of our press releases as well as additional information about us. Our filings with the SEC will be available free of charge through the website as soon as reasonably practicable after being electronically filed with or furnished to the SEC. Information contained in our website is not a part of, nor incorporated by reference into, this Annual Report on Form 10-K or our other filings with the SEC, and should not be relied upon.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information in this Annual Report, including our financial statements and the related notes appearing at the end of this Annual Report and "Management's Discussion and Analysis of Results of Operations and Financial Condition," before deciding whether to purchase, hold or sell shares of our common stock. If any of the following risks are realized, our business, financial condition, results of operations, stock price and prospects could be materially and adversely affected. In that event, the price of our common stock could decline, and you could lose part or all of your investment. 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 to be immaterial may also adversely affect our business.

Risks Related to our Financial Position and Need for Additional Capital

We have incurred significant losses since our inception and anticipate that we will incur significant and increasing losses for the foreseeable future and we may never achieve or maintain profitability.

We are a clinical stage biopharmaceutical company, and our operations to date have been focused substantially on organizing and staffing our company, business planning, raising capital, creating, assessing, and developing our technology, establishing our intellectual property portfolio, identifying potential product candidates, undertaking preclinical studies, commencing clinical trials and manufacturing. Additionally, as an organization, we have not yet demonstrated an ability to successfully complete clinical development, obtain regulatory approvals, manufacture a commercial-scale product, or conduct sales and marketing activities necessary for successful commercialization. We have never generated any revenue from commercially approved product sales and have incurred significant operating losses. Our net loss was $5.2 million and $16.4 million for the years ended December 31, 2022 and 2021, respectively. As December 31, 2022, we had an accumulated deficit of $189.8 million. We expect to continue to incur significant and increasing operating losses for the foreseeable future. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' deficit and working capital.

We expect that it will be several years, if ever, before we have a commercialized product. The net losses we incur may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially if, and as, we:

- advance the Phase 3 registration clinical trial for our lead product candidate, Olvi-Vec, in PRROC;
- initiate planned and future clinical trials of Olvi-Vec in other cancer indications;
- discover and develop new product candidates, and conduct research and development activities, preclinical studies and clinical trials;
- manufacture preclinical, clinical and commercial supplies of our product candidates;
- broaden and strengthen our internal manufacturing capabilities, including the expansion and upgrade of our in-house manufacturing facility;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- maintain, expand and protect our intellectual property portfolio;
- hire additional research and development, clinical, scientific and management personnel;
- add operational, financial and management information systems and personnel;
- establish a sales, marketing and distribution infrastructure to commercialize any product candidate for which we may obtain regulatory approval and we commercialize on our own or in collaboration with others; and
- incur additional legal, accounting and other expenses operating as a public company.

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials, obtaining regulatory approval for product candidates and manufacturing, marketing and selling products for which we may obtain marketing approval and satisfying any post-marketing requirements. We are only in the development stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenue that is significant enough to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts or even continue our operations. A decline in the value of our company could also cause stockholders to lose all or part of their investment.

We will require substantial additional financing to advance the development of our product candidates, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital could force us to delay, limit, reduce or terminate our product development programs, potential commercialization efforts or other operations.

The development of biopharmaceutical product candidates is capital-intensive. Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to continue the preclinical and clinical development of, and seek regulatory approval for, our current and future product candidates. If we are able to gain marketing approval of any product candidate that we develop, including Olvi-Vec, we will require significant additional amounts of cash in order to launch and commercialize such product either alone or in collaboration with others. Because the design and outcome of our ongoing, anticipated and any future clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of any product candidate we develop.

Our future capital requirements depend on many factors, including:

- the scope, progress, results and costs of researching and developing Olvi-Vec and our other product candidates and programs, and of conducting preclinical studies and clinical trials;
- the timing of, and the costs involved in, obtaining marketing approvals for Olvi-Vec and future product candidates we develop if clinical trials are successful;
- the success of any future collaborations;
- the cost of commercialization activities for any approved product, including marketing, sales and distribution costs;
- the cost and timing of establishing, equipping, and operating our current and planned manufacturing activities;
- the cost of manufacturing Olvi-Vec and future product candidates for clinical trials in preparation for marketing approval and commercialization;
- our ability to establish and maintain strategic licensing or other arrangements and the financial terms of such agreements;
- the cost, timing and outcome of seeking FDA and any other regulatory approvals for any future product candidates;
- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- our ability to establish and maintain healthcare coverage and adequate reimbursement for our future products, if any;
- the timing, receipt, and amount of sales of, or royalties on, our future products, if any;
- the emergence of competing cancer therapies and other adverse market developments;

- our efforts to enhance operational systems and our ability to attract, hire and retain qualified personnel, including personnel to support the development of our product candidates;
- the costs associated with being a public company;
- our need and ability to retain key management and hire scientific, technical, medical and business personnel;
- the costs associated with expanding our facilities or building out our laboratory space; and
- the effects of the recent disruptions to and volatility in the credit and financial markets in the United States and the overall impact of the COVID-19 pandemic.

We do not have any committed external source of funds or other support for our development efforts. Until we can generate sufficient product revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings and debt financings, or other capital sources such as potential collaborations, strategic alliances, licensing arrangements and other arrangements. Based on our research and development plans, we expect that the net proceeds from our IPO, together with our existing cash balance, will enable us to fund our planned operating expenses and capital expenditure requirements for at least 12 months from the closing of our IPO. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. In addition, because the design and outcome of our anticipated and any future clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of Olvi-Vec or any future product candidates. Our existing cash balance, may not be sufficient to complete development of Olvi-Vec or any other product candidate. Accordingly, we will be required to obtain further funding to achieve our business objectives.

We have never generated any revenue from commercially approved product sales and may never become profitable.

Our ability to generate revenue from product sales and achieve profitability depends on our ability, alone or with future partners, to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize, our development programs. We have no products approved for commercial sale, have not generated any revenue from commercially approved product sales, and do not anticipate generating any revenue from commercially approved product sales until after we have received marketing approval for the commercial sale of a product candidate, if ever. Our ability to generate revenue and achieve profitability depends heavily on our success in achieving a number of goals, including:

- completing research regarding, and preclinical and clinical development of, product candidates and programs, including Olvi-Vec, and identifying and developing new product candidates;
- obtaining marketing approvals for any product candidates for which we complete clinical trials;
- obtaining regulatory approval to use and sell products generated by our existing or future manufacturing processes for Olvi-Vec and future product candidates, including at our existing manufacturing facility and/or by establishing and maintaining supply and manufacturing relationships with third parties;
- launching and commercializing product candidates for which we obtain marketing approvals, either directly by establishing a sales force and marketing, medical affairs and distribution infrastructure or, alternatively, with a collaborator or distributor;
- establishing and maintaining healthcare coverage and adequate reimbursement for our future products, if any;
- obtaining market acceptance of product candidates that we develop as viable treatment options;
- addressing any competing technological and market developments;

- identifying, assessing, acquiring and developing new product candidates;
- negotiating favorable terms in any collaboration, licensing, or other arrangements into which we may enter and performing our obligations in such collaborations;
- maintaining, protecting, and expanding our portfolio of intellectual property rights, including patents, trade secrets, and know-how; and
- attracting, hiring, and retaining qualified personnel.

Even if Olvi-Vec or any future product candidates that we develop are approved for commercial sale, we anticipate incurring significant costs associated with commercializing any such product candidate that we commercialize on our own or in collaboration with others. Our expenses could increase beyond expectations if we are required by the FDA or comparable foreign regulatory authorities, to change our manufacturing processes or assays, or to perform clinical, nonclinical, or other types of studies in addition to those that we currently anticipate.

If we are successful in obtaining regulatory approvals to market Olvi-Vec or any future product candidates, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain marketing 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 patients is not as significant as we estimate, the indications approved by regulatory authorities are narrower than we expect, the labels for our product candidates contain significant safety warnings, regulatory authorities impose burdensome or restrictive distribution requirements, or the reasonably accepted patient populations for treatment are narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. If we are not able to generate revenue from the sale of any approved products, we could be prevented from or significantly delayed in achieving profitability.

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

To the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, our stockholders' ownership interest may be diluted. Any future debt financings we undertake, if available, are likely to involve restrictive covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through licensing or collaboration arrangements with third parties, we may have to relinquish valuable rights to our product candidates, or grant licenses on terms that are not favorable to us. We also could be required to seek collaborators for product candidates at an earlier stage than otherwise would be desirable or relinquish our rights to product candidates or technologies that we otherwise would seek to develop or commercialize ourselves.

Failure to obtain capital when needed on acceptable terms may force us to delay, limit or terminate our product development and commercialization of our current or future product candidates, which could have a material and adverse effect on our business, financial condition, results of operations, stock price and prospects. Securing additional financing could also require a substantial amount of time from our management and may divert a disproportionate amount of their attention away from daily activities, which may adversely affect our management's ability to oversee the development of Olvi-Vec or any future product candidates.

The report of our independent registered public accounting firm included a "going concern" explanatory paragraph.

The report of our independent registered public accounting firm on our financial statements as of and for the years ended December 31, 2022 and 2021 included an explanatory paragraph indicating that there was substantial doubt about our ability to continue as a going concern. If we are unable to raise additional capital as and when needed, our business, financial condition and results of operations will be materially and adversely affected, and

we may be forced to delay our development efforts, limit our activities and reduce research and development costs. If we are unable to continue as a going concern, we may have to liquidate our assets, and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements. The inclusion of a going concern explanatory paragraph by our independent registered public accounting firm, our lack of cash resources and our potential inability to continue as a going concern may materially adversely affect our share price and our ability to raise new capital, enter into licensing and collaboration arrangements or other contractual relationships with third parties and otherwise execute our development strategy.

Risks Related to Product Discovery, Development and Regulatory Approval

Our development of product candidates based on our technology platform is limited, and we do not know whether we will be able to develop any products of commercial value.

The success of our business depends primarily upon our ability to identify novel product candidates based on our CHOICE platform and to successfully develop and commercialize those product candidates. While we have had promising preclinical and clinical study results for Olvi-Vec, to date, it remains our only product candidate that has moved into clinical trials. We have not yet succeeded and may not succeed in demonstrating efficacy and safety in commercializing Olvi-Vec. We also may be unsuccessful in identifying additional product candidates beyond Olvi-Vec using our CHOICE platform, and any of our product candidates may be shown to have harmful side effects or may have other characteristics that may necessitate additional clinical testing, or make the product candidates unmarketable or unlikely to receive marketing approval. In particular, because all of our product candidates have been derived from our CHOICE platform, the failure of any one of our development programs could create a perception that our other programs are less likely to succeed or that our discovery platform is not viable. Similarly, adverse developments with respect to other companies that attempt to use a similar approach to our approach may adversely impact the actual or perceived value and potential of our discovery platform and resulting product candidates.

If any of these events occur, our ability to successfully discover, develop and commercialize any product candidates may be impaired and the value of our company could decline significantly.

Our product candidates are in preclinical and clinical stages of development, are not approved for commercial sale and might never receive regulatory approval or become commercially viable.

All of our product candidates are in research, preclinical or clinical development. We have not completed the development of any product candidates, we currently generate no revenue, and we may never be able to develop a marketable product. Enrollment was completed in September 2019, and we reported multiple data readouts in 2020 (and expect final, long-term readout by the end of 2022) of our Phase 2 clinical trial, an open-label, single-arm study, of our lead product candidate, Olvi-Vec, in patients with PRROC. Our Phase 3 registration trial of Olvi-Vec in PRROC initiated enrollment in the third quarter of 2022.

Subject to FDA authorization, we anticipate beginning regulatory study start-up of a Phase 2, open-label, randomized, and controlled clinical trial designed to evaluate the efficacy and safety of intravenously delivered Olvi-Vec oncolytic VACV followed by treatment as per the NCCN Guidelines for patients with recurrent NSCLC in the United States in the first half of 2023, which will be funded in its entirety by Newsoara. We plan to conduct this trial under our current open IND and, subject to regulatory authorization, potentially launch a multi-regional clinical trial with Newsoara in the United States and China. We further anticipate Newsoara will initiate a Phase 1 clinical trial of Olvi-Vec in patients with recurrent SCLC in the first half of 2023, and thereafter initiate trials in recurrent NSCLC and recurrent ovarian cancer in China.

Additionally, we have a portfolio of oncolytic VACV constructs that are in early-to-mid stages of discovery and preclinical development and may never advance to clinical-stage development or marketing approval. Our ability to generate product revenues, which we do not expect will occur for several years, if ever, will depend on obtaining marketing approvals for, and successfully commercializing our product candidates, either alone or in collaboration with others, and we cannot guarantee that we will ever obtain marketing approval for any of our product candidates. Before obtaining marketing approval for the commercial distribution of our product candidates, we, or a future collaborator, must conduct extensive preclinical tests and clinical trials to demonstrate the safety and efficacy in humans of our product candidates.

The success of our current and future product candidates will depend on several factors, including the following:

- successful completion of preclinical studies and clinical trials;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- acceptance of INDs/IND amendments for our planned clinical trials or future clinical trials;
- successful enrollment and completion of clinical trials;
- successful data from our clinical trials that support FDA conclusion of an acceptable risk-benefit profile of our product candidates in the intended populations;
- receipt of regulatory and marketing approvals from applicable regulatory authorities;
- obtaining and maintaining patent and trade secret protection or regulatory exclusivity for our product candidates;
- obtaining regulatory approval to use our existing or future manufacturing processes for the clinical and commercial manufacture of our product candidates at our existing or future manufacturing facilities or at the facilities of one or more third-party manufacturers with whom we would need to establish supply arrangements;
- successfully launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others;
- acceptance of any products we develop and their benefits and uses, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- obtaining and maintaining healthcare coverage and adequate reimbursement from third-party payors; and
- maintaining a continued acceptable safety profile of the products following approval.

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

We currently have only one product candidate, Olvi-Vec, in clinical development. A failure of this product candidate in clinical development would adversely affect our business and may require us to discontinue development of other product candidates based on the same therapeutic approach.

We have invested a significant portion of our efforts and financial resources in our oncolytic VACV platform and, in particular, in the development of our lead product candidate, Olvi-Vec. We have completed enrollment for only one Phase 2 clinical trial, an open-label single-arm study, of Olvi-Vec in patients with PRROC in September 2019. Our Phase 3 registration trial of Olvi-Vec in PRROC initiated enrollment in the third quarter of 2022. Olvi-Vec, as well as our other product candidates, are susceptible to the risks of failure inherent at any stage of product development, including the occurrence of unexpected or unacceptable adverse events or the failure to demonstrate efficacy in clinical trials. We will need to successfully complete such trials before submitting a marketing application to the FDA.

We have submitted an IND application with respect to only one product candidate, Olvi-Vec. V2ACT, a joint venture between TVAX and us, has also filed its own IND for V2ACT Immunotherapy, a combination of Olvi- Vec and vaccine-enhanced adoptive cell therapy for the treatment of newly diagnosed, surgically-resectable pancreatic cancer patients. For V2ACT Immunotherapy, no clinical trial is yet scheduled to be initiated. We have not previously submitted a Biologics License Application (BLA) to the FDA, or similar regulatory approval filings to comparable foreign authorities, for any product candidate, and we cannot be certain that our product candidates will be successful in clinical trials or receive regulatory approval. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials.

Since Olvi-Vec is based on our oncolytic VACV platform, if Olvi-Vec fails in development as a result of any underlying problem with our oncolytic VACV platform, then we may be required to discontinue development of all product candidates that are based on this therapeutic approach. If we were required to discontinue development of Olvi-Vec or our other future product candidates, or if any of them were to fail to receive regulatory approval or achieve sufficient market acceptance, we could be prevented from or significantly delayed in achieving profitability. We can provide no assurance that we would be successful at developing other product candidates based on an alternative therapeutic approach.

Our product candidates are based on a novel approach to the treatment of cancer, which makes it difficult to predict the time and cost of product candidate development.

We have concentrated all of our research and development efforts on product candidates based on our oncolytic VACV platform, which is novel. We only have conducted clinical development of Olvi-Vec in human cancer patients and V-VET1 in canine cancer patients. Our future success depends on the successful development of our oncolytic VACV platform. Any development problems we experience in the future may cause significant delays or unanticipated costs, and we may not be able to solve any such development problems. Should we encounter development problems, including unfavorable preclinical or clinical trial results, the FDA or foreign regulatory authorities may place all, or part, of our clinical development on hold or refuse to approve our product candidates, or may require additional information, tests, or trials, which could significantly delay product development and significantly increase our development costs. Moreover, even if we are able to provide the requested information or trials to the FDA, there would be no guarantee that the FDA would accept them or approve our product candidates. We may also experience delays in developing and obtaining regulatory approval for a sustainable, reproducible and scalable manufacturing process, or developing or qualifying and validating product release assays, other testing and manufacturing methods, and our equipment and facilities in a timely manner, which may prevent us from completing our clinical trials or commercializing our product candidates on a timely or profitable basis, if at all.

In addition, the clinical trial requirements of the FDA and comparable foreign regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential products. The FDA and comparable foreign regulatory authorities have limited experience with the approval of viral immunotherapies. To date, there is only one FDA-approved viral immunotherapy—talimogene laherparepvec (IMLYGIC). Any viral immunotherapies that are approved may be subject to extensive post-approval regulatory requirements, including post-approval studies as well as requirements pertaining to manufacturing, distribution and promotion. We may need to devote significant time and resources to compliance with these requirements.

Preclinical and clinical development involve a lengthy and expensive process with an uncertain outcome and stringent regulations, and delays can occur for a variety of reasons.

In order to obtain FDA approval to market a new biological product, we must demonstrate proof of safety as well as purity and potency (i.e., efficacy) in humans. To meet these requirements, we will have to conduct adequate and well-controlled clinical trials. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies that support our planned INDs in the United States. We only have one product candidate currently being evaluated in human clinical development, Olvi-Vec. In addition, the FDA has granted permission to proceed with a clinical trial under the IND for V2ACT Immunotherapy, but no clinical trial has been initiated or is currently scheduled to initiate. The rest of our product candidates are in preclinical development, have not yet been evaluated in IND-enabling studies and their risk of failure is high. We cannot be

certain of the timely completion or outcome of our preclinical testing and studies or clinical trials and cannot predict if the FDA will accept our proposed clinical programs or if the outcome of our preclinical testing and studies or clinical trials will ultimately support the further development of our programs. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our preclinical programs on the timelines we expect, if at all, we cannot be sure that submission of INDs or similar applications will result in the FDA or other regulatory authorities allowing clinical trials to begin and we cannot be sure that our planned clinical trials will begin on time or that our ongoing clinical trials will be completed on schedule.

Conducting preclinical testing and clinical development is a lengthy, time-consuming and expensive process. The length of time may vary substantially according to the type, complexity and novelty of the program, and often can be several years or more per program. Delays associated with programs for which we are directly conducting preclinical testing and studies may cause us to incur additional operating expenses. Moreover, we may be affected by delays associated with the preclinical testing and studies of certain programs that are the responsibility of any potential future partners over which we have no control. The commencement and rate of completion of preclinical studies and clinical trials for a product candidate may be delayed by many factors, including, for example:

- inability to generate sufficient preclinical or other in vivo or in vitro data to support the initiation of clinical trials;
- unexpected toxicities observed in preclinical IND-enabling studies precluding the identification of a safe dose to move forward in human clinical trials;
- delays in obtaining regulatory approval for, and production or manufacturing of, clinical supply;
- delays in reaching a consensus with regulatory agencies on study or trial design; and
- regulatory authorities not allowing us to rely on previous findings of safety and efficacy for other similar but approved products and published scientific literature.

We may experience delays in initiating or completing clinical trials. We also may experience numerous unforeseen events during, or as a result of, any ongoing or future clinical trials that we could conduct that could delay or prevent our ability to receive marketing approval or commercialize Olvi-Vec or any future product candidates, including:

- delays or failures related to the COVID-19 pandemic, which may result in clinical site closures, delays to patient enrollment, patients withdrawing prior to receiving treatment (e.g., catheter implantation failure), patients discontinuing their treatment or follow up visits or changes to trial protocols;
- regulators or institutional review boards (IRBs), may not authorize us or our investigators to commence a clinical trial, conduct a clinical trial at a prospective trial site, or amend trial protocols, or may require that we modify or amend our clinical trial protocols;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites and/or contract research organizations (CROs);
- clinical trials of our product candidates may produce negative or inconclusive results, or our studies may fail to reach the necessary level of statistical significance, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the unsuccessful implantation of catheters used to deliver Olvi-Vec;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials or be lost to follow-up at a higher rate than we anticipate, or may elect to participate in alternative clinical trials sponsored by our competitors with product candidates that treat the same indications as our product candidates;
- third-party contractors may fail to comply with regulatory requirements or the clinical trial protocol, or meet their contractual obligations to us in a timely manner, or at all, or we may be required to engage in additional clinical trial site monitoring;
- manufacturing delays;
- we, regulators, or IRBs may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks, undesirable side effects, emergent drug- drug interactions between Olvi-Vec and any of the other therapeutic agents given to the clinical trial subjects or other unexpected characteristics of the product candidate, or due to findings of undesirable effects caused by a biologically, chemically or mechanistically similar therapeutic or therapeutic candidate;
- changes could be adopted in marketing approval policies during the development period, rendering our data insufficient to obtain marketing approval;
- statutes or regulations could be amended, or new ones could be adopted;
- changes could be adopted in the regulatory review process for submitted product applications;
- the cost of clinical trials of our product candidates may be greater than we anticipate, or we may have insufficient funds for a clinical trial or product manufacture or to pay the substantial user fees required by the FDA upon the submission of a BLA or equivalent authorizations from comparable foreign regulatory authorities;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;

- we may decide, or regulators may require us, to conduct or gather, as applicable, additional clinical trials, analyses, reports, data, or preclinical trials, or we may abandon product development programs;
- we may fail to reach an agreement with regulators or IRBs regarding the scope, design, or implementation of our clinical trials, and the FDA or comparable foreign regulatory authorities may require changes to our study designs that make further study impractical or not financially prudent;
- regulators may ultimately disagree with the design or our conduct of our preclinical studies or clinical trials, finding that they do not support product candidate approval;
- we may have delays in adding new investigators or clinical trial sites, or we may experience a withdrawal of clinical trial sites;
- patients that enroll in our studies may misrepresent their eligibility or may otherwise not comply with the clinical trial protocol, resulting in the need to drop the patients from the study or clinical trial, increase the needed enrollment size for the clinical trial or extend its duration;
- there may be regulatory questions or disagreements regarding interpretations of data and results, or new information may emerge regarding our product candidates;
- the FDA or comparable foreign regulatory authorities may disagree with our trial design, including endpoints, or our interpretation of data from preclinical studies and clinical trials or find that a product candidate's benefits do not outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may not accept data from studies with clinical trial sites in foreign countries;
- the FDA or comparable foreign regulatory authorities may disagree with our intended indications;
- the FDA or comparable foreign regulatory authorities may fail to approve or subsequently find fault with the manufacturing processes or our manufacturing facilities for clinical and future commercial supplies;
- the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of a BLA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may take longer than we anticipate to make a decision on our product candidates; and
- we may not be able to demonstrate that a product candidate provides an advantage over current standards of care or current or future competitive therapies in development, including, for example due to a longer-and/or-higher-than-expected response rate determination in the active comparator group or a shorter-and/or-lower-than-expected response rate determination in the experimental drug group.

For example, during an End-of-Phase 2 meeting in March 2021, the FDA informed us that when submitting for regulatory authorization of our planned Phase 3 registration clinical trial of Olvi-Vec we must demonstrate comparability of product manufactured under our new in-house manufacturing process to product used in the Phase 2 clinical trial. Based on our discussions with the FDA, on June 28, 2021 we formally submitted to the FDA an IND amendment for our new manufacturing process, and on August 18, 2021, we submitted the data to demonstrate comparability of Olvi-Vec prepared in mammalian cells as compared to being prepared in chicken embryo fibroblasts (CEF) cells. On November 17, 2021 we received an information request from the FDA regarding our IND manufacturing amendments and we responded on December 1, 2021. On February 16, 2022, we received additional comments regarding the CMC sections of our IND amendments submitted in 2021. We submitted further responses to the last round of questions on February 24, 2022. In July 2022, we received and responded to FDA comments regarding an assay used in our clinical trial.

Our Phase 3 registration trial of Olvi-Vec in PRROC initiated enrollment in the third quarter of 2022. The FDA may issue further comments to our Phase 3 clinical trial protocol and may conclude Olvi-Vec produced in mammalian cells is not comparable to material produced in CEF cells, and/or place our IND on clinical

hold. Placing our IND on clinical hold may cause delays in the initiation of our Phase 3 registration clinical trial. Any delay in obtaining or failure to obtain authorization from FDA to conduct our Phase 3 clinical trial could materially adversely affect our ability to generate revenue from Olvi-Vec, which may materially harm our business, financial condition, results of operations, stock price and prospects.

Our product development costs will also increase if we experience delays in clinical testing or marketing approvals, and we may not have sufficient funding to complete the testing and approval process for any of our current or future product candidates. We may be required to obtain additional funds to complete clinical trials and prepare for possible commercialization of our product candidates. We do not know whether any preclinical tests or clinical trials beyond what we currently have planned will be required, will begin as planned, will need to be restructured, or will be completed on schedule or at all. Significant delays relating to any preclinical studies or clinical trials also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates and may harm our business and results of operations. In addition, many of the factors that cause, or lead to, delays in clinical trials may ultimately lead to the denial of marketing approval of any of our product candidates. Any delays in our clinical development programs may harm our business, financial condition and results of operations significantly.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or foreign regulatory authorities.

Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the clinical trial, the design of the clinical trial, competing clinical trials, and clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. We may experience difficulties in patient enrollment or retention in our clinical trials for a variety of reasons. The enrollment of patients depends on many factors, including:

- availability and efficacy of approved therapies for the disease under investigation;
- patient eligibility criteria for the trial in question;
- risks that enrolled subjects will drop out before completion of the trial, including as a result of emergent drug-drug interactions between Olvi-Vec and any of the other therapeutic agents given to the clinical trial subjects, contracting COVID-19 or other health conditions or being forced to quarantine;
- risks of excessive catheter implantation failures leading to elimination of particular study sites from the trial in question;
- perceived risks and benefits of the product candidate under study;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;

- proximity and availability of clinical trial sites for prospective patients;
- withdraw of consent for any reasons;
- unforeseen limitations of protocol design; and
- protocol amendment by the sponsor and/or as requested by applicable regulatory authorities.

In addition, our planned clinical trials may compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us because some patients who might have opted to enroll in our trials may instead opt to enroll in a competing clinical trial.

Our inability to enroll a sufficient number of patients for our anticipated and any future clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which could have an adverse effect on our business, financial condition, results of operations, and prospects. In addition, disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter patient enrollment difficulties.

Results of preclinical studies and early clinical trials may not be predictive of results of future clinical trials.

For our lead product candidate, Olvi-Vec, we completed enrollment, and we reported multiple data readouts in 2020 and 2021 for our Phase 2 clinical trial and expect the final readout by the end of 2022. Our Phase 3 registration trial of Olvi-Vec in PRROC initiated enrollment in the third quarter of 2022. Other product candidates that may be generated from our oncolytic VACV platform are in preclinical development. For the PRROC indication, we will be required to conduct at least one additional clinical trial of Olvi-Vec before we can submit a marketing application to the applicable regulatory authorities. Clinical development is expensive and can take many years to complete and its outcome is inherently uncertain. Olvi-Vec may not perform as we expect in clinical trials, particularly in our open-label, randomized, and controlled Phase 3 registration clinical trial, may ultimately have a different or no impact on tumors, may have a different mechanism of action than we expect and may not ultimately prove to be safe and effective.

The results of previous clinical trials of Olvi-Vec and results of preclinical studies or early clinical trials of any other product candidate we develop, may not be predictive of the results of subsequent and later-stage clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in registration-stage clinical trials after achieving positive results in earlier development, and we could face similar setbacks. The design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We do not have experience in designing a registration-stage clinical trial and may be unable to design and execute a clinical trial to support marketing approval. In addition, preclinical and clinical data are often susceptible to varying interpretations and analyses. Many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for the product candidates. Even if we, or future collaborators, believe that the results of clinical trials for our product candidates warrant marketing approval, the FDA or comparable foreign regulatory authorities may disagree and may not grant marketing approval of our product candidates.

In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols, variations in conducting clinical trial at different sites, changes in medical practice, FDA requirements based on agency guidelines or precedence which may be more strict for a Phase 3 clinical trial, the rate of dropout among clinical trial participants and changes in the manufacturing process. Moreover, should there be an issue with the design of any of our clinical trials, our results may be impacted. We may not discover such a flaw until the clinical trial is at an advanced stage.

Interim, topline, and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose interim, topline, or preliminary data from our clinical trials, which is 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 interim, topline, 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. Interim, topline, and preliminary 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, such data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our clinical trials. Interim, topline, and preliminary 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. Adverse differences between preliminary, interim or topline data and final data could significantly harm our business prospects.

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 the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product, product candidate, or our business. If the interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize Olvi-Vec and any future product candidates may be harmed, which could harm our business, operating results, prospects, or financial condition.

Serious adverse events, undesirable side effects (including emergent drug-drug interactions between Olvi-Vec and any of the other therapeutic agents given to the clinical trial subjects) or other unexpected properties of our current or future product candidates may be identified during development or after approval, which could halt their development or lead to the discontinuation of our clinical development programs, refusal by regulatory authorities to approve our product candidates or, if discovered following marketing approval, revocation of marketing authorizations or limitations on the use of our product candidates thereby limiting the commercial potential of such product candidate.

To date, Olvi-Vec is the only product candidate we have tested in humans. The most advanced trial conducted was our open-label, single-arm Phase 1b/2 clinical trial in PRROC. Enrollment was completed in September 2019, and we reported multiple data readouts in 2020 and 2021, and expect the final, long-term readout by the end of 2022. Additionally, we previously conducted five Phase 1 clinical trials and one Expanded Access Program (EAP) in different indications, using different routes of administration and different dosing regimens. The most common treatment-related toxicities generally observed in our trials from different routes of administration were pyrexia, nausea, chills and fatigue with additional common treatment-related toxicities observed in our intraperitoneal administration trials being abdominal pain and abdominal distension. As we continue our development of Olvi-Vec and initiate clinical trials of any future product candidates, serious adverse events, undesirable side effects or unexpected characteristics may emerge or be reported, causing us to abandon

these product candidates or limit their development to more narrow uses or subpopulations in which the serious adverse events, undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Even if our product candidates initially show promise in early clinical trials, the side effects of therapies are frequently only detectable after they are tested in large, Phase 3 clinical trials or, in some cases, after they are made available to patients on a commercial scale after approval. Sometimes, it can be difficult to determine if the serious adverse or unexpected side effects were caused by the product candidate or another factor, especially in oncology subjects who may suffer from other medical conditions and be taking other medications. If serious adverse or unexpected side effects are identified during development and are determined to be attributed to our product candidates, or the result of drug-drug interactions between our product candidate and any of the concomitant therapies given to the trial subjects, we, the FDA or comparable foreign regulatory authorities, or IRBs and other reviewing entities, could interrupt, delay, or halt clinical trials and could result in a more restrictive label, a Risk Evaluation and Mitigation Strategy (REMS) or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authorities may also require, or we may voluntarily develop strategies for managing adverse events during clinical development, which could include restrictions on our enrollment criteria, the use of stopping criteria, adjustments to a study's design, or the monitoring of safety data by a data monitoring committee, among other strategies. Any requests from the FDA or comparable foreign regulatory authority for additional data or information could also result in substantial delays in the approval of our product candidates.

Drug-related side effects could also affect subject recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

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

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we may be forced to suspend marketing of that product, or decide to remove the product form the marketplace;
- we may be required to change the way the product is administered;
- we could be subject to fines, injunctions, or the imposition of criminal or civil penalties;
- we could be sued and held liable for harm caused to patients; and
- the product may become less competitive, and our reputation may suffer.

The therapeutic-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, financial condition, results of operations, stock price and prospects.

We anticipate that many of our product candidates will be used in combination with third-party drugs and/or devices, some of which may still be in development, and we have limited or no control over the supply, regulatory status or regulatory approval of such drugs and/or devices.

We anticipate developing our product candidates for use in combination with other oncology therapeutics, including chemotherapies and cellular and targeted therapies (e.g., immune checkpoint inhibitors), or medical devices (e.g. intraperitoneal catheter). For example, in our Phase 3 registration clinical trial, we are developing

the intraperitoneal (catheter) delivery of Olvi-Vec in combination with a platinum-based chemotherapy doublet and bevacizumab (e.g., AVASTIN). Our ability to develop and ultimately commercialize our product candidates used in combination with platinum-based and other chemotherapies, and bevacizumab, or any other combination products (e.g., cellular and targeted therapies), and used with devices (e.g., catheters) will depend on our ability to access such drugs and devices on commercially reasonable terms for the clinical trials and their availability for use with the commercialized product, if approved. We cannot be certain that current or potential future commercial relationships will provide us with a steady supply of such drugs or devices on commercially reasonable terms or at all.

Any failure to maintain or enter into new successful commercial relationships, or the expense of purchasing platinum-based and other chemotherapies, and bevacizumab, or any other combination products, or any devices in the market, may delay our development timelines, increase our costs and jeopardize our ability to develop our product candidates as commercially viable therapies. If any of these occur, our business, financial condition, results of operations, stock price and prospects may be materially harmed.

Moreover, the development of product candidates for use in combination with another product or product candidate may present challenges that are not faced for single agent product candidates. For our product candidates that may be used in combination with platinum-based and other chemotherapies, and bevacizumab, or any other combination products or any devices, the FDA may require us to use more complex clinical trial designs in order to evaluate the contribution of each product and product candidate to any observed effects. It is possible that the results of these trials could show that there are adverse events tied to the interaction of Olvi-Vec with any of the other therapies, or that any positive previous trial results are attributable to the combination therapy and not our product candidates. Moreover, following product approval, the FDA may require that products or devices used in conjunction with each other be cross labeled for combined use. To the extent that we do not have rights to the other product or device, this may require us to work with a third party to satisfy such a requirement. The ability to obtain cooperation from the third party may impact our ability to respond to the FDA's requests which could impact our ability to achieve regulatory approval. Moreover, developments related to the other product or device may impact our clinical trials as well as our commercial prospects should we receive marketing approval. Such developments may include changes to the safety or efficacy profile of the other product or device, changes to the availability of the approved product or device, and changes to the standard of care.

In the event that any future collaborator or supplier of platinum-based and other chemotherapies, and bevacizumab, or any other products administered in combination, or any devices used, with our product candidates does not supply their products on commercially reasonable terms or in a timely fashion, we would need to identify alternatives for accessing these products. This could cause our clinical trials to be delayed and limit the commercial opportunities for our product candidates, in which case our business, financial condition, results of operations, stock price and prospects may be materially harmed.

We may not be successful in our efforts to expand our pipeline of product candidates and develop marketable products.

We expect initially to develop our lead product candidate, Olvi-Vec. We anticipate pursuing clinical development of other product candidates, alone or in collaboration with our partners. Research programs to identify new product candidates require substantial technical, financial and human resources. Developing, obtaining marketing approval for, and commercializing additional product candidates will require substantial additional funding and will be subject to the risks of failure inherent in medical product development. We cannot assure you that we will be able to successfully advance any of these additional product candidates through the development process.

Even if we obtain approval from the FDA or comparable foreign regulatory authorities to market additional product candidates for the treatment of cancer, we cannot assure you that any such product candidates will be successfully commercialized, widely accepted in the marketplace, or more effective than other commercially available alternatives. If we are unable to successfully develop and commercialize additional product candidates our commercial opportunity may be limited and our business, financial condition, results of operations, stock price and prospects may be materially harmed.

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

Because we have limited financial and managerial resources, we must prioritize our research programs and will need to focus our product candidates on the potential treatment of certain indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products.

Additionally, we may pursue additional in-licenses or acquisitions of development-stage assets or programs, which entails additional risk to us. Identifying, selecting and acquiring promising product candidates requires substantial technical, financial, and human resources expertise. Efforts to do so may not result in the actual acquisition or license of a particular product candidate, potentially resulting in a diversion of our management's time and the expenditure of our resources with no resulting benefit. For example, if we are unable to identify programs that ultimately result in approved products, we may spend material amounts of our capital and other resources evaluating, acquiring and developing products that ultimately do not provide a return on our investment.

If we do not achieve our product development goals in the timeframes we announce and expect, the commercialization of our product candidates may be delayed and as a result our share price may decline.

Drug development is inherently risky and uncertain. We cannot be certain that we will be able to:

- complete IND-enabling preclinical studies or develop manufacturing processes and associated analytical methods that meet current good manufacturing practice (cGMP) requirements in time to initiate or to complete our anticipated or future clinical trials in the timeframes we announce;
- obtain sufficient clinical supply of our product candidates to support our anticipated or future clinical trials;
- initiate clinical trials within the timeframes we announce;
- enroll and maintain a sufficient number of subjects to complete or timely complete any clinical trials; or
- collect and analyze the data from any completed clinical trials in the timeframes we announce.

The actual timing of our development milestones could vary significantly compared to our estimates, in some cases for reasons beyond our control. If we are unable to achieve our goals within the timeframes we announce, the commercialization of our product candidates may be delayed and, as a result, the stock price of our common stock could fall and you may lose all of your investment.

Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain and may prevent us or any of our existing or potential future collaboration partners from obtaining approvals for the commercialization of Olvi-Vec, V-VET1, V2ACT Immunotherapy and any other product candidate we develop.

Any current or future product candidate we may develop, and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, and distribution, are subject to comprehensive regulation by the FDA and other regulatory authorities in the United States and by comparable authorities in other countries. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate in a given jurisdiction. We have not received approval to market any product candidates from regulatory authorities in any jurisdiction and it is possible that none of the product candidates we may seek to develop in the future will ever obtain regulatory approval.

Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy for that indication. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities and clinical trial sites by, the regulatory authorities. If we do not receive approval from the FDA and comparable foreign regulatory authorities for any of our product candidates, we will not be able to commercialize such product candidates in the United States or in other jurisdictions. If significant delays in obtaining approval for and commercializing our product candidates occur in any jurisdictions, our business, financial condition, results of operations, stock price and prospects will be materially harmed. Even if our product candidates are approved, they may:

- be subject to limitations on the indicated uses or patient populations for which they may be marketed, distribution restrictions, or other conditions of approval;
- contain significant safety warnings, including boxed warnings;
- contain significant contraindications, and precautions which could reduce the size of the patient population;
- not be approved with label statements necessary or desirable for successful commercialization;
- contain requirements for costly post-market testing and surveillance, or other requirements, including the submission of a REMS to monitor the safety or efficacy of the products; or
- be withdrawn from the market because of a serious safety issue becomes know after approval is granted.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, takes many years even if successful, and can vary substantially in and among jurisdictions based upon a variety of factors, including the type, complexity, and novelty of the product candidates involved. The number and types of preclinical studies and clinical trials that will be required for regulatory approval also varies depending on the product candidate, the disease or condition that the product candidate is designed to address, and the regulations applicable to any particular product candidate. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit, or prevent marketing approval of a product candidate. It is possible that our product candidates will never obtain the appropriate regulatory approvals necessary for us to commence product sales, or any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

If we experience delays in obtaining approval or if we fail to obtain approval of any current or future product candidates we may develop, the commercial prospects for those product candidates may be harmed, and our ability to generate revenues will be materially impaired.

We plan to conduct our Phase 2 clinical trial for Olvi-Vec in recurrent NSCLC in the United States and potentially in China as part of a multi-regional clinical trial with our collaboration partner Newsoara. However, the FDA and other foreign equivalents may not accept data from such trial, in which case our development plans will be delayed, which could materially harm our business.

Subject to FDA authorization, we anticipate beginning regulatory study start-up of a Phase 2, open-label, randomized, and controlled clinical trial designed to evaluate the efficacy and safety of intravenously delivered Olvi-Vec oncolytic VACV followed by treatment as per the NCCN Guidelines for patients with recurrent NSCLC in the United States in the first half of 2023, which will be funded in its entirety by Newsoara. We plan to conduct this trial under our current open IND and, subject to regulatory authorization, potentially launch a multi-regional clinical trial with Newsoara in the United States and China. We further anticipate Newsoara will initiate a Phase 1 clinical trial of Olvi-Vec in patients with recurrent SCLC in the first half of 2023, and thereafter initiate trials in recurrent NSCLC and recurrent ovarian cancer in China.

The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, the FDA will not accept the data as support for an application for marketing approval unless the study is well-designed and well-conducted in accordance with Good Clinical Practice (GCP) requirements and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in current or future product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction.

We believe that clinical data generated in China and the United States will be accepted by the FDA and its foreign equivalents outside of China, which would enable us to commence Phase 3 and possibly registration clinical trials in the United States without the need for us to conduct additional Phase 2 clinical trials in the United States. However, there can be no assurance the FDA or applicable foreign authorities will accept data from our planned Phase 2 clinical trial in Olvi-Vec. If the FDA or applicable foreign authorities do not accept any such data, we would likely be required to conduct additional Phase 2 clinical trials, which would be costly and time consuming, and delay aspects of our development plan, which could harm our business.

Conducting clinical trials outside the United States exposes us to additional risks, including risks associated with:

- additional foreign regulatory requirements;
- compliance with foreign manufacturing, customs, shipment and storage requirements;
- cultural differences in medical practice and clinical research; and
- diminished protection of intellectual property in some countries.

Regulatory approval by the FDA or comparable foreign regulatory authorities is limited to those specific indications and conditions for which approval has been granted, and we may be subject to substantial fines, criminal penalties, injunctions, or other enforcement actions if we are determined to be promoting the use of any products for unapproved or "off-label" uses, resulting in damage to our reputation and business.

We must comply with requirements concerning advertising and promotion for any product candidates for which we obtain marketing approval. Promotional communications with respect to therapeutics are subject to a variety of legal and regulatory restrictions and continuing review by the FDA, Department of Justice, Department of Health and Human Services' Office of Inspector General, state attorneys general, members of Congress, and the public. When the FDA or comparable foreign regulatory authorities issue regulatory approval for a product candidate, the regulatory approval is limited to those specific uses and indications for which a product is approved. If we are not able to obtain FDA approval for desired uses or indications for our product candidates, we may not market or promote them for those indications and uses, referred to as off-label uses, and our business, financial condition, results of operations, stock price and prospects will be materially harmed. We also must sufficiently substantiate any claims that we make for any products we develop, including claims comparing our products to other companies' products, and must abide by the FDA's strict requirements regarding the content of promotion and advertising.

Because regulatory authorities in the United States generally do not restrict or regulate the behavior of physicians in their choice of treatment within the practice of medicine, physicians may in their independent medical judgment choose to prescribe products for uses that are not described in the product's labeling and for uses that differ from those tested in clinical trials and approved by the regulatory authorities. Regulatory authorities do, however, limit communications by biopharmaceutical companies concerning off-label use. Therefore, we are prohibited from marketing and promoting the products for indications and uses that are not specifically approved by the FDA.

If we are found to have impermissibly promoted any products that we may develop, we may become subject to significant liability and government fines. The FDA and other agencies actively enforce the laws and regulations regarding product promotion, particularly those prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted a product may be subject to significant sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

In the United States, the promotion of biopharmaceutical products is subject to additional FDA requirements and restrictions on promotional statements. If after one or more of our product candidates obtains marketing approval the FDA determines that our promotional activities violate its regulations and policies pertaining to product promotion, it could request that we modify our promotional materials or subject us to regulatory or other enforcement actions, including issuance of warning letters or untitled letters, suspension or withdrawal of an approved product from the market, requests for recalls, payment of civil fines, disgorgement of money, imposition of operating restrictions, injunctions or criminal prosecution, and other enforcement actions. Similarly, industry codes in foreign jurisdictions may prohibit companies from engaging in certain promotional activities and regulatory agencies in various countries may enforce violations of such codes with civil penalties. If we become subject to regulatory and enforcement actions our business, financial condition, results of operations, stock price and prospects will be materially harmed.

Engaging in the impermissible promotion of our products, in the United States, following approval, for off-label uses can also subject us to false claims and other litigation under federal and state statutes. These include fraud and abuse and consumer protection laws, which can lead to civil and criminal penalties and fines, agreements with governmental authorities that materially restrict the manner in which we promote or distribute therapeutic products and conduct our business. These restrictions could include corporate integrity agreements, suspension or exclusion from participation in federal and state healthcare programs, and suspension and debarment from government contracts and refusal of orders under existing government contracts. These False Claims Act (FCA) lawsuits against manufacturers of drugs and biological products have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements, up to $3.0 billion, pertaining to certain sales practices and promoting off-label uses. In addition, FCA lawsuits may expose manufacturers to follow-on claims by private payors based on fraudulent marketing practices. This growth in litigation has increased the risk that a biopharmaceutical company will have to defend a false claim action, pay settlement fines

or restitution, as well as criminal and civil penalties, agree to comply with burdensome reporting and compliance obligations, and be excluded from Medicare, Medicaid, or other federal and state healthcare programs. If we do not lawfully promote our approved products, if any, we may become subject to such litigation and, if we do not successfully defend against such actions, those actions may have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

Obtaining and maintaining marketing approval for our product candidates in one jurisdiction would not mean that we will be successful in obtaining marketing approval of that product candidate in other jurisdictions, which could prevent us from marketing our products internationally.

Obtaining and maintaining marketing approval of our product candidates in one jurisdiction would not guarantee that we will be able to obtain or maintain marketing approval in any other jurisdiction, while a failure or delay in obtaining marketing approval in one jurisdiction may have a negative effect on the marketing approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable foreign regulatory authorities must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means.

Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign marketing approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed. If we obtain approval for any product candidate and ultimately commercialize that product in foreign markets, we would be subject to additional risks and uncertainties, including the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements and the reduced protection of intellectual property rights in some foreign countries.

Even if our product candidates receive regulatory approval, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense and limit how we manufacture and market our products.

Any product candidate for which we obtain marketing approval will be subject to extensive and ongoing requirements of and review by the FDA or comparable foreign regulatory authorities, including requirements related to the manufacturing processes, post-approval clinical data, labeling, packaging, distribution, adverse event reporting, storage, recordkeeping, export, import, advertising, marketing, and promotional activities for such product. These requirements further include submissions of safety and other post-marketing information, including manufacturing deviations and reports, registration and listing requirements, the payment of annual fees, continued compliance with cGMP requirements relating to manufacturing, quality control, quality assurance, and corresponding maintenance of records and documents, and GCPs for any clinical trials that we conduct post-approval.

The FDA and comparable foreign regulatory authorities will continue to closely monitor the safety profile of any product even after approval. If the FDA or comparable foreign regulatory authorities become aware of new safety information after approval of any of our product candidates, they may withdraw approval, issue public safety alerts, require labeling changes or establishment of a REMS or similar strategy, impose significant restrictions on a product's indicated uses or marketing, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. Any such restrictions could limit sales of the product.

We and any of our suppliers or collaborators, including our contract manufacturers, could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with cGMPs and other FDA regulatory requirements. Application holders must further notify the FDA, and depending on the nature of the change, obtain FDA pre-approval for product and manufacturing changes.

In addition, later discovery of previously unknown adverse events or of the product being less effective than previously thought or other problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements both before and after approval, may yield various negative results, including:

- restrictions on manufacturing, distribution, or marketing of such products;
- restrictions on the labeling, including required additional warnings, such as black boxed warnings, contraindications, precautions, and restrictions on the approved indication or use;
- modifications to promotional pieces;
- issuance of corrective information;
- requirements to conduct post-marketing studies or other clinical trials;
- clinical holds or termination of clinical trials;
- requirements to establish or modify a REMS or similar strategy;
- changes to the way the product candidate is administered;
- liability for harm caused to patients or subjects;
- reputational harm;
- the product becoming less competitive;
- warning, untitled, or cyber letters;
- suspension of marketing or withdrawal of the products from the market;
- regulatory authority issuance of safety alerts, Dear Healthcare Provider letters, press releases, or other communications containing warnings or other safety information about the product candidate;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recalls of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure or detention;
- FDA debarment, suspension and debarment from government contracts, and refusal of orders under existing government contracts, exclusion from federal healthcare programs, consent decrees, or corporate integrity agreements; or
- injunctions or the imposition of civil or criminal penalties, including imprisonment.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, or could substantially increase the costs and expenses of commercializing such product, which in turn could delay or prevent us from generating significant revenues from its marketing and sale. Any of these events could further have other material and adverse effects on our operations and business and could adversely impact our business, financial condition, results of operations, stock price and prospects.

The FDA's policies or those of comparable foreign regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates, limit the marketability of our product candidates, or impose additional regulatory obligations on us. Changes in medical practice and standard of care may also impact the marketability of our product candidates.

If we are slow or unable to adapt to changes in existing requirements, standards of care, or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and be subject to regulatory enforcement action.

Should any of the above actions take place, we could be prevented from or significantly delayed in achieving profitability. Further, the cost of compliance with post-approval regulations may have a negative effect on our operations and business and could adversely impact our business, financial condition, results of operations, stock price and prospects.

Risks Related to Manufacturing

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

The manufacture of biopharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. The process of manufacturing viral immunotherapies, including our product candidates, is particularly complex, time- consuming, highly-regulated and costly.

Manufacturers of therapeutics often encounter difficulties in production, particularly in scaling up initial production, with such risks including:

- quality control, including stability of the product candidate and quality assurance testing;
- shortages of qualified personnel or key raw materials or components;
- product loss during the manufacturing process, including loss caused by contamination, equipment failure or improper installation or operation of equipment, or operator error. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our products or in the manufacturing facilities in which our products are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination;
- the manufacturing facilities in which our product candidates are made could be adversely affected by equipment failures, labor and raw material shortages, natural disasters, power failures and numerous other factors; and
- any adverse developments affecting manufacturing operations for our products may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our product candidates. We may also have to take inventory write-offs and incur other charges and expenses for product candidate batches that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives.

As product candidates are developed through preclinical studies to later-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results.

Changes in product candidate manufacturing or formulation may result in additional costs or delay.

We previously engaged a third-party contract manufacturing organization (CMO) that specializes in the manufacture of vaccines to produce clinical-grade Olvi-Vec for all of our prior clinical trials.

We have leased a building in San Diego, California and have established and equipped our own manufacturing facility in order to secure supplies for pivotal studies and commercial launch. This building is intended to give us control over key aspects of the supply chain for our products and product candidates and has additional space for expansion.

We have developed a new process for larger-scale manufacturing using a closed, mammalian-cell-based production system. This process is being implemented in our manufacturing facility and is intended to produce Olvi-Vec and other clinical products for use in our subsequent clinical trials and in our commercial launches. We may also make further changes to our manufacturing facilities and processes at various points during development or commercialization, for a number of reasons, such as controlling costs, achieving scale,decreasing processing time, increasing manufacturing success rate or other reasons. The manufacturing changes could require changes in raw materials, components and services that are obtained from third-party suppliers. The inability of suppliers to provide those supplies or services or delays in acquiring the supplies or services would delay the manufacture of clinical or commercial product supplies.

These changes carry the risk that they will not achieve their intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of our planned or future clinical trials. In some circumstances, changes in the facility or the manufacturing process, as was done with regard to changing to mammalian-cell manufacture, require notification to, or authorization by the FDA or a comparable foreign regulatory authority, which may be delayed or which we may never receive. Such changes may also require, prior to undertaking more advanced clinical trials, additional ex vivo or clinical testing, to show the comparability of the product used in earlier clinical phases or at earlier portions of a trial to the product used in later clinical phases or later portions of the trial. For example, in a Type C meeting with the FDA held on August 9, 2019 and in an End-of-Phase 2 meeting in March 2021, we discussed our plan to change the product manufacturing process to support our planned Phase 3 clinical trial. The FDA instructed us to submit our Chemistry, Manufacturing and Controls information for the Phase 3 product, for their review of product comparability between product made in CEF versus mammalian cells. Based on our discussions with the FDA, on June 28, 2021, we formally submitted an IND amendment for our new manufacturing process, and on August 18, 2021, we submitted data to demonstrate comparability of Olvi-Vec prepared in mammalian cells as compared to being prepared in CEF cells. We received FDA comments in November 2021 regarding the manufacturing amendments and responded in December 2021. Also, in February 2022, we received and responded to additional FDA comments regarding the manufacturing amendments. In May 2022, we submitted an amended protocol that made minor clarifying revisions. In July 2022, we received and responded to additional FDA comments regarding an assay used in our clinical trial. We do not know whether the FDA ultimately will find the data and information to be complete and satisfactory.

Even if the FDA agrees the products are comparable, the products may, in fact, perform differently and affect the results of our ongoing, planned or future clinical trials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or studies, require the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and/or jeopardize our ability to commence product sales and generate revenue.

We may rely on CMOs to conduct large-scale manufacture of Olvi-Vec in the future. The inability to identify and contract with suitable CMOs or their failure to meet their obligations to us could affect our ability to develop or commercialize Olvi-Vec in a timely manner.

If the FDA, state or a comparable foreign regulatory authority does not approve our manufacturing facility for the manufacture of our product candidates or if it withdraws any such approval in the future, or our current facility is unable to meet our volume requirements, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Any alternative manufacturing facility would require obtaining the necessary equipment and materials and, if a third-party manufacturer, the necessary manufacturing know-how, which may take substantial time and investment. We must also receive FDA approval for the use of any manufacturing facility for commercial supply.

In such instance, we may need to enter into an appropriate third-party relationship. We may not succeed in our efforts to establish manufacturing relationships or other alternative arrangements for any of our product candidates or programs. Any product candidates we develop compete with other products and product candidates for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations that are both capable of manufacturing and filling our viral product for us and willing to do so.

Reliance on third-party providers for certain manufacturing activities will reduce our control over these activities but will not relieve us of our responsibility to ensure compliance with all required regulations. Under certain circumstances, these third-party providers may be entitled to terminate their engagements with us. If a third-party provider terminates its engagement with us, or does not successfully carry out its contractual duties, meet expected deadlines or manufacture Olvi-Vec or any other product candidates in accordance with regulatory requirements, or if there are disagreements between us and a third-party provider, we may need to identify and qualify replacement suppliers, which may not be readily available or available on acceptable terms. In this instance, we may not be able to complete, or may be delayed in completing, the preclinical studies required to support future IND submissions, the clinical trials required for approval, and commercial supply of Olvi-Vec or any other product candidate and would thereby have a negative impact on our business, financial condition, results of operations and prospects.

If we are unable to manufacture and release any product candidates in the volumes that we require on a timely basis, or fail to comply with stringent regulations applicable to biopharmaceutical manufacturers, we may face delays in the development and commercialization of, or be unable to meet demand for, any product candidates, and may lose potential revenues.

We intend to self-manufacture our clinical trial and commercial product supplies for the foreseeable future. We currently have only one manufacturing facility for use in our clinical trials. Our clinical product supply may be limited, interrupted, or of satisfactory quality or continue to be available at acceptable prices. Any delays in obtaining adequate supplies of our product candidates that meet the necessary quality standards may delay our development or commercialization.

We may be unable to comply with our specifications, applicable cGMP requirements or other FDA, state or foreign regulatory requirements of our product candidates for clinical trials and, if approved, commercial supply, and will be subject to FDA and comparable foreign regulatory authority inspection. These requirements include the qualification and validation of our manufacturing equipment and processes. We may not be able to develop, retain or acquire the internal expertise and resources necessary for effectively managing our ongoing manufacturing operations and complying with these requirements. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of a product candidate that may not be detectable in final product testing. If we cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other regulatory authorities, we will not be able to secure or maintain regulatory approval for our manufacturing facility. Any such deviations may also require remedial measures that may be costly and/or time-consuming for us to implement, particularly in areas relating to operations, quality, regulatory, facilities and information technology. Any such remedial measures imposed upon us may include the temporary or permanent suspension of a clinical trial or the temporary or permanent closure of our facility and could materially harm our business.

A failure to comply with the applicable regulatory requirements, including periodic regulatory inspections, may result in regulatory enforcement actions against us or our raw material and component suppliers (including fines and civil and criminal penalties, including imprisonment) suspension or restrictions of production, injunctions, delay or denial of product approval or supplements to approved products, clinical holds or

termination of clinical trials, warning or untitled letters, regulatory authority communications warning the public about safety issues with the product candidate, refusal to permit the import or export of the products, product seizure, detention, or recall, operating restrictions, consent decrees, withdrawal of product approval, environmental or safety incidents and other liabilities. If the safety of any quantities supplied is compromised due to our failure or our raw material and component suppliers' failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize our product candidates.

Any problems or delays we experience in commercial-scale manufacturing of a product candidate or component may result in a delay in product development timelines and FDA or comparable foreign regulatory authority approval of the product candidate or may impair our ability to manufacture commercial quantities or such quantities at an acceptable cost and quality, which could result in the delay, prevention, or impairment of clinical development and commercialization of any product candidates and may materially harm our business, financial condition, results of operations, stock price and prospects.

Risks Related to Reliance on Third Parties

We rely, and expect to continue to rely, on third parties to supply and quality-test the ingredients for our product candidates and components for our manufacturing process.

While we are responsible for the manufacturing of our product candidates, drug substance and drug product, reliance on raw material and component suppliers entails risks, including:

- reduced control for certain aspects of our manufacturing activities;
- termination or nonrenewal of the applicable supplier and service agreements in a manner or at a time that is costly or damaging to us;
- the possible breach by our third-party suppliers and service providers of our agreements with them;
- the failure of our third-party suppliers and service providers to comply with applicable regulatory requirements;
- disruptions to the operations of our third-party suppliers and service providers caused by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or service provider; and
- the possible misappropriation of our proprietary information, including our trade secrets and know-how.

Any failure or refusal to supply our product candidates or components for our product candidates that we may develop could delay, prevent or impair our clinical development or commercialization efforts. In addition, we do not have any long-term commitments or guaranteed prices from our suppliers of raw materials, manufacturing equipment components or devices or combination products. In particular, any change in our suppliers could require significant effort and expertise because there may be a limited number of qualified replacements. Further, the terms of any new arrangement could be less favorable and transfer costs relating to technology and processes could be significant.

Any of these events could lead to clinical trial delays or failure to obtain regulatory approval, impact our ability to successfully commercialize any of our product candidates or otherwise harm our business, financial condition, results of operations, stock price and prospects. Some of these events could be the basis for FDA or other regulatory authority action, including injunction, recall, seizure or total or partial suspension of product manufacture.

We rely, and expect to continue to rely, on third parties to conduct, supervise, and monitor our preclinical studies and clinical trials. If those third parties do not perform satisfactorily, including failing to meet deadlines for the completion of such trials or failing to comply with regulatory requirements, we may be unable to obtain regulatory approval for our product candidates or any other product candidates that we may develop in the future.

We rely, and will rely, on third-party CROs, study sites and others to conduct, supervise, and monitor our preclinical studies and clinical trials for our product candidates. We expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions, and clinical investigators, to conduct our preclinical studies and clinical trials. Although we have agreements governing their activities, we have limited influence over their actual performance and control only certain aspects of their activities. The failure of these third parties to successfully carry out their contractual duties or meet expected deadlines could substantially harm our business because we may be delayed in completing or unable to complete the studies required to support future approval of our product candidates, or we may not obtain marketing approval for or commercialize our product candidates in a timely manner or at all. Moreover, these agreements might terminate for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements, our product development activities would be delayed and our business, financial condition, results of operations, stock price and prospects may be materially harmed.

Our reliance on these third parties for development activities will reduce our control over these activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards and our reliance on third parties does not relieve us of our regulatory responsibilities. For example, we will remain responsible for ensuring that each of our trials is conducted in accordance with the general investigational plan and protocols for the trial. We must also ensure that our preclinical trials are conducted in accordance with the FDA's Good Laboratory Practice (GLP) regulations, as appropriate. Moreover, the FDA and comparable foreign regulatory authorities require us to comply with standards, commonly referred to as GCP guidelines, for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of trial participants are protected. Regulatory authorities enforce these requirements through periodic inspections of trial sponsors, clinical investigators, and trial sites. If we or any of our third parties fail to comply with applicable GCPs or other regulatory requirements, we or they may be subject to enforcement or other legal actions. For example, the data generated in our trials may not have been appropriately collected or documented, and thereby be deemed unreliable and the FDA or comparable foreign regulatory authorities may conclude the study findings are not adequate and require us to perform additional studies.

In addition, we will be required to report certain financial interests of our third-party investigators if these relationships exceed certain financial thresholds or meet other criteria. The FDA or comparable foreign regulatory authorities may question the integrity of the data from those clinical trials conducted by investigators who may have conflicts of interest.

We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our trials complies with the applicable regulatory requirements. In addition, our clinical trials must be conducted with product candidates that were produced under cGMP regulations. Failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. We also are required to register certain clinical trials and post the results of certain completed clinical trials on one or more government-sponsored databases, e.g., ClinicalTrials.gov, within specified timeframes. Failure to do so can result in enforcement actions and adverse publicity.

The third parties with which we work may also have relationships with other entities, some of which may be our competitors, for whom they may also be conducting trials or other therapeutic development activities that could harm our competitive position. In addition, such third parties are not our employees, and except for remedies available to us under our agreements with such third parties we cannot control whether or not they

devote sufficient time and resources to our ongoing clinical, non-clinical, and preclinical programs. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our preclinical studies or clinical trials in accordance with regulatory requirements or our stated protocols, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our protocols, regulatory requirements or for other reasons, our trials may be repeated, extended, delayed, or terminated; we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates; we may not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates; or we or they may be subject to regulatory enforcement actions. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed. To the extent we are unable to successfully identify and manage the performance of third-party service providers in the future, our business, financial condition, results of operations, stock price and prospects may be materially harmed.

If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative providers or to do so on commercially reasonable terms. Switching or adding additional third parties involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays could occur, which could compromise our ability to meet our desired development timelines.

We will also rely on other third parties to store and distribute our product candidates for the clinical trials that we conduct. Any performance failure on the part of our distributors could delay clinical development, marketing approval, or commercialization of our product candidates, which could result in additional losses and deprive us of potential product revenue.

We have entered into, and may in the future enter into, certain collaboration agreements and strategic alliances to maximize the potential of our product candidates, and we may not realize the anticipated benefits of such collaborations or alliances. We expect to continue to form collaborations in the future with respect to our product candidates, but may be unable to do so or to realize the potential benefits of such transactions, which may cause us to alter or delay our development and commercialization plans.

We may form or seek other strategic alliances, joint ventures, or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to product candidates we develop. These transactions can entail numerous operational and financial risks, including exposure to unknown liabilities, disruption of our business and diversion of our management's time and attention in order to manage a collaboration. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or other anticipated benefits that led us to enter into the arrangement. Additionally, the success of any collaboration arrangements may depend on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these arrangements. Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable product candidate and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision-making authority.

If we are not able to establish future collaborations on commercially reasonable terms, we may have to alter our development and commercialization plans for one or more of our other development programs.

We face significant competition in seeking appropriate additional collaborators. Our ability to reach a definitive agreement for any collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors.

If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms, or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market or continue to develop our product platform and our business may be materially and adversely affected.

Our current and any future collaborations are not a guarantee of success, and all collaborations are as risky, or more risky, than undertaking the activities ourselves.

Our current collaborations with TVAX, Newsoara and ELIAS, and potential future collaborations we might enter into for Olvi-Vec or our other product candidates, may pose a number of risks, including the following:

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

- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability.

In addition, all of the risks relating to product development, regulatory approval and commercialization described in this Annual Report also apply to the activities of any of our current or future collaborators.

Collaborations with biopharmaceutical companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration could adversely affect us financially and could harm our business reputation.

If any collaborations we have entered into or might enter into do not result in the successful development and commercialization of products or if one of our collaborators subsequently terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under such collaboration. If we do not receive the funding we expect under the agreements, our development of our product candidates could be delayed and we may need additional resources to develop our product candidates and our product platform.

Additionally, if any collaborator of ours is involved in a business combination, the collaborator might deemphasize or terminate development or commercialization of any product candidate licensed to it by us. If one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our reputation in the business and financial communities could be adversely affected.

We face significant competition in seeking appropriate collaborators. Our ability to reach a definitive agreement for any collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors.

If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms, or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market or continue to develop our product platform and our business may be materially and adversely affected.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, 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 other government agencies 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 for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical 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.

Separately, the FDA and regulatory authorities outside the United States adopted restrictions or other policy measures in response to the COVID-19 pandemic that diverted resources and delayed their attention to routine submissions. If a prolonged government shutdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Risks Related to Commercialization

If we, or our collaboration partners, are unable to successfully commercialize any product candidate for which we receive regulatory approval, or experience significant delays in doing so, our business will be materially harmed.

If we, or our collaboration partners, are successful in obtaining marketing approval from applicable regulatory authorities for Olvi-Vec or any other product candidate, our ability to generate revenues from any such products will depend on our success in:

- launching commercial sales of such products, whether alone or in collaboration with others;
- receiving approved labels with claims that are necessary or desirable for successful marketing, and that do not contain safety or other limitations that would impede our ability to market such products;
- creating market demand for such products through marketing, sales and promotion activities;
- hiring, training, and deploying a sales force or contracting with third parties to commercialize such products in the United States;
- creating partnerships with, or offering licenses to, third parties to promote and sell such products in foreign markets where we receive marketing approval;
- manufacturing such products in sufficient quantities and at acceptable quality and cost to meet commercial demand at launch and thereafter;
- establishing and maintaining agreements with wholesalers, distributors, and group purchasing organizations on commercially reasonable terms;
- maintaining patent and trade secret protection and regulatory exclusivity for such products;
- achieving market acceptance of such products by patients, the medical community, and third-party payors;
- achieving coverage and adequate reimbursement from third-party payors for such products;
- achieving patients' willingness to pay out-of-pocket in the absence of such coverage and adequate reimbursement from third-party payors;
- competing effectively with other therapies; and
- maintaining a continued acceptable safety profile of such products following launch.

To the extent we are not able to do any of the foregoing, our business, financial condition, results of operations, stock price and prospects will be materially harmed.

We face significant competition from other biopharmaceutical and biotechnology companies, academic institutions, government agencies, and other research organizations, which may result in others discovering, developing or commercializing products more quickly or marketing them more successfully than us. If their product candidates are shown to be safer or more effective than ours, our commercial opportunity may be reduced or eliminated.

The development and commercialization of cancer immunotherapy products is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary rights. We face competition with respect to our current product candidates and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major biopharmaceutical companies, specialty biopharmaceutical companies, and biotechnology companies worldwide. There are a number of large biopharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of solid tumors, including viral immunotherapy and cancer vaccine approaches. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization.

We are aware of a number of companies developing competing therapies for the treatment of cancer which generally fall into the following treatment groups:

- Oncolytic viral immunotherapies, including Amgen's IMLYGIC (talimogene laherparepvec), the only FDA-approved oncolytic immunotherapy, which is approved for the local treatment of unresectable cutaneous, subcutaneous, and nodal lesions in patients with melanoma recurrent after initial surgery and is in development for several other indications, and other oncolytic viruses in development by companies such as AstraZeneca PLC, Boehringer Ingelheim, CG Oncology, Inc., Candel Therapeutics, Inc., Daiichi Sankyo Company, Limited, DNAtrix Inc., Johnson & Johnson, Merck & Co., Inc. (Merck), Oncolytics Biotech Inc., Oncorus, Otsuka Holdings Co. Ltd., PsiOxus Therapeutics, Ltd., Regeneron Pharmaceuticals, Inc., Replimune Group, Inc., SillaJen, Inc. (SillaJen), Targovax USA, Transgene SA, Turnstone Biologics Corp. and Vyriad, Inc.;
- Approved immunotherapy antibodies and immunotherapy agents in clinical development, including antibody agents, bispecific T cell engagers, including those in development by Amgen, and immuno- oncology companies focused on IL-12, such as Ziopharm Oncology Inc.;
- Cancer vaccines, including personalized vaccines and those targeting tumor neoantigens, including neoantigen therapies in development by companies such as Advaxis, Inc., Agenus Inc., AstraZeneca, Bavarian Nordic A/S, BioNTech SE, Genocea Biosciences, Inc., Gritstone Oncology, Inc., Heat Biologics, Inc., ImmunityBio, Inc., Iovance Biotherapeutics, Inc., IMV Inc., Moderna, Inc., SOTIO a.s., Transgene SA, Turnstone Biologics Inc. and VBI Vaccines Inc.;
- Cell-based therapies, including tumor infiltrating lymphocytes (TILs) in development by Iovance and approved and in-development CAR T cell therapies, including those commercialized by BMS, Gilead Sciences Inc. and Novartis AG, T cell receptor and NK cell therapies;
- Therapies aimed at activating innate immunity such as those targeting stimulator of interferon genes protein (STING) and toll-like receptors (TLRs) including those in development by BMS, Checkmate Pharmaceuticals Inc., Chinook Therapeutics Inc., GlaxoSmithKline plc (GSK), Idera Pharmaceuticals, Inc., Merck, Mologen AG, Nektar Therapeutics, TriSalus Life Sciences, and UroGen Pharma Inc.; and
- Traditional cancer therapies, including chemotherapy, surgery, radiation and targeted therapies.

We are aware of several other companies developing therapies based on VACV. To our knowledge, the only clinical product based on VACV that has advanced beyond Phase 1 clinical development is Pexa-Vec, being jointly developed by SillaJen and Transgene. Pexa-Vec has a different product profile from Olvi-Vec, including a different strain of VACV and different transgenes. In August 2019, SillaJen announced the discontinuation of its Phase 3 PHOCUS trial of Pexa-Vec in advanced liver cancer for futility.

While certain of our product candidates may be used in combination with other drugs with different mechanisms of action, if and when marketed they will still compete with a number of drugs that are currently marketed or in development that also target cancer. To compete effectively with these drugs, our product candidates will need to demonstrate advantages in clinical efficacy and safety compared to these competitors when used alone or in combination with other drugs.

Our commercial opportunities could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are easier to administer or are less expensive alone or in combination with other therapies than any products that we may develop alone or in combination with other therapies. Our competitors also may obtain FDA or comparable foreign regulatory authorities' approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by third-party payors' coverage and reimbursement decisions.

Many of the companies with which we are competing or may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do. Mergers and acquisitions in the biopharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. 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 and establishing clinical trial sites and patient registration for clinical trials, as well as in developing or acquiring technologies complementary to, or necessary for, our programs. If we are unable to successfully compete with these companies our business, financial condition, results of operations, stock price and prospects may be materially harmed.

If we are unable to establish effective marketing, sales and distribution capabilities or enter into agreements with third parties to market and sell our product candidates, if they are approved, the revenues that we generate may be limited and we may never become profitable.

We currently do not have a commercial infrastructure for the marketing, sale, and distribution of any products that we may develop. If and when our product candidates receive marketing approval, we intend to commercialize our product candidates on our own or in collaboration with others and potentially with pharmaceutical or biotechnology partners in other geographies. In order to commercialize our products, we must build our marketing, sales, and distribution capabilities or make arrangements with third parties to perform these services. We may not be successful in doing so. Should we decide to move forward in developing our own marketing capabilities, we may incur expenses prior to product launch or even approval in order to recruit a sales force and develop a marketing and sales infrastructure. If a commercial launch is delayed as a result of the FDA or comparable foreign regulatory authority requirements or other reasons, we would incur these expenses prior to being able to realize any revenue from sales of our product candidates. Even if we are able to effectively hire a sales force and develop a marketing and sales infrastructure, our sales force and marketing teams may not be successful in commercializing our product candidates. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

We may also or alternatively decide to collaborate with third-party marketing and sales organizations to commercialize any approved product candidates, in which event, our ability to generate product revenues may be limited. To the extent we rely on third parties to commercialize any products for which we obtain regulatory approval, we may receive less revenues than if we commercialized these products ourselves, which could materially harm our prospects. In addition, we would have less control over the sales efforts of any other third parties involved in our commercialization efforts, and could be held liable if they failed to comply with applicable legal or regulatory requirements.

We have no prior experience in the marketing, sale, and distribution of biopharmaceutical products, and there are significant risks involved in building and managing a commercial infrastructure. The establishment and development of commercial capabilities, including compliance plans, to market any products we may develop will be expensive and time consuming and could delay any product launch, and we may not be able to successfully develop this capability. We will have to compete with other biopharmaceutical and biotechnology companies, including oncology-focused companies, to recruit, hire, train, manage, and retain marketing and sales personnel, which is expensive and time consuming and could delay any product launch. Developing our sales capabilities may also divert resources and management attention away from product development.

In the event we are unable to develop a marketing and sales infrastructure, we may not be able to commercialize our product candidates, which could limit our ability to generate product revenues and materially harm our business, financial condition, results of operations, stock price and prospects. Factors that may inhibit our efforts to commercialize our product candidates include:

- the inability to recruit, train, manage, and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or educate adequate numbers of physicians on the benefits of prescribing our product candidates;
- our inability to effectively oversee a geographically dispersed sales and marketing team;
- the costs associated with training personnel, including sales and marketing personnel, on compliance matters and monitoring their actions;
- an inability to secure coverage and adequate reimbursement by third-party payors, including government and private health plans;
- the unwillingness of patients to pay out-of-pocket in the absence of coverage and adequate reimbursement from third-party payors;
- the clinical indications for which the products are approved and the claims that we may make for the products;
- limitations or warnings, including distribution or use restrictions, contained in the products' approved labeling;
- any distribution and use restrictions imposed by the FDA or comparable foreign regulatory authorities or to which we agree as part of a mandatory REMS or voluntary risk management plan;
- liability for our personnel, including sales or marketing personnel, who fail to comply with applicable law;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization or engaging a contract sales organization.

Even if any of our product candidates receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, hospitals, cancer treatment centers, third-party payors and others in the medical community necessary for commercial success. The revenues that we generate from their sales may be limited, and we may never become profitable.

We have never commercialized a product candidate for any indication. Even if our product candidates are approved by the appropriate regulatory authorities for marketing and sale, they may not gain acceptance among physicians, patients, third-party payors, and others in the medical community. If any product candidates for which we obtain regulatory approval does not gain an adequate level of market acceptance, we could be prevented from or significantly delayed in achieving profitability. Market acceptance of our product candidates by the medical community, patients, and third-party payors will depend on a number of factors, some of which are beyond our control. For example, physicians are often reluctant to switch their patients and patients may be reluctant to switch from existing therapies even when new and potentially more effective or safer treatments enter the market.

Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may not be successful. If any of our product candidates is approved but does not achieve an adequate level of market acceptance, we could be prevented from or significantly delayed in achieving profitability. The degree of market acceptance of any product for which we receive marketing approval will depend on a number of factors, including:

- the efficacy of our product, including in combination with other cancer therapies;
- the commercial success of any cancer therapies with which our product may be co-administered;
- the prevalence and severity of adverse events associated with our product or those products with which it is co-administered;
- the clinical indications for which our product is approved and the approved claims that we may make with respect to the product;
- limitations or warnings contained in the FDA-approved labeling of the product or the labeling approved by comparable foreign regulatory authorities, including potential limitations or warnings for our product that may be more restrictive than other competitive products;
- changes in the standard of care for the targeted indications for our product, which could reduce the marketing impact of any claims that we could make following FDA approval or approval by comparable foreign regulatory authorities, if obtained;
- the relative convenience and ease of administration of our product and any products with which it is co-administered;
- the cost of treatment compared with the economic and clinical benefit of alternative treatments or therapies;
- the availability of coverage and adequate reimbursement by third-party payors, such as private insurance companies and government healthcare programs, including Medicare and Medicaid;
- the ability to have our product placed on approved formularies;
- patients' willingness to pay out-of-pocket in the absence of such coverage and adequate reimbursement from third-party payors;
- the price concessions required by third-party payors to obtain coverage and adequate reimbursement;
- the extent and strength of our marketing and distribution of our product;
- the safety, efficacy, and other potential advantages over, and availability of, alternative treatments already used or that may later be approved;
- distribution and use restrictions imposed by the FDA or comparable foreign regulatory authorities with respect to our product or to which we agree as part of a REMS or voluntary risk management plan;
- the timing of market introduction of our product, as well as competitive products;
- our ability to offer our product for sale at competitive prices;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the extent and strength of our raw material supplier and service provider support;
- the actions of companies that market any products with which our product is co-administered;
- the approval of other new products;
- adverse publicity about our product or any products with which it is co-administered, or favorable publicity about competitive products; and
- potential product liability claims.

The size of the potential market for our product candidates is difficult to estimate and, if any of our assumptions are inaccurate, the actual markets for our product candidates may be smaller than our estimates. If the market opportunities for any product candidates we develop are smaller than we believe they are, our potential revenues may be adversely affected, and our business may suffer.

The potential market opportunities for our product candidates are difficult to estimate and will depend in large part on the drugs with which our product candidates are co-administered and the success of competing therapies and therapeutic approaches. In particular, the market opportunity for viral immunotherapies is hard to estimate given that it is an emerging field with only one existing FDA-approved viral immunotherapy, T-VEC, which has yet to enjoy broad market acceptance. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on estimates. Our estimates of the potential market opportunities are predicated on many assumptions, which may include industry knowledge and publications, third-party research reports, and other surveys. Although we believe that our internal assumptions are reasonable, these assumptions involve the exercise of significant judgment on the part of our management, are inherently uncertain, and their reasonableness has not been assessed by an independent source. These estimates may prove to be incorrect and new studies may change the estimated incidence or prevalence of these diseases. The number of patients in the United States, Europe, and elsewhere may turn out to be lower than expected, and patients may not be amenable to treatment with our product. If any of the assumptions proves to be inaccurate, the actual markets for our product candidates could be smaller than our estimates of the potential market opportunities. Additionally, because of the potential that any product candidates we develop could cure a target disease, we may not receive recurring revenues from patients and may deplete the patient population prevalence through curative therapy.

Negative developments in the field of immuno-oncology could damage public perception of our oncolytic VACV platform and our product candidates, including Olvi-Vec, and negatively affect our business.

The commercial success of our product candidates will depend in part on public acceptance of the use of cancer viral immunotherapies. Adverse events in clinical trials of our product candidates, including Olvi-Vec, or in clinical trials of others developing similar products and the resulting publicity, as well as any other negative developments with respect to the field of immuno-oncology that may occur in the future, including in connection with competitor therapies, or with respect to products with which our product is co-administered, could result in a decrease in demand for Olvi-Vec or any other product candidates that we may develop. These events could also result in the suspension, discontinuation, or clinical hold of or modification to our clinical trials. If public perception is influenced by claims that the use of cancer immunotherapies is unsafe, whether related to our therapies or those of our competitors, our product candidates may not be accepted by the general public or the medical community and potential clinical trial subjects may be discouraged from enrolling in our clinical trials. As a result, we may not be able to continue or may be delayed in conducting our development programs.

As our product candidates consist of oncolytic VACVs, adverse developments in anti-cancer vaccines or clinical trials of other viral immunotherapy products based on viruses may result in a disproportionately negative effect for Olvi-Vec or our other product candidates as compared to other products in the field of immuno- oncology that are not based on viruses. We do not fully understand the biological characteristics of our therapeutic viruses, and their interactions with other drugs and the human immune and other defense systems, which may cause us to fail to demonstrate the safety and effectiveness of our product candidates in clinical trials. Therapeutic viruses are novel, and we are still determining the biological characteristics of these viruses. In addition, we are still investigating the response of the human immune system to our therapeutic viruses, and the immune system may play a role in limiting their tumor-killing effect. We also do not know the extent to which therapeutic viruses and our treatment processes may be toxic. Moreover, we do not understand all of the many factors that contribute to the formation of each individual patient’s cancer; these factors make each tumor unique. The novelty and scientific uncertainties regarding our therapeutic viruses and the uniqueness of human cancers from patient to patient increase the risk that we will not successfully develop our product candidates or prove their safety and effectiveness in clinical trials. Even if we succeed in developing our product candidates, our product candidates may not have a therapeutic effect in a broad patient population.

Future negative developments in the field of immuno-oncology or the biopharmaceutical industry could also result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approvals of our products. Any increased scrutiny could delay or increase the costs of obtaining marketing approval for Olvi-Vec or our other product candidates.

Risks Related to Our Intellectual Property

If we are unable to obtain, maintain and protect our intellectual property rights for our technology and product candidates, or if our intellectual property rights are inadequate, our competitive position could be harmed.

Our commercial success will depend in part on our ability to obtain and maintain patent and other intellectual property protection in the United States and other countries with respect to our technology, including our oncolytic VACV platform, and Olvi-Vec, V-VET1, V2ACT Immunotherapy and our other product candidates. We also rely in part on trade secret, copyright and trademark laws, and confidentiality, licensing and other agreements with employees and third parties, all of which offer only limited protection. We seek to protect our proprietary position by filing and prosecuting patent applications in the United States and abroad related to our technology and product candidates.

The patent positions of biotechnology and pharmaceutical companies generally are highly uncertain, involve complex legal and factual questions and have in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our licensed patents and any patents we own are highly uncertain. The steps we have taken to protect our proprietary rights may not be adequate to preclude misappropriation of our proprietary information or infringement of our intellectual property rights, both inside and outside of the United States.

Further, the examination process may require us to narrow the claims for our pending patent applications, which may limit the scope of patent protection that may be obtained if these applications issue. Our pending and future patent applications may not result in patents being issued that protect our product candidates, in whole or in part, or which effectively prevent others from commercializing competitive product candidates. The scope of a patent may also be reinterpreted after issuance. The rights that may be granted under our issued patents may not provide us with the proprietary protection or competitive advantages we are seeking. Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. If we are unable to obtain and maintain patent protection for our technology or for Olvi-Vec, V-VET1, V2ACT Immunotherapy or our other product candidates, or if the scope of the patent protection obtained is not sufficient, our competitors could develop and commercialize products similar or superior to ours in a non-infringing manner, and our ability to successfully commercialize Olvi-Vec, V-VET1, V2ACT Immunotherapy or our other product candidates and future technologies may be adversely affected. It is also possible that we will fail to identify patentable aspects of inventions made in the course of our development and commercialization activities before it is too late to obtain patent protection on them.

In addition, the patent prosecution process is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, collaborators, and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. It is also possible that we will fail to identify patentable aspects of our research and development efforts in time to obtain patent protection.

For the core technology in our CHOICE platform and Olvi-Vec and our other product candidates, patents have issued and applications are pending at each of the U.S. provisional, Patent Cooperation Treaty (PCT), and national stages with, at a minimum, filings submitted to the United States, European Patent Conventions (EPC) and Japan. As of December 31, 2022, our patent portfolio consisted of 19 issued U.S. patents, one pending U.S. patent application, 20 issued foreign patents, two pending foreign patent applications and one PCT application, which relate generally to the composition of our current and potential future products, and their methods of use. V2ACT has one pending U.S. patent application and two pending non-U.S. patent applications. Any future provisional patent applications are not eligible to become issued patents until, among other things, we file a non-provisional patent application within 12 months of filing of one or more of our related provisional patent applications. If we do not timely file any non-provisional patent applications, we may lose our priority date with respect to our provisional patent applications and any patent protection on the inventions disclosed in our provisional patent applications. Although we intend to timely file non-provisional patent applications relating to our provisional patent applications, we cannot predict whether any of our future patent applications will result in the issuance of patents that effectively protect our technology or Olvi-Vec, V-VET1, V2ACT Immunotherapy or our other product candidates, or if any of our future issued patents will effectively prevent others from commercializing competitive products. We may be subject to a third-party pre-issuance submission of prior art to the U.S. Patent and Trademark Office (USPTO). Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or in some cases not at all until they are issued as a patent. Therefore, we cannot be certain that we were the first to make the inventions claimed in our pending patent applications, or that we were the first to file for patent protection of such inventions.

Our pending applications cannot be enforced against third parties practicing the inventions claimed in such applications unless and until a patent issues from such applications with a claim that covers infringing third-party activity. Because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, issued patents that we license from third parties or own in the future may be challenged in the courts or patent offices in the United States and abroad, including through opposition proceedings, derivation proceedings, post- grant review, *inter partes* review, interference proceedings or litigation. Such proceedings may result in the loss of patent protection, the narrowing of claims in such patents or the invalidity or unenforceability of such patents, which could limit our ability to stop others from using or commercializing similar or identical products, or limit the duration of the patent protection for our technology. Protecting against the unauthorized use of our patented inventions, trademarks and other intellectual property rights is expensive, time consuming, difficult and in some cases may not be possible. In some cases, it may be difficult or impossible to detect third-party infringement or misappropriation of our intellectual property rights, even in relation to issued patent claims, and proving any such infringement may be even more difficult. If we are unable to obtain, maintain, and protect our intellectual property our competitive advantage could be harmed, and it could result in a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

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 intellectual property rights that are important to our business.

We may need to obtain licenses from others to advance our research and development activities or allow the commercialization of our current or future product candidates. We expect any such license agreements will impose various development, diligence, commercialization, and other obligations on us. In spite of our efforts, our licensors might conclude that we have materially breached our obligations under such license agreements and might therefore terminate the license agreements, thereby removing or limiting our ability to develop and commercialize products and technology covered by the intellectual property under any such license agreements. If such in-licenses were to be terminated, or if the underlying patents were to fail to provide the intended exclusivity, competitors or other third parties would have the freedom to seek regulatory approval of, and to market, products identical to ours and we may be required to cease our development and commercialization our product candidates. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Moreover, disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our product candidates, technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we may license intellectual property or technology from third parties are likely to be complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.

In addition to seeking patent protection, we also rely on other proprietary rights, including protection of trade secrets, know-how and confidential and proprietary information. To maintain the confidentiality of our trade secrets and proprietary information, we enter into confidentiality agreements with our employees, consultants, collaborators, contractors, and other third parties who have access to our trade secrets. Our agreements with employees and consultants also provide that any inventions conceived by the individual employee or consultant in the course of rendering services to us shall be our exclusive property. However, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. In addition, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets or other confidential information. To the extent that our employees, consultants or contractors use technology or know-how owned by third parties in their work for us, disputes may arise between us and those third parties as to the rights in related inventions.

Adequate remedies may not exist in the event of unauthorized use or disclosure of our confidential information including a breach of our confidentiality agreements. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, and time consuming, and the outcome is unpredictable. In addition, some courts in and outside of the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. The disclosure of our trade secrets or the independent development of our trade secrets by a competitor or other third party would impair our competitive position and may materially harm our business, financial condition, results of operations, stock price and prospects.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could harm our business.

Our commercial success depends on our ability and the ability of any future collaborators to develop, manufacture, market and sell Olvi-Vec and our other product candidates, and to use our related proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and proprietary rights of third parties. The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. We may become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our current and any other future product candidates, including interference proceedings, post-grant review, *inter partes* review and derivation proceedings before the USPTO. Third parties may assert infringement or other intellectual property claims against us based on existing patents or patents that may be granted in the future. Numerous U.S. and foreign- issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are pursuing development candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that we may be subject to claims of infringement of the patent rights of third parties. If we are found to infringe a third party's intellectual property rights, and we are unsuccessful in demonstrating that such intellectual property rights are invalid or unenforceable, we could be required to obtain a license from such third party to continue developing, manufacturing and commercializing Olvi-Vec and our other product candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. We also could be forced, including by court order, to cease developing, manufacturing, and commercializing Olvi-Vec or our other product candidates. In addition, in any such proceeding or litigation, we could be found liable for significant monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, stock price and prospects. Any claims by third parties that we have misappropriated their confidential information or trade secrets could have a similar material adverse effect on our business. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business.

Parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

Furthermore, we plan to develop our product candidates in combination with products developed by companies that may be covered by patents or licenses held by those entities to which we do not have a license or a sublicense. In the event that a labeling instruction is required in product packaging recommending that combination, we could be accused of, or held liable for, infringement of the third-party patents covering the product candidate or product recommended for administration with Olvi-Vec or our other product candidates. In such a case, we could be required to obtain a license from the other company or institution to use the required or desired package labeling, which may not be available on commercially reasonable terms, or at all.

We may not be able to protect our intellectual property and proprietary rights throughout the world.

Filing, prosecuting and defending patents on our technology throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws and practices of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop and/or manufacture their own products, and may export otherwise infringing products to territories where we have patent protection but where enforcement is not as strong as that in the United States. These products may compete with our products and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the granting or enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to obtain patent rights or stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally in those countries. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to protect and enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property we develop or license.

In addition, the laws of certain foreign countries may not protect our rights to the same extent as the laws of the United States, and those foreign laws may also be subject to change. For example, methods of treatment and manufacturing processes may not be patentable in certain jurisdictions, and the requirements for patentability may differ in certain countries. Furthermore, biosimilar product manufacturers or other competitors may challenge the scope, validity and enforceability of our patents, requiring us to engage in complex, lengthy and costly litigation or proceedings.

Moreover, many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. Many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business and results of operations may be adversely affected.

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

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and to maintain patents after they are issued. For example, periodic maintenance fees, renewal fees, annuity fees and various other government fees on issued patents and patent applications often must be paid to the USPTO and foreign patent agencies over the lifetime of our licensed patents or any patents we own. In certain circumstances, we may rely on future licensing partners to take the necessary action to comply with these requirements with

respect to licensed intellectual property. Although an unintentional lapse can be cured for a period of time by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to obtain and maintain the patents and patent applications covering our products or procedures, we may not be able to stop a competitor from marketing products that are the same as or similar to Olvi-Vec or our other product candidates, which could have a material adverse effect on our business.

Changes to the patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect Olvi-Vec, V-VET1, V2ACT Immunotherapy and our other product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States or other jurisdictions in which we have or seek patent protection could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act (the Leahy-Smith Act) signed into law in the United States on September 16, 2011, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. After March 2013, under the Leahy-Smith Act, the United States transitioned to a first inventor to file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time-consuming and unsuccessful and have a material adverse effect on the success of our business.

Competitors may infringe our licensed patents or any patent we own, or misappropriate or otherwise violate our intellectual property rights. Litigation may be necessary in the future to enforce or defend our intellectual property rights, to protect our trade secrets, or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. If we were to initiate legal proceedings against a third party to enforce a patent covering our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant

counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, written description or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable. Our licensed patents and any patents we own in the future may become involved in priority or other intellectual property related disputes. Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications. Also, third parties may initiate legal proceedings against us to challenge the validity or scope of our owned or licensed intellectual property rights. These proceedings can be expensive and time consuming. Many of our current and potential competitors have the ability to dedicate substantially greater resources to conduct intellectual property related litigations or proceedings than we can. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. Litigation and other intellectual property related proceedings could result in substantial costs and diversion of management resources, which could harm our business and financial results. In addition, in an infringement proceeding, a court may decide that a patent owned by or licensed to us is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or other intellectual property related proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation in the United States, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments in any such proceedings. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock, and could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development partnerships that would help us bring our product candidates to market. Any of the foregoing may have a material adverse effect our business, financial condition, results of operations, stock price and prospects.

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

Many of our employees, including our senior management team, were previously employed at, or consulted for, universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these people, including each member of our senior management team, executed proprietary rights, non-disclosure and non-competition agreements, or similar agreements, in connection with such previous employment or consulting agreements, that assigned ownership of intellectual property relating to work performed under such agreements to the contracting third party. Although we try to ensure that our employees do not use, claim as theirs, or misappropriate the intellectual property, proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used, claimed as theirs, misappropriated or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual’s current or former employer. Litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms, or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management. Any of the foregoing may have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed confidential information of third parties or are in breach of non-competition or non-solicitation agreements with our competitors.

We could be subject to claims that we or our employees, including senior management, have inadvertently or otherwise used or disclosed alleged trade secrets or other confidential information of former employers or competitors or others. Although we try to ensure that our employees and consultants do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may be subject to claims that we caused an employee to breach the terms of their non-competition or non-solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a former employer or competitor or other party. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. If our defenses to these claims fail, in addition to requiring us to pay monetary damages, a court could prohibit us from using technologies or features that are essential to Olvi-Vec and our other product candidates, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers, competitors or other parties. An inability to incorporate such technologies or features would have a material adverse effect on our business, and may prevent us from successfully commercializing Olvi-Vec and our other product candidates. In addition, we may lose valuable intellectual property rights or personnel as a result of such claims. Moreover, any such litigation or the threat thereof may adversely affect our ability to hire employees or consultants. A loss of key personnel or their work product could hamper or prevent our ability to develop and commercialize Olvi-Vec and our other product candidates, which could have an adverse effect on our business, financial condition, results of operations, stock price and prospects.

If we obtain any issued patents covering our technology, such patents could be found invalid or unenforceable if challenged in court or before the USPTO or comparable foreign regulatory authority.

If we or one of our licensing partners initiate legal proceedings against a third party to enforce a patent covering any of our technology, the defendant could counterclaim that the patent covering our product candidate is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Grounds for a validity challenge could be, among other things, an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be, among other things, an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, *inter partes* review, post-grant review, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions, such as opposition proceedings. Such proceedings could result in revocation, cancellation or amendment to our patents in such a way that they no longer cover and protect Olvi-Vec, V-VET1, V2ACT Immunotherapy and our other product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. For example, with respect to the validity of our licensed patents or any patents we obtain in the future, we cannot be certain that there is no invalidating prior art of which we, our patent counsel or our licensing partner’s patent counsel(s), and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on Olvi-Vec, V-VET1, V2ACT Immunotherapy and our other product candidates. Such a loss of patent protection could have a material adverse impact on our business.

Patent terms may be inadequate to protect our competitive position on our products for an adequate amount of time, and our product candidates for which we intend to seek approval as biological products may face competition sooner than anticipated.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, such as Olvi-Vec and our other product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the normal expiration of the patent, but no longer than 14 years from the product's approval date, which is limited to the approved indication (or any additional indications approved during the period of extension). However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authorities in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their products earlier than might otherwise be the case, which could have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

The enactment of the Biologics Price Competition and Innovation Act of 2009 (BPCIA) as part of the Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the ACA) created an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biological products, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an existing brand product. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the original branded product was approved under a BLA. Certain changes, however, and supplements to an approved BLA, and subsequent applications filed by the same sponsor, manufacturer, licensor, predecessor in interest, or other related entity do not qualify for the 12-year exclusivity period.

Olvi-Vec and our other product candidates are all biological product candidates. We anticipate being awarded market exclusivity for each of our biological product candidates that is subject to its own BLA for 12 years in the United States, 10 years in Europe and significant durations in other markets. However, the term of the patents that cover such product candidates may not extend beyond the applicable market exclusivity awarded by a particular country. For example, in the United States, if all of the patents that cover our particular biological product expire before the 12-year market exclusivity expires, a third party could submit a marketing application for a biosimilar product four years after approval of our biological product, the FDA could immediately review the application and approve the biosimilar product for marketing 12 years after approval of our biological product, and the biosimilar sponsor could then immediately begin marketing. Alternatively, a third party could submit a full BLA for a similar or identical product any time after approval of our biological product, and the FDA could immediately review and approve the similar or identical product for marketing and the third party could begin marketing the similar or identical product upon expiry of all of the patents that cover our particular biological product.

There is also a risk that this exclusivity could be changed in the future. For example, this exclusivity could be shortened due to congressional action or through other actions, including future proposed budgets, international trade agreements and other arrangements or proposals. Additionally, there is a risk that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. The extent to which a biosimilar, once approved, will be substituted for any one of our 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. It is also possible that payors will give reimbursement preference to biosimilars over reference biological products, even absent a determination of interchangeability.

To the extent that we do not receive any anticipated periods of regulatory exclusivity for our product candidates, or the FDA or foreign regulatory authorities approve any biosimilar, interchangeable, or other competing products to our product candidates, it could have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our current or future trademarks or trade names may be challenged, infringed, circumvented or declared generic or descriptive or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest.

During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively, and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Although these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names.

Moreover, any name we have proposed to use with our product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA (or an equivalent administrative body in a foreign jurisdiction) objects to any of our proposed proprietary product names, it may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. If we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Risks Related to Government Regulation

If we fail to comply with federal and state healthcare laws, including fraud and abuse laws, we could face substantial penalties and our business, financial condition, results of operations, stock price and prospects will be materially harmed.

Our current and future arrangements with healthcare providers, third-party payors, customers, and others may expose us to broadly applicable healthcare fraud and abuse, and other healthcare laws, which may constrain the business or financial arrangements and relationships through which we research, as well as sell, market and distribute any products for which we obtain marketing approval. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include, but are not limited to:

- The federal Anti-Kickback Statute, which prohibits, among other things, individuals and entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs.
- The federal civil and criminal false claims laws, including, without limitation, the civil FCA, and the federal Civil Monetary Penalties Law, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment of federal funds, and knowingly making, or causing to be made, a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government.
- HIPAA, which prohibits, among other things, knowingly and willfully executing, or attempting to execute, a scheme or artifice to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private), willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious or fraudulent statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters.
- The U.S. Federal Food, Drug and Cosmetic Act, which prohibits, among other things, the adulteration or misbranding of drugs, biological products and medical devices.
- The federal physician payment transparency requirements, sometimes referred to as the Physician Payments Sunshine Act, created under the ACA and its implementing regulations, which require certain manufacturers of drugs, devices, biological products and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare & Medicaid Services (CMS) information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, as well as ownership and investment interests held by such physicians and their immediate family members.
- Analogous state and foreign anti-kickback and false claims laws that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, or that apply regardless of payor; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state and local laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state laws that require the reporting of information related to drug pricing; and state and local laws requiring the registration of pharmaceutical sales representatives.

If we or our operations are found to be in violation of any federal or state healthcare law, or any other governmental laws or regulations that apply to us, we may be subject to penalties, including significant civil, criminal, and administrative penalties, damages, monetary fines, disgorgement, imprisonment, suspension and debarment from government contracts, and refusal of orders under existing government contracts, exclusion from participation in U.S. federal or state health care programs, additional reporting requirements and/or oversight if we become subject to corporate integrity agreements or similar agreement to resolve allegations of non-compliance, contractual damages, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could materially adversely affect our ability to operate our business and our financial results. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, it may be subject to significant criminal, civil or administrative sanctions, including but not limited to, exclusions from participation in U.S. federal or state healthcare programs, which could also materially affect our business.

Although an effective compliance program can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Moreover, achieving and sustaining compliance with such laws may prove costly. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

If the government or third-party payors fail to provide adequate coverage, reimbursement and payment rates for our product candidates, or if health maintenance organizations or long-term care facilities choose to use therapies that are less expensive or considered a better value, our revenue and prospects for profitability will be limited.

In both domestic and foreign markets, sales of our products will depend in part upon the availability of coverage and adequate reimbursement from third-party payors or placement on approved product formularies. Such third-party payors include government health programs such as Medicare and Medicaid, managed care providers, private health insurers, and other organizations. Coverage decisions may depend upon clinical and economic standards that disfavor new therapeutic products when more established or lower cost therapeutic alternatives are already available or subsequently become available, even if our products are alone in a class. Third-party payors establish reimbursement levels. Therefore, even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain a market share sufficient to realize a sufficient return on our or their investments. If reimbursement is not available, or is available only to limited levels, our product candidates may be competitively disadvantaged, and we may not be able to successfully commercialize our product candidates. Alternatively, securing favorable reimbursement terms may require us to compromise pricing and prevent us from realizing an adequate margin over cost. Our failure to obtain or maintain timely or adequate pricing or formulary placement of our products, or failure to obtain such formulary placement at favorable pricing may negatively impact our revenue.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved therapeutics. Marketing approvals, pricing, and reimbursement for new therapeutic products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a therapeutic before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription biopharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay commercial launch of the product, possibly for lengthy time periods, which may negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval. Our ability to commercialize our product candidates will depend in part on the extent to which coverage and reimbursement for these products and related treatments will be available from third-party payors.

A significant trend within the healthcare industry is cost containment, both in the United States and elsewhere. Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs, including use of formularies. Exclusion of a product from a formulary or other restrictions can significantly impact drug usage in the patient population and beyond. Consequently, pharmaceutical companies compete to gain access to formularies for their products, typically on the basis of unique product features, such as greater efficacy, better patient ease of use, or fewer side effects, as well as the overall cost of the therapy. Certain third-party payors are requiring that companies provide them with predetermined discounts from list prices, are using preferred drug lists to leverage greater discounts in competitive classes, are disregarding therapeutic differentiators within classes, are challenging the prices charged for therapeutics, and are negotiating price concessions based on performance goals. In addition, third-party payors are increasingly requiring higher levels of evidence of the benefits and clinical outcomes of new technologies, benchmarking against other therapies, seeking performance-based discounts, and challenging the prices charged. We cannot be sure that coverage will be available for any product candidate that we commercialize and, if available, that the reimbursement rates will be adequate. If payors subject our product candidates to maximum payment amounts or impose limitations that make it difficult to obtain reimbursement, providers may choose to use therapies which are less expensive when compared to our product candidates. Additionally, if payors require high copayments, beneficiaries may seek alternative therapies. We may need to conduct post-marketing studies in order to demonstrate the cost-effectiveness of any products to the satisfaction of hospitals, other target customers and their third-party payors. Such studies might require us to commit a significant amount of management time and financial and other resources. Our products might not ultimately be considered cost-effective. Adequate third-party coverage and reimbursement might not be available to enable us to maintain price levels sufficient to realize an appropriate return on investment in product development.

In addition, in the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. Further, we believe that future coverage and reimbursement will likely be subject to increased restrictions both in the United States and in international markets. Third-party coverage and reimbursement for our products or product candidates for which we receive regulatory approval may not be available or adequate in either the United States or international markets, which could have a negative effect on our business, financial condition, results of operations, stock price and prospects.

There may also be delays in obtaining coverage and reimbursement for newly approved therapeutics, and coverage may be more limited than the indications for which the product is approved by the FDA or comparable foreign regulatory authorities. Such delays have made it increasingly common for manufacturers to provide newly approved drugs to patients experiencing coverage delays or disruption at no cost for a limited period in order to ensure that patients are able to access the drug. Moreover, eligibility for reimbursement does not imply that any therapeutic 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 therapeutics, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates may vary, by way of example, according to the use of the product and the clinical setting in which it is used. Reimbursement rates may also be based on reimbursement levels already set for lower cost products or may be incorporated into existing payments for other services.

An inability to promptly obtain coverage and adequate reimbursement from third-party payors for any of our product candidates for which we obtain marketing approval could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

We are subject to new legislation, regulatory proposals and third-party payor initiatives that may increase our costs of compliance, and adversely affect our ability to market our products, obtain collaborators, and raise capital.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any products for which we obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we may receive for any approved products.

For example, the ACA was passed in March 2010 and substantially changed the way healthcare is financed by both governmental and private insurers and continues to significantly impact the U.S. pharmaceutical industry.

There have been executive, judicial and congressional challenges to certain aspects of the ACA. For example, legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act of 2017 (the Tax Act), includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. In addition, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (the IRA) into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost through a newly established manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and the healthcare reform measures of the Biden administration will impact the ACA and our business.

Other legislative changes have been proposed and adopted in the United States since the ACA. For example, through the process created by the Budget Control Act of 2011, there are automatic reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect in April 2013 and, following passage of the Bipartisan Budget Act of 2018 (BBA) and the Infrastructure Investment and Jobs Act, will remain in effect until 2031 unless additional Congressional action is taken. Under current legislation the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester.

In addition, there have been a number of other legislative and regulatory proposals aimed at changing the biopharmaceutical industry. For instance, the Drug Quality and Security Act of 2013 imposes obligations on manufacturers of biopharmaceutical products related to product tracking and tracing. Further, manufacturers have product investigation, quarantine, disposition, and notification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products that would result in serious adverse health consequences of death to humans, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death.

Compliance with the federal track and trace requirements may increase our operational expenses and impose significant administrative burdens. As a result of these and other new proposals, we may determine to change our current manner of operation, provide additional benefits or change our contract arrangements, any of which could have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

There has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biological products. Such scrutiny has resulted in presidential executive orders, congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products.

At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, the Trump administration announced several executive orders related to prescription drug pricing that attempted to implement several of the administration's proposals. The FDA concurrently released a final rule and guidance in September 2020, implementing a portion of the importation executive order providing pathways for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the U.S. Department of Health and Human Services (HHS) finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. The implementation of the rule has been delayed until 2032. On March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. In addition, the IRA directs the Secretary of HHS to establish a Drug Price Negotiation Program (the Program) to lower prices for certain single-source prescription drugs and biologics covered under Medicare Parts B and D, based on criteria established under the IRA. Under the Program, the Secretary of HHS will publish a list of "selected drugs," and will then negotiate maximum fair prices (MFP) with their manufacturers. Beginning in 2026, the first year of the Program, the number will be limited to 10 Part D drugs and biologics. By 2029, and in subsequent years thereafter, the number will increase to 20 drugs and biologics covered under Part D and Part B. Agreements between HHS and manufacturers will remain in place until a drug or biologic is no longer considered a "selected drug" for negotiation purposes. Manufacturers who do not comply with the negotiated prices set under the Program will be subject to an excise tax based on a percentage of total sales of a "selected drug" up to 95% and the potential of civil monetary penalties. Further, the IRA imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. In addition, the Biden administration released an additional executive order on October 14, 2022, directing HHS to report on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Any new laws or regulations, including those that may result in additional reductions in Medicare and other healthcare funding, could have a material adverse effect on customers for our products, if approved, and, accordingly, on our results of operations.

We expect that the ACA, as well as other federal and state healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria, increased regulatory burdens and operating costs, decreased net revenue from our biopharmaceutical products, decreased potential returns from our development efforts, and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government healthcare programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from commercializing our products and being able to generate revenue, and we could be prevented from or significantly delayed in achieving profitability.

We are subject to the U.S. Foreign Corrupt Practices Act and other anti-corruption laws, as well as import and export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, and other consequences, which could adversely affect our business, financial condition, results of operations, stock price and prospects.

Our operations are subject to anti-corruption laws, including the U.S. Foreign Corrupt Practices Act (FCPA) and other anti-corruption laws that apply in countries where we do business. The FCPA and these other anti- corruption laws generally prohibit us and our employees and intermediaries from authorizing, promising, offering, providing, soliciting, or receiving, directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. We can be held liable for the corrupt or other illegal activities of our personnel or intermediaries, even if we do not explicitly authorize or have prior knowledge of such activities.

We are also subject to other laws and regulations governing our international operations, including applicable import and export control regulations, economic sanctions on countries and persons, anti-money laundering laws, customs requirements and currency exchange regulations, collectively referred to as the trade control laws.

We can provide no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws or other legal requirements, including trade control laws. If we are not in compliance with applicable anti-corruption laws or trade control laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations, stock price and prospects. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted. An investigation of any potential violations of anti-corruption laws or trade control laws by U.S. or other authorities could also have an adverse impact on our reputation, our business, financial condition, results of operations, stock price and prospects.

We are subject to stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse business consequences.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). For example, HIPAA as amended by HITECH, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. We may obtain health information or other personal information from third parties, including research institutions from which we obtain clinical trial data that are subject to privacy and security requirements under HIPAA. While we do not believe that we are currently acting as a covered entity or business associate under HIPAA and thus are not directly regulated under HIPAA, any person may be prosecuted under HIPAA's criminal provisions if it knowingly receives individually identifiable health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA's

requirements for disclosure of individually identifiable health information under aiding-and-abetting or conspiracy principles. As another example, the California Consumer Privacy Act of 2018 (CCPA) applies to personal information of consumers, business representatives and employees who are California residents, and requires covered businesses to provide specific disclosures in privacy notices and to honor certain requests of California residents related to their personal data. The CCPA allows for administrative penalties for noncompliance (up to $7,500 per violation) and allows private litigants affected by certain data breaches to recover statutory damages. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA increases compliance costs and potential liability with respect to other personal data we maintain about California residents. In addition, the California Privacy Rights Act of 2020 (CPRA)expanded the CCPA's requirements, including by establishing a new California Privacy Protection Agency to implement and enforce the CPRA and adding a new right for individuals to correct their personal information. Other states have enacted or proposed data privacy laws. For example, Virginia passed the Consumer Data Protection Act, and Colorado passed the Colorado Privacy Act, which take effect in 2023. While these states, like the CCPA, also exempt some data processed in the context of clinical trials, these developments further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon which we rely.

Outside the United States, an increasing number of laws, regulations, and industry standards apply to data privacy and security. For example, the EU GDPR, the UK GDPR, and the Swiss Federal Act on Data Protection impose strict requirements for processing personal data. For example, under the EU GDPR, government regulators may impose temporary or definitive bans on data processing, as well as fines of up to 20 million euros or 4% of annual global revenue, whichever is greater. Further, companies may face private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests.

In the ordinary course of business, we may transfer personal data from Europe and other jurisdictions to the United States or other countries. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the EEA and the UK have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws.

Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA and UK's standard contractual clauses, these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States.

If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, which could limit our ability to conduct clinical trial activities in the EEA, the UK or elsewhere, and injunctions against our processing or transferring of personal data necessary to operate our business. Some European regulators have prevented companies from transferring personal data out of the EEA or the UK for allegedly violating the EU and UK GDPR and their cross-border data transfer limitations.

In addition, we may be contractually subject to data privacy and security obligations, including industry standards adopted by industry groups and may become subject to new data privacy and security obligations in the future. For example, certain privacy laws, such as the EU GDPR and the CCPA, require companies to impose specific contractual restrictions on their service providers. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information.

We publish privacy policies, marketing materials and other statements regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

Obligations related to data privacy and security are quickly changing, becoming increasingly stringent and, creating regulatory uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires significant resources and may necessitate changes to our information technologies, systems, and practices and to those of any third parties that process personal data on our behalf.

Although we endeavor to comply with all applicable data privacy and security obligations, we may at times fail (or be perceived to have failed) to do so. Moreover, despite our efforts, our personnel or third parties upon whom we rely may fail to comply with such obligations, which could negatively impact our business operations. Such failures can subject us to potential foreign, local, state and federal action if they are found to be deceptive, unfair, or misrepresentative of our actual practices, which could negatively impact our business operations and compliance posture. For example, any failure by a third-party processor to comply with applicable law, regulations, or contractual obligations could result in adverse effects, including inability to or interruption in our ability to operate our business and proceedings against us by governmental entities or others. If we fail, or are perceived to have failed, to address or comply with data privacy and security obligations, we could face significant consequences. These consequences may include, but are not limited to, government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-related claims); additional reporting requirements and/or oversight; bans on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including, as relevant, clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or revision or restructuring of our operations.

Violations of or liabilities under environmental, health and safety laws and regulations could subject us to fines, penalties or other costs that could have a material adverse effect on the success of our business.

We are subject to numerous federal, state and local environmental, health and safety laws and regulations, including those governing laboratory procedures, the handling, use, storage, treatment and disposal of hazardous materials and wastes and the cleanup of contaminated sites. Our operations involve the controlled production, storage, use and disposal of hazardous and flammable materials, including chemicals and biological materials such as infectious agents and various radioactive compounds. We would incur substantial costs as a result of violations of or liabilities under environmental requirements in connection with our operations or property, including fines, penalties and other sanctions, investigation and cleanup costs and third-party claims. Although we generally contract with third parties for the disposal of hazardous materials and wastes from our operations, we cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties, as well as our curtailment of the use of these materials or even shutting down our facilities and operations.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. While we maintain insurance covering our manufacturing facility only, and not our other facilities, for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological or hazardous materials, such insurance coverage may not be sufficient to cover extraordinary or unanticipated events at our manufacturing facility.

Risks Related to Our Business and Operations

We are highly dependent on our key personnel, including our President, Chief Executive Officer and Chairman. If we are not successful in attracting, motivating and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract, motivate and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management and particularly on the services of our personnel including Thomas Zindrick, J.D., our President, Chief Executive Officer and Chairman. We believe that their drug discovery and development experience and overall biopharmaceutical company management experience, would be difficult to replace. Any of our executive officers could leave our employment at any time, as all of our employees are "at-will" employees. We currently do not have "key person" insurance on any of our employees. The loss of the services of our key personnel and any of our other executive officers, key employees, and scientific and medical advisors, and our inability to find suitable replacements, could result in delays in our research and development objectives and harm our business.

Recruiting and retaining qualified employees, consultants and advisors for our business, including scientific and technical personnel, also will be critical to our success. We conduct our operations at our facilities in Southern California, a region that is home to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies and academic institutions for skilled individuals. In addition, failure to succeed in preclinical studies, clinical trials or applications for marketing approval may make it more challenging to recruit and retain qualified personnel. The inability to recruit, or the loss of services of certain executives, key employees, consultants or advisors, may impede the progress of our research, development and commercialization objectives and have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided stock option grants that vest over time. The value to employees of these equity grants that vest over time may be significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Although we have employee agreements with our key employees, these agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain "key person" insurance policies on the lives of all of these individuals or the lives of any of our other employees.

We will need to continue to expand the size of our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

As of December 31, 2022, we had 15 full-time and part-time employees, including eight employees engaged in research and development and manufacturing. As our development and commercialization plans and strategies develop, and as we transition into operating as a public company, we expect to need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical, FDA and comparable foreign regulatory review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to commercialize Olvi-Vec, V-VET1, V2ACT Immunotherapy and any other product candidates we develop will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services. The services include substantially all aspects of clinical trial management and manufacturing. We cannot assure you that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain marketing approval of Olvi-Vec and our other product candidates or otherwise advance our business. We cannot assure you that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring qualified new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize Olvi-Vec and our other product candidates and, accordingly, may not achieve our research, development and commercialization goals.

If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

We may evaluate various acquisitions and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies, or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management’s attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;

- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party, their regulatory compliance status, and their existing products or product candidates and marketing approvals; and
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business. Any of the foregoing may materially harm our business, financial condition, results of operations, stock price and prospects.

Unfavorable market and economic conditions may have serious adverse consequences on our business, financial condition, results of operations, stock price and prospects.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including a reduced ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

Public health crises such as pandemics, including the ongoing COVID-19 pandemic, or similar future outbreaks could materially and adversely affect our preclinical studies and clinical trials, business, financial condition and results of operations.

In March 2020, the World Health Organization declared COVID-19 a global pandemic and the United States declared a national emergency with respect to COVID-19. In response to the COVID-19 pandemic, a number of governmental orders and other public health guidance measures have been implemented across much of the United States, including in the locations of our office, clinical trial sites and third parties on whom we rely. As the COVID-19 pandemic started to spread in the first half of 2020, our clinical trial sites reported it had the most impact on patient care as facilities were generally ill prepared to conduct business as usual; adequate clinical evaluations, physical exams and tests were either absent or drastically reduced. Our clinical trial sites further reported that their institutions better adjusted to pandemic conditions beginning in the second half of 2020. Additionally, we have experienced disruption to our manufacturing supply chain which has delayed receipt of ordered materials and delayed our manufacturing timeline; while we now have received all ordered materials, we do not have insight into whether, or to what extent, there may be future delays.

Any further negative impact on our clinical development timelines could materially and adversely affect our business, financial condition and results of operations. Further, we have implemented a work-from-home policy allowing employees who can work from home to do so, while those needing to work in laboratory and manufacturing facilities work in shifts to reduce the number of people gathered together at one time. Business travel has been suspended, and online and teleconference technology is used to meet virtually rather than in person. We have taken measures to secure our research and development project activities, while work in laboratories has been organized to reduce risk of COVID-19 transmission. Our increased reliance on personnel working from home may negatively impact productivity, or disrupt, delay or otherwise adversely impact our business. For example, with our personnel working from home, some of our research activities that require our personnel to be in our laboratories could be delayed.

As a result of the COVID-19 pandemic, or similar pandemics, and related governmental orders and other public health guidance measures, we have and may in the future experience disruptions that could materially and adversely impact our preclinical studies, clinical trials, business, financial condition and results of operations. Potential disruptions might include but are not limited to:

- delays or difficulties in enrolling patients in our clinical trials;

- delays or difficulties in initiating or expanding clinical trials, including delays or difficulties with clinical site initiation and recruiting clinical site investigators and clinical site staff;
- increased rates of patients withdrawing from our clinical trials following enrollment as a result of contracting COVID-19 or other health conditions or being forced to quarantine;
- interruption of key clinical trial activities, such as clinical trial site data monitoring and efficacy, safety and translational data collection, processing and analyses, due to limitations on travel imposed or recommended by federal, state or local governments, employers and others or interruption of clinical trial subject visits, which may impact the collection and integrity of subject data and clinical study endpoints;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- delays or disruptions in preclinical experiments and studies due to restrictions of on-site staff and unforeseen circumstances at CROs and vendors;
- interruption or delays in the operations of the FDA and comparable foreign regulatory agencies;
- interruption of, or delays in receiving, supplies of our product candidates from third-party providers due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- limitations on employee or other resources that would otherwise be focused on the conduct of our clinical trials and preclinical work, including because of sickness of employees or their families, the desire of employees to avoid travel or contact with large groups of people, an increased reliance on working from home, school closures or mass transit disruptions;
- changes in regulations as part of a response to the COVID-19 pandemic which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether; and
- delays in necessary interactions with regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government or contractor personnel.

The extent to which the ongoing COVID-19 global pandemic may affect our preclinical activities, clinical trials, business, financial condition and results of operations will depend on future developments, which are highly uncertain and cannot be predicted at this time, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions and actions to contain the outbreak or treat its impact, such as social distancing and quarantines or lock-downs or vaccine rollout in the United States, business closures or business disruptions and the effectiveness of actions taken in the United States to contain and treat the disease. Future developments in these and other areas present material uncertainty and risk with respect to our clinical trials, business, financial condition and results of operations.

If our information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse consequences.

In the ordinary course of our business, we may process proprietary, confidential, and sensitive data, including de-identified personal data (such as health-related data), intellectual property, proprietary business information and trade secrets (collectively, sensitive information).

Cyber-attacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties upon which we rely. Such threats are prevalent and continue to increase, are becoming increasingly difficult to detect, and come from a variety of sources, including traditional computer “hackers,” “hacktivists,” organized criminal threat actors, personnel (such as through theft or misuse),

sophisticated nation states, and nation-state-supported actors. Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services. We and the third parties upon which we rely are subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks (such as credential stuffing), credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, and other similar threats. Ransomware attacks, including by organized criminal threat actors, nation-states, and nation-state-supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions in our operations, disruption of clinical trials, loss of data (including data related to clinical trials), and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

Remote work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers, and devices outside our premises or network, including working at home, while in transit and in public locations.

Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

We rely upon third-party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, third-party providers of information technology infrastructure, cloud-based infrastructure, encryption and authentication technology, employee email, content delivery to customers, and other functions. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or our third-party partners' supply chains have not been compromised.

Any of the previously identified or similar threats could cause a security incident or other interruption. A security incident or other interruption could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to provide our products. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Certain data privacy and security obligations may require us to implement and maintain specific security measures, industry-standard or reasonable security measures to protect our information technology systems and sensitive information.

While we have established physical, electronic and organizational security measures designed to safeguard and secure our systems against security incidents, there can be no assurance that these measures will be effective. We take steps to detect and remediate vulnerabilities in our information technology systems because the threats and techniques used to exploit the vulnerability change frequently and are often sophisticated in nature. Therefore, such vulnerabilities could be exploited but may not be detected until after a security incident has occurred. These vulnerabilities pose material risks to our business. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities.

Applicable data privacy and security obligations may require us to notify relevant stakeholders of security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences. These consequences may include: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may cause customers to stop using our products, deter new customers from using our products, and negatively impact our ability to grow and operate our business.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position.

We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability and have to limit the commercialization of any approved products and/or our product candidates.

The use of our product candidates in clinical trials, and the sale of any product for which we obtain regulatory approval, exposes us to the risk of product liability claims. We face inherent risk of product liability related to the testing of our product candidates in human clinical trials, including liability relating to the actions and negligence of our investigators, and will face an even greater risk if we commercially sell any product candidates that we may develop. For example, we may be sued if any product candidate we develop allegedly causes injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. Product liability claims might be brought against us by consumers, healthcare providers or others using, administering or selling our products. If we cannot successfully defend ourselves against these claims, we will incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of merit or eventual outcome, liability claims may result in:

- loss of revenue from decreased demand for our products and/or product candidates;
- impairment of our business reputation or financial stability;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;
- diversion of management attention;

- withdrawal of clinical trial participants and potential termination of clinical trial sites or entire clinical programs;
- the inability to commercialize our product candidates;
- significant negative media attention;
- decreases in our stock price;
- initiation of investigations and enforcement actions by regulators; and
- product recalls, withdrawals or labeling, marketing or promotional restrictions, including withdrawal of marketing approval.

We believe we have sufficient insurance coverage in place for our business operations. However, our insurance coverage may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. We intend to expand our insurance coverage to include clinical trials and the sale of commercial products if we obtain FDA or comparable foreign regulatory approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing, or at all. Failure to obtain and retain sufficient product liability insurance at an acceptable cost could prevent or inhibit the commercialization of products we develop. On occasion, large judgments have been awarded in class action lawsuits based on therapeutics that had unanticipated side effects. A successful product liability claim or series of claims brought against us could cause our stock price to fall and, if judgments exceed our insurance coverage, could decrease our cash, and materially harm our business, financial condition, results of operations, stock price and prospects.

Our employees, independent contractors, consultants, commercial partners, principal investigators, CMOs, or CROs may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading, which could have a material adverse effect on our business.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees, independent contractors, consultants, commercial partners, principal investigators, CMOs or CROs could include intentional, reckless, negligent, or unintentional failures to comply with FDA regulations, comply with applicable fraud and abuse laws, provide accurate information to the FDA, properly calculate pricing information required by federal programs, report financial information or data accurately or disclose unauthorized activities to us. This misconduct could also involve the improper use or misrepresentation 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 this type of 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. Moreover, it is possible for a whistleblower to pursue a FCA case against us even if the government considers the claim unmeritorious and/or declines to intervene, which could require us to incur costs defending against such a claim. In addition, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. 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, financial condition, results of operations, stock price and prospects, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in U.S. federal healthcare programs, integrity oversight and reporting obligations to resolve allegations of non-compliance, imprisonment, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations.

We have generated significant net operating loss (NOL) carryforwards and research and development tax credits, and our ability to utilize our net operating loss carryforwards and research and development tax credits to reduce future tax payments may be limited or restricted.

We have generated significant NOL carryforwards and research and development tax credits (R&D credits) as a result of our incurrence of losses and our conduct of research activities since inception. As of December 31, 2022, we had federal and state NOL carryforwards of approximately $132.0 million and $100.0 million, respectively. We do not anticipate generating revenue from sales of products for the foreseeable future, if ever, and we may never achieve profitability. Our U.S. federal NOL carryforwards generated in taxable years beginning before January 1, 2018, can be carried forward to each of the 20 taxable years following the year of the loss. These NOL carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under current law, U.S. federal NOLs incurred in tax years beginning after December 31, 2017, totaling $22.3 million, may be carried forward indefinitely, but the utilization of U.S. federal NOLs generated in tax years beginning after December 31, 2020 is limited. As of December 31, 2022, we also had federal and state R&D credit carryforwards of $2.6 million and $2.0 million, respectively. Our U.S. federal R&D credit carryforwards can be carried forward 20 taxable years. If not utilized in that period, these R&D credit carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under current law, the California state R&D credits carry forward indefinitely until utilized.

Under Sections 382 and 383 of the Code, and corresponding provisions of state law, if a corporation undergoes an “ownership change,” the corporation’s ability to use its pre-change NOL carryforwards and R&D credits to offset its post-change income and taxes, respectively, may be limited. For purposes of these rules, an “ownership change” generally occurs if one or more stockholders or groups of stockholders who own at least 5% of our stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. The application of these rules could limit the amount of NOLs or R&D credit carryforwards that we can utilize annually to offset future taxable income or tax liabilities. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

Our NOL and R&D credit carryforwards are subject to review and possible adjustment by U.S. and state tax authorities.

If we fail to maintain proper and effective internal controls over financial reporting our ability to produce accurate and timely financial statements could be impaired.

We are required to maintain internal controls over financial reporting. Commencing with our fiscal year ending December 31, 2024, we must perform system and process design evaluation and testing of the effectiveness of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Form 10-K filing for that year, as required by Section 404 of the Sarbanes-Oxley Act. This will require that we incur substantial additional professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts. Prior to our IPO, we had never been required to test our internal controls within a specified period and, as a result, we may experience difficulty in meeting these reporting requirements in a timely manner.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls over financial reporting, we may not be able to produce timely and accurate financial statements. If that were to happen, our investors could lose confidence in our reported financial information, the market price of our stock could decline, and we could be subject to sanctions or investigations by the SEC, Nasdaq or other regulatory authorities.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make a required related party transaction disclosure. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act. We must design our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. We may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our consolidated financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make a required related party transaction disclosure. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Risks Related to Our Common Stock

An active, liquid and orderly trading market for our common stock may not be sustained.

Prior to the closing of our IPO in January 2023, there was no public market for shares of our common stock. An active trading market for our shares may not be sustained. You may not be able to sell your shares quickly or at the market price if trading in shares of our common stock is not active. As a result of these and other factors, you may be unable to resell your shares of our common stock. Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or products by using our shares of common stock as consideration.

Our operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.

We expect our operating results to be subject to quarterly fluctuations, which makes it difficult for us to predict our future operating results. Our net loss and other operating results will be affected by numerous factors, including:

- the timing and cost of, and level of investment in, research and development and commercialization activities relating to our current and any future product candidates, which will change from time to time;
- the total expenses we incur in connection with establishing, equipping, and operating our current and any future manufacturing facility(ies);
- the cost of manufacturing our current and any future product candidates, which may vary depending on the FDA's and comparable foreign regulatory authorities' guidelines and requirements, the quantity of production and the terms of any agreements with suppliers;
- results of preclinical studies and future clinical trials, or the addition or termination of future clinical trials or funding support by us, or future collaborators or licensing partners;
- our execution of any collaboration, licensing or similar arrangements, and the timing of payments we may make or receive under existing or future arrangements or the termination or modification of any such existing or future arrangements;
- any intellectual property infringement lawsuit or opposition, interference or cancellation proceeding in which we may become involved;
- additions and departures of key personnel;
- strategic decisions by us, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;

- if any of our product candidates receives regulatory approval, the terms of such approval and market acceptance and demand for such product candidates;
- regulatory developments affecting our product candidates;
- changes in accounting pronouncements or changes in our accounting policies;
- changes in the variables used as a basis for valuing these stock-based awards, resulting in a changes in the magnitude of the expense that we must recognize; and
- potential unforeseen business disruptions that increase our costs or expenses.

These factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance.

This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue and/or earnings guidance we may provide.

The market price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock.

The market price of our common stock has fluctuated, and may continue to fluctuate, widely, due to many factors, some of which may be beyond our control. These factors include, without limitation:

- “short squeezes”;
- comments by securities analysts or other third parties, including blogs, articles, message boards and social and other media;
- large stockholders exiting their position in our common stock or an increase or decrease in the short interest in our common stock;
- actual or anticipated fluctuations in our financial and operating results;
- risks and uncertainties associated with the ongoing COVID-19 pandemic;
- negative public perception of us, our competitors, or industry; and
- overall general market fluctuations.

The stock market in general, and the markets for pharmaceutical, biopharmaceutical and biotechnology stocks in particular, have experienced extreme price and volume fluctuations that have been often unrelated or disproportionate to the operating performance of the issuer. In particular, the trading prices for pharmaceutical, biopharmaceutical and biotechnology companies have been highly volatile, and we note recent instances of extreme stock price run-ups followed by rapid price declines and stock price volatility seemingly unrelated to company performance following a number of recent initial public offerings, particularly among companies with relatively smaller public floats. For example, on March 7, 2023, our common stock experienced an intra-day trading high of $39.27 per share and a low of $26.26 per share. In addition, from January 26, 2023 to March 27, 2023, the closing price of our common stock on the Nasdaq Capital Market ranged from as low as $5.56 to as high as $30.35 and daily trading volume ranged from approximately 7,000 to 1,545,800 shares. During this time, we have not experienced any material changes in our financial condition or results of operations that would explain such price volatility or trading volume. These broad market fluctuations may adversely affect the trading price of our common stock. In particular, a large proportion of our common stock has been and may continue to be traded by short sellers which has put and may continue to put pressure on the supply and demand for our common stock, further influencing volatility in its market price. Additionally, these and other external factors have caused and may continue to cause the market price and demand for our common stock to fluctuate, which may limit or prevent investors from readily selling their shares of common stock and may otherwise negatively affect the liquidity of our common stock.

In addition, if the trading volumes of our common shares are low, persons buying or selling in relatively small quantities may easily influence prices of our common shares. This low volume of trades could also cause the price of our common shares to fluctuate greatly, with large percentage changes in price occurring in any trading day session. Holders of our common shares may also not be able to readily liquidate their investment or may be forced to sell at depressed prices due to low volume trading. A decline in the market price of our common shares also could adversely affect our ability to issue additional shares of common shares or other securities and our ability to obtain additional financing in the future. No assurance can be given that an active market in our common shares will develop or be sustained.

The market price for our common stock may be influenced by many factors, including:

- results from, and any delays in, our clinical trial for Olvi-Vec, our preclinical studies and any other future clinical development programs, including any delays related to the COVID-19 pandemic;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- commencement or termination of collaboration, licensing or similar arrangements for our development programs;
- announcements by our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- failure or discontinuation of any of our development programs;
- our ability to commercialize Olvi-Vec and our other product candidates, if approved, inside and outside of the United States, either independently or working with third parties;
- our partners' and collaborators' ability to successfully commercialize their licensed product candidates;
- developments or setbacks related to drugs that are co-administered with any of our product candidates, such as cellular and targeted therapies;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to the development of Olvi-Vec and any other product candidate we may develop;
- changes in the competitive landscape in our industry, including results of clinical trials of existing and potential future products that compete with Olvi-Vec and our other product candidates;
- our ability to adequately support future growth;
- variations in our financial results or those of companies that are perceived to be similar to us;
- future accounting pronouncements or changes in our accounting policies;
- announcements or expectations of additional financing efforts by us;
- sales of our common stock by us, our insiders or other stockholders;
- expiration of market stand-off or lock-up agreements;
- recommendations and changes in estimates or recommendations by securities analysts, if any, that cover our stock;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;

- general economic, political, and market conditions and overall fluctuations in the financial markets in the United States and abroad, including the COVID-19 pandemic and bank failures; and
- investors' general perception of us and our business.

These and other market and industry factors may cause the market price and demand for our common stock to fluctuate rapidly and substantially, including any stock price run-up, regardless of our actual or expected operating performance and financial condition or prospects, which may limit, prevent or make it difficult for prospective investors to assess the rapidly changing value of our common stock or to sell their shares at or above the price paid for the shares and may otherwise negatively affect the liquidity of our common stock.

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

You should not rely on an investment in our common stock to provide dividend income. 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 appreciation of their stock, which may never occur, as the only way to realize any return on their investment.

Our principal stockholders and management own a significant percentage of our stock and are able to exert significant control over matters subject to stockholder approval.

Our executive officers and directors, combined with our stockholders who own more than 5% of our outstanding capital stock, beneficially own shares representing a significant percentage of our common stock. Therefore, these stockholders have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

Conflicts of interest may arise because some members of our board of directors are representatives of our principal stockholders.

Certain of our principal stockholders or their affiliates are investment funds or other investment vehicles that could invest in companies that directly or indirectly compete with us. As a result of these relationships, conflicts may arise between the interests of the principal stockholders or their affiliates and the interests of other stockholders, and members of our board of directors that are representatives of such principal stockholders may not be disinterested in such conflicts. We expect that all decisions made by our executive officers and directors will be made in accordance with their duties and obligations to deal fairly and in good faith and to act in the best interests of us and our stockholders, as well as in compliance with our Code of Conduct, which includes a "conflicts of interest" section applicable to all employees, executive officers and directors.

Sales of a substantial number of shares of our common stock by our existing stockholders in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market could occur at any time after the lock-up and other legal restrictions on resale lapse. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. As of March 27, 2023, there were 24,553,470 shares of our common stock outstanding. Of these shares, only the shares of common stock sold in the IPO by us, other than to our affiliates, and other than our 737,203 shares of our common stock that are not subject to lock-up agreements, are freely tradable without restriction in the public market.

The lock-up agreements pertaining to the IPO will expire on July 24, 2023. After the lock-up agreements expire, up to 24,553,470 shares of common stock will be eligible for sale in the public market, of which 7,910,426 shares are held by directors, executive officers, and other affiliates and will be subject to volume limitations under Rule 144 under the Securities Act of 1933, as amended (the Securities Act). In addition, shares of common stock

that are either subject to outstanding options or reserved for future issuance under our employee benefit plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements, and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

Further, the holders of 21,888,804 shares of our common stock are entitled to rights with respect to the registration of their shares under the Securities Act, subject to the 180-day lock-up agreements described above. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that we will need significant additional capital in the future to continue our planned operations, including conducting clinical trials, commercialization efforts, expanded research and development activities, and costs associated with operating a public company. To raise capital, 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, 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, preferences and privileges senior to the holders of our common stock.

Pursuant to our 2022 Plan, our management is authorized to grant stock options to our employees, directors and consultants. Additionally, the number of shares of our common stock reserved for issuance under our 2022 Plan will automatically increase on January 1 of each year, beginning on January 1, 2024 and continuing through and including January 1, 2032, by 5% of the total number of shares of our capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by our board of directors. In addition, pursuant to our ESPP, the number of shares of our common stock reserved for issuance will automatically increase on January 1 of each calendar year, beginning on January 1, 2024 through January 1, 2032, by the lesser of (i) 1% of the total number of shares of our common stock outstanding on the last day of the calendar month before the date of the automatic increase, and (ii) shares; provided that before the date of any such increase, our board of directors may determine that such increase will be less than the amount set forth in clauses (i) and (ii). Unless our board of directors elects not to increase the number of shares available for future grant each year, our stockholders may experience additional dilution, which could cause our stock price to fall.

We are an emerging growth company and a smaller reporting company, and the reduced reporting requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.

We are an "emerging growth company" as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of certain exemptions from various public company reporting requirements, including being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure in this Annual Report, not being required to have our internal control over financial reporting audited by our independent registered public accounting firm under Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in this Annual Report and 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. We may take advantage of these exemptions until the last day of the fiscal year ending after the fifth anniversary of our IPO (i.e. January 25, 2028) or until we are no longer an emerging growth company, whichever is earlier. We will cease to be an emerging growth company prior to the end of such five-year period if certain earlier events occur, including if we become a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, our annual gross revenues exceed $1.235 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to use this extended transition period under the JOBS Act until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act.

We are also a "smaller reporting company" as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company, which would allow us to take advantage of many of the same exemptions available to emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation. We will be able to take advantage of these scaled disclosures for so long as our voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter. Investors may 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.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our amended and restated certificate of incorporation and our amended and restated bylaws and provisions of Delaware law may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions also could limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified board of directors such that not all members of the board are elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from the board;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- prohibit our stockholders from calling a special meeting of our stockholders;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a stockholder rights plan, or so-called “poison pill,” that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 66 2/3% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns 15% or more of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired 15% or more of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. These provisions could discourage potential acquisition proposals and could delay or prevent a change in control transaction. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock.

Our amended and restated certificate of incorporation will provide that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders’ ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation will provide that the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- any derivative action or proceeding brought on our behalf;
- any action asserting a breach of fiduciary duty;
- any action asserting a claim against us arising under the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws; and
- any action asserting a claim against us that is governed by the internal affairs doctrine.

This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act.

Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation further provides that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid and several state trial courts have enforced such provisions and required that suits asserting Securities Act claims be filed in federal court, there is no guarantee that courts of appeal will affirm the enforceability of such provisions and a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and the provisions may be enforced by a court in those other jurisdictions.

If a court were to find the exclusive forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with litigating Securities Act claims in state court, or both state and federal court, which could harm our business, financial condition, results of operations, and prospects. Further, this exclusive forum provision 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 lawsuits against us and our directors, officers and other employees.

General Risk Factors

We will incur significantly increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, we will incur significant legal, accounting, and other expenses that we did not incur as a private company. We will be subject to the reporting requirements of the Exchange Act, which will require, among other things, that we file with the SEC annual, quarterly, and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and Nasdaq to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act (the Dodd-Frank Act) was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access. Emerging growth companies and smaller reporting companies are exempted from certain of these requirements, but we may be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition, and results of operations. The increased costs will decrease our net income or increase our net loss, and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

Failure to build our finance infrastructure and improve our accounting systems and controls could impair our ability to comply with the financial reporting and internal controls requirements for publicly traded companies.

As a public company, we will operate in an increasingly demanding regulatory environment, which requires us to comply with the Sarbanes-Oxley Act, the regulations of the Nasdaq Capital Market, the rules and regulations of the Securities and Exchange Commission, expanded disclosure requirements, accelerated reporting requirements and more complex accounting rules. Company responsibilities required by the Sarbanes-Oxley Act include establishing corporate oversight and adequate internal control over financial reporting and disclosure controls and procedures. Effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent financial fraud. Commencing with our fiscal year ending December 31, 2024, we must perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Form 10-K filing for that year, as required by Section 404 of the Sarbanes-Oxley Act. Prior to our IPO, we had never been required to test our internal controls within a specified period and, as a result, we may experience difficulty in meeting these reporting requirements in a timely manner.

We anticipate that the process of building our accounting and financial functions and infrastructure will require significant additional professional fees, internal costs and management efforts. For example, we expect that we will need to implement new systems to enhance and streamline the management of our financial, accounting, human resources and other functions.

However, such systems will likely require us to complete many processes and procedures for the effective use of the systems, which may result in substantial costs. Any disruptions or difficulties in implementing or using these systems could adversely affect our controls and harm our business. Moreover, such disruption or difficulties could result in unanticipated costs and diversion of management attention. In addition, we may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected. If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If we cannot provide reliable financial reports or prevent fraud, our business and results of operations could be harmed, investors could lose confidence in our reported financial information and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities.

Future changes in financial accounting standards or practices may cause adverse and unexpected revenue fluctuations and adversely affect our reported results of operations.

Future changes in financial accounting standards may cause adverse, unexpected revenue fluctuations and affect our reported financial position or results of operations. Financial accounting standards in the United States are constantly under review and new pronouncements and varying interpretations of pronouncements have occurred with frequency in the past and are expected to occur again in the future. As a result, we may be required to make changes in our accounting policies. Those changes could affect our financial condition and results of operations or the way in which such financial condition and results of operations are reported. We intend to invest resources to comply with evolving standards, and this investment may result in increased general and administrative expenses and a diversion of management time and attention from business activities to compliance activities. See the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations—Recent Accounting Pronouncements."

Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition or results of operations.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, the Tax Act, the Coronavirus Aid, Relief, and Economic Security Act, and the Inflation Reduction Act enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to such legislation may affect us, and certain aspects thereof could be repealed or modified in future legislation. In addition, it is uncertain if and to what extent various states will conform to federal tax legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses under the Tax Act or future reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense.

If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.

The trading market for our common stock will rely, in part, on the research and reports that industry or financial analysts publish about us or our business. We may never obtain research coverage by industry or financial analysts. If no or few analysts commence coverage of us, the trading price of our stock would likely decrease. Even if we do obtain analyst coverage, if one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which, in turn, could cause our stock price to decline.

Our failure to meet Nasdaq's continued listing requirements could result in a delisting of our common stock.

If we fail to satisfy the continued listing requirements of Nasdaq, such as the corporate governance requirements or the minimum closing bid price requirement, Nasdaq may take steps to delist our common stock. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with the listing requirements of Nasdaq.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against public companies following declines in the market prices of their securities. This risk is especially relevant for biopharmaceutical companies, which have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and our resources, which could harm our business.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Our current corporate headquarters are located in Westlake Village, California, consisting of 4,050 square feet of office space. The lease for this facility expires in July 2027. Additionally, we lease 6,880 square feet in San Diego, California for research and development and pharmaceutical development laboratory and office space; the lease expires in February 2023. We also lease a 7,569 square-foot facility in San Diego, California, which contains our manufacturing operations and our translational science laboratory. The lease expires in September 2028, and we have the option to extend the lease for an additional five years. We have a business office located in Redlands, California, consisting of 1,884 square feet; the lease for this facility is on a month-to-month basis.

We believe that our existing and planned facilities will be adequate to meet our current needs and that our leases can be renewed, or suitable alternative spaces will be available in the future, on commercially reasonable terms.

Item 3. Legal Proceedings.

We are currently involved in one pending litigation. Although the results of the pending legal proceeding in which we currently are involved cannot be predicted with certainty, we do not believe that there is a reasonable possibility that the final outcome of this matter will have a material adverse effect on our business or financial results. Regardless of the final outcome, however, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources, harm to our reputation and brand, and other factors.

In the future, we may be involved in additional actual and/or threatened legal proceedings, claims, investigations and government inquiries arising in the ordinary course of our business, including legal proceedings, claims, investigations and government inquiries involving intellectual property, data privacy and data protection, privacy and other torts, illegal or objectionable content, consumer protection, securities, employment, contractual rights, civil rights infringement, false or misleading advertising, or other legal claims relating to our business.

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 for Common Stock

Our common stock is listed on the Nasdaq Global Market under the symbol "GNLX". Trading of our common stock commenced on January 26, 2023, following the completion of our IPO. Prior to that time, there was no established public trading market for our common stock.

Record Holders

As of March 27, 2023, there were approximately 1,544 stockholders of record of our common stock. This number does not include beneficial owners whose shares are held in street name.

Dividends

We have never declared or paid a cash dividend on our common stock and do not anticipate paying any cash dividends in the foreseeable future.

Use of Proceeds from IPO

On January 25, 2023, our Registration Statement on Form S-1, as amended (File No. 333-265828) was declared effective in connection with the IPO of our common stock, pursuant to which we registered an aggregate of 2,500,000 shares of our common stock, of which we sold 2,653,000 shares, including the partial exercise of the underwriters' option to purchase additional shares, at a price to the public of $6.00 per share, for aggregate gross proceeds of $15.9 million. The offering closed on January 30, 2023. The underwriting discounts and commissions for the IPO totaled approximately $1.4 million. We incurred additional costs of approximately $2.1 million in offering expenses, which when added to the underwriting discounts and commissions paid by us, amounts to total fees and costs of approximately $3.5 million. Thus, estimated net offering proceeds to us, after deducting underwriting discounts, commissions and offering expenses, were approximately $12.4 million, including the partial exercise of the underwriters' overallotment option. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning 10 percent or more of any class of our equity securities or to any other affiliates. The Benchmark Company, LLC and Brookline Capital Markets, a division of Arcadia Securities, LLC, acted as joint book-running managers for the IPO.

As of March 27, 2023, we have not used any of the proceeds from our IPO. We anticipate that we will use the net proceeds from the IPO to advance our clinical programs, to expand our manufacturing capabilities and for working capital and general corporate purposes, which may include capital expenditures, other corporate expenses and acquisitions of complementary technologies or assets. We currently have no agreements or commitments with respect to acquisitions of complementary technologies or assets. The timing and amount of our actual expenditures will be based on many factors, including cash flows from operations.

Pending such uses, we have invested, and plan to continue to invest, the balance of the net proceeds in a variety of short-term, interest-bearing, investment grade securities. There has been no material change in the planned use of proceeds from our IPO from those disclosed in the final prospectus that forms a part of the Registration Statement filed by us with the SEC pursuant to Rule 424(b) on January 26, 2023.

Securities Authorized for Issuance Under Equity Compensation Plans

See Item 12 of Part III of this Annual Report for information about our equity compensation plans, which is incorporated by reference herein.

Recent Sales of Unregistered Securities

Set forth below is information regarding unregistered securities issued by us since January 1, 2022. Also included is the consideration received by us for such securities and information relating to the section of the Securities Act under which exemption from registration was claimed.

(1) In May 2022, a common stock warrant holder exercised their warrant totaling 3,333 shares at an exercise price of $0.03 per share for proceeds of $100.

(2) In August 2022, a common stock warrant holder exercised their warrant totaling 13,333 shares at an exercise price of $9.00 per share for proceeds of $120,000.

(3) In September 2022, we granted stock options to purchase an aggregate of 238,299 shares of our common stock with exercise prices of $9.00 and $10.50, per share subject to the Stock Option Repricing, to certain of our employees, consultants and directors in connection with services provided to us by such persons.

(4) In December 2022, we issued warrants to purchase up to a certain number of shares of common stock to certain investors at an exercise price equal to 90% of the initial offering price per share.

(5) From January 1, 2022 to December 31, 2022, we granted stock options under our 2009 Equity Incentive Plan (the 2009 Plan) and 2019 Equity Incentive Plan (the 2019 Plan, and together with the 2009 Plan, the Prior Plans), to purchase up to an aggregate of 247,785 shares of our common stock to our employees, directors and consultants, at a weighted-average exercise price of $10.40 per share. From January 1, 2022 to December 31, 2022, no shares of common stock were issued upon the exercise of options granted to employees, directors and consultants.

The offers, sales and issuances of the securities described in paragraphs (1) through (4) were deemed to be exempt from registration under the Securities Act in reliance on Section 4(a)(2) (or Regulation D promulgated thereunder) in that the issuance of securities to the accredited investors did not involve a public offering. The recipients of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions was an accredited investor under Rule 501 of Regulation D. No underwriters were involved in these transactions.

The offers, sales and issuances of the securities described in paragraph (5) were deemed to be exempt from registration under the Securities Act in reliance on either Rule 701 in that the transactions were under compensatory benefit plans and contracts relating to compensation as provided under Rule 701 or Section 4(a)(2) in that the issuance of securities to the accredited investors did not involve a public offering. The recipients of such securities were our employees, directors or bona fide consultants and received the securities under the Prior Plans.

Appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions had adequate access, through employment, business or other relationships, to information about us.

Issuance of Common Stock upon Conversion of Redeemable Convertible Preferred Stock and Convertible Promissory Notes

On January 25, 2023, upon consummation of our IPO, (i) all shares of our then-outstanding redeemable convertible preferred stock automatically converted into 8,355,610 shares of common stock, (ii) certain convertible promissory notes and accrued and unpaid interest and loan fees thereunder automatically converted into 4,134,367 shares of common stock and (iii) certain earned and unpaid dividends on our Series H preferred stock were issued in satisfaction of such obligations into 272,101 shares of common stock. The common stock was issued pursuant to the exemption from the registration requirements of the Securities Act provided by Section 3(a)(9) or Section 4(2) of the Securities Act.

Item 6. Reserved

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

The following discussion and analysis should be read in conjunction with "Selected Financial Data" and our financial statements and related notes included elsewhere in this Annual Report. This discussion and analysis and other parts of this Annual Report contain forward-looking statements based upon current beliefs that involve risks, uncertainties and assumptions, such as statements regarding our plans, objectives, expectations and intentions. Our actual results and the timing of selected events could differ materially from those described in or implied by these forward-looking statements as a result of several factors, including those set forth under "Risk Factors" and elsewhere in this Annual Report. You should carefully read the "Risk Factors" section of this Annual Report to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section entitled "Special Note Regarding Forward- Looking Statements."

Overview

Genelux is a late clinical-stage biopharmaceutical company focused on developing a pipeline of next-generation oncolytic viral immunotherapies for patients suffering from aggressive and/or difficult-to-treat solid tumor types. Our most advanced product candidate, Olvi-Vec, is a proprietary, modified strain of the VACV, a stable DNA virus with a large engineering capacity. We have met the preestablished endpoint for our Phase clinical 2 trial of Olvi-Vec in PRROC. Employing our CHOICE platform, we have developed an extensive library of isolated and engineered oncolytic vaccinia virus immunotherapeutic product candidates. These provide potential utility in multiple tumor types in both the monotherapy and combination therapy settings, via physician- preferred administration techniques, including regional (e.g., intraperitoneal), local and systemic (e.g., intravenous) delivery routes. Informed by our CHOICE platform and supported by extensive clinical and pre-clinical data, we believe we have the capacity to develop a pipeline of treatment options to address high unmet medical needs for those patients with insignificant or unsatisfactory responses to standard-of-care therapies, including chemotherapies. From this library, we selected Olvi-Vec, which we believe has the potential to exhibit anti-tumor properties, including potent oncolytic properties (tumor cell lysis) and to activate both the innate and adaptive arms of the immune system, to produce favorable changes within the tumor microenvironment. The personalized and multi-modal immune activation generated by Olvi-Vec is designed with the goal to yield clinically- meaningful anti-tumor responses to virus treatment alone and in combination with other existing treatment modalities. We believe Olvi-Vec currently represents the most advanced clinical development program throughout the oncolytic treatment landscape involving the non-local administration (e.g., non-intratumorally) of viral immunotherapies.

Since inception, our operations have focused on organizing and staffing our company, business planning, raising capital, acquiring and developing our technology, establishing our intellectual property portfolio, identifying potential product candidates and undertaking preclinical and clinical studies and manufacturing. We do not have any products approved for sale and have not generated any revenue from product sales.

Since inception, we have incurred significant operating losses. Our net losses were $5.2 million and $16.4 million for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, we had an accumulated deficit of $189.8 million. We expect to continue to incur significant and increasing expenses and operating losses for the foreseeable future, as we advance our current and future product candidates through preclinical and clinical development, manufacture drug product and drug supply, seek regulatory approval for our current and future product candidates, maintain and expand our intellectual property portfolio, hire additional research and development and business personnel and operate as a public company.

In March 2020, the World Health Organization declared COVID-19 a global pandemic and the United States declared a national emergency with respect to COVID-19. In response to the COVID-19 pandemic, a number of governmental orders and other public health guidance measures have been implemented across much of the United States, including in the locations of our office, clinical trial sites and third parties on whom we rely. As the COVID-19 pandemic started to spread in the first half of 2020, our clinical trial sites reported it had the most impact on patient care as facilities were generally ill prepared to conduct business as usual; adequate clinical evaluations, physical exams and tests were either absent or drastically reduced. Our clinical trial sites further reported that their institutions better adjusted to pandemic conditions beginning in the second half of 2020. Further, we have implemented a work-from-home policy allowing employees who can work from home to do so, while those needing to work in manufacturing facilities work in shifts to reduce the number of people gathered together at one time. Business travel has been suspended, and online and teleconference technology is used to meet virtually rather than in person. We have taken measures to secure our research and development project activities, while work in laboratories has been organized to reduce risk of COVID-19 transmission. Our increased reliance on personnel working from home may negatively impact productivity, or disrupt, delay or otherwise adversely impact our business.

We will not generate revenue from commercially approved product sales unless and until we successfully complete clinical development and obtain regulatory approval for our product candidates. In addition, if we obtain regulatory approval for our product candidates and do not enter into a third-party commercialization partnership, we expect to incur significant expenses related to developing our commercialization capability to support product sales, marketing, manufacturing, and distribution activities.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of public or private equity offerings and debt financings or other sources, such as potential collaboration agreements, strategic alliances and licensing arrangements. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on acceptable terms, or at all. Our failure to raise capital or enter into such agreements as, and when needed, could have a material adverse effect on our business, results of operations and financial condition.

The report of our independent registered public accounting firm on our financial statements as of and for the years ended December 31, 2022 and 2021 included an explanatory paragraph indicating that there was substantial doubt about our ability to continue as a going concern. See Note 1 to our annual financial statements for additional information on our assessment.

As of December 31, 2022, we had a cash balance of $0.4 million. Subsequent to December 31, 2022, we closed our IPO of our common stock and received net proceeds of approximately $12.4 million. We expect the proceeds from the IPO, plus our cash on hand, will last for at least 12 months from the closing of our IPO.

Joint Venture with TVAX Biomedical, Inc.

In January 2019, we formed V2ACT as a joint venture with TVAX for the purpose of developing and testing V2ACT Immunotherapy. The joint venture is governed by an Amended and Restated Limited Liability Company Agreement entered into in June 2021, which provides each of us and TVAX with 50% ownership interests, identical voting and management rights and responsibilities, equal representation on the governing four-member management committee, and equal sharing of profits and losses of V2ACT. To date, V2ACT’s expenses have been de minimis and have been funded through equal capital contributions made to V2ACT by us and TVAX, and we expect this to continue for the foreseeable future.

Through December 31, 2022, there had been virtually no operating activities at V2ACT and de minimis financial activities, all of which our joint venture partner had day-to-day control over. For accounting purposes, we treated the joint venture as a non-consolidated subsidiary and all expenses, totaling less than $0.1 million during the years ended December 31, 2022 and 2021, have been expensed as incurred. Through the date of this filing, the joint venture has also not entered into any material third party commitments.

Components of Results of Operations

Net Sales

There was no revenue recorded from any sources during the year ended December 31, 2021. During the years ended December 31, 2022 and 2021, we received a combined $9.9 million of upfront and milestone payments under our license agreements with Newsoara and ELIAS (this amount was net of a 10% foreign income tax on the Newsoara payments). As of December 31, 2021, we determined that since we did not complete certain obligations under those agreements as of that date, that revenue recognition would be recognized at such time as we met those performance obligations. As such, as of December 31, 2021, we delayed recognition of any revenue under these contracts and the cash received of $4.5 million had been recorded as deferred revenue. During the year ended December 31, 2022, under our Newsoara agreement, we completed the transfer of our manufacturing technology, at which point we completed our performance obligation and thus recognized the related revenue of $11.0 million, with the 10% foreign income tax of $1.1 million being recorded as a provision for foreign income taxes. Under no circumstances would we be required to repay the $9.9 million received under the license agreement. During the year ended December 31, 2022, under our ELIAS agreement, we completed the transfer of our manufacturing technology, at which point we completed our performance obligation and thus recognized the related revenue of $0.06 million.

Operating Expenses

Our operating expenses consist of (i) research and development expenses and (ii) general and administrative expenses.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our research and development activities, including our product candidate discovery efforts and preclinical and clinical studies under our research programs, which include:

- employee-related expenses, including salaries, benefits and stock-based compensation expense for our research and development personnel;
- costs of funding research performed by third parties that conduct research and development and preclinical and clinical activities on our behalf;
- costs of manufacturing drug product and drug supply related to our current or future product candidates;
- costs of conducting preclinical studies and clinical trials of our product candidates;
- consulting and professional fees related to research and development activities, including equity-based compensation to non-employees;
- costs of maintaining our laboratory, including purchasing laboratory supplies and non-capital equipment used in our preclinical studies;
- costs related to compliance with clinical regulatory requirements; and
- facility costs and other allocated expenses, which include expenses for rent and maintenance of facilities, insurance, depreciation and other supplies.

Research and development costs are expensed as incurred. Costs for certain activities are recognized based on an evaluation of the progress to completion of specific tasks using data such as information provided to us by our vendors and analyzing the progress of our preclinical and clinical studies or other services performed. Significant judgment and estimates are made in determining the accrued expense balances at the end of any reporting period.

The successful development of our product candidates is highly uncertain. We cannot reasonably estimate or know the nature, timing, and estimated costs of the efforts that will be necessary to complete development of our current or future product candidates. We are also unable to predict when, if ever, material net cash inflows will commence from the sale of our product candidates, if they are approved. This is due to the numerous risks and uncertainties associated with developing product candidates, including the uncertainty of:

- the scope, rate of progress, and expenses of our ongoing research activities as well as any preclinical studies and clinical trials and other research and development activities;
- establishing an appropriate safety profile;
- successful enrollment in and completion of clinical trials;
- whether our product candidates show safety and efficacy in our clinical trials;
- receipt of marketing approvals from applicable regulatory authorities;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- commercializing product candidates, if and when approved, whether alone or in collaboration with others; and
- continued acceptable safety profile of the products following any regulatory approval.

A change in the outcome of any of these variables with respect to the development of our current and future product candidates would significantly change the costs and timing associated with the development of those product candidates.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect research and development costs to increase significantly for the foreseeable future as we commence clinical trials and continue the development of our current and future product candidates. However, we do not believe that it is possible at this time to accurately project expenses through commercialization. There are numerous factors associated with the successful commercialization of any of our product candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. Additionally, future commercial and regulatory factors beyond our control will impact our clinical development programs and plans.

General and Administrative Expenses

General and administrative expenses include salaries and other compensation-related costs, including stock-based compensation, for personnel in executive, finance and accounting, business development, operations and administrative roles. Other significant costs include professional service and consulting fees, including legal fees relating to intellectual property and corporate matters, accounting fees, recruiting costs and costs for consultants who we utilize to supplement our personnel, insurance costs, travel costs, facility and office-related costs not included in research and development expenses.

We anticipate that our general and administrative expenses will increase in the future as our business expands to support expected growth in research and development activities, including our future clinical programs. These increases will likely include increased costs related to the hiring of additional personnel and fees to outside service providers, among other expenses. We also anticipate increased expenses associated with being a public company, including costs for audit, legal, regulatory and tax-related services related to compliance with the rules and regulations of the SEC, and listing standards applicable to companies listed on a national securities exchange, director and officer insurance premiums, and investor relations costs. In addition, if we obtain regulatory approval for any of our product candidates and do not enter into a third-party commercialization collaboration, we expect to incur significant expenses related to building a sales and marketing team to support product sales, marketing and distribution activities.

Results of Operations

Comparison of the Years Ended December 31, 2022 and 2021

The following table summarizes our results of operations for the years ended December 31, 2022 and 2021 (in thousands):

	December 31, 2022	December 31, 2021
Revenues	$ 11,068	$ —
Operating Expenses:		
Research and development	9,078	6,319
General and administrative	5,003	8,294
Total operating expenses	14,081	14,613
Loss from operations	(3,013)	(14,613)
Interest expense	(1,150)	(1,221)
Debt discount amortization	(258)	(196)
Financing costs	—	(398)
Gain on forgiveness of PPP loan payable	314	—
Gain on settlement of convertible notes payable	—	50
Loss before provision for foreign income taxes	(4,107)	(16,378)
Provision for foreign income taxes	(1,100)	—
Net loss	$ (5,207)	$ (16,378)

Research and Development Expenses

The table below summarizes our research and development expenses for the years ended December 31, 2022 and 2021 (in thousands):

Research and Development Expenses:	December 31, 2022	December 31, 2021
Employee compensation and related expenses	$ 1,531	$ 1,414
Stock compensation	368	957
Manufacturing and laboratory materials and other expenses	937	810
Outsourced manufacturing services	908	770
Clinical and regulatory expenses	3,252	400
Facility-related expenses, including depreciation	1,278	1,137
Consulting expenses	746	797
Other expenses	58	34
Total research and development expenses	$ 9,078	$ 6,319

Research and development expenses were $9.1 million and $6.3 million for the years ended December 31, 2022 and 2021, respectively, an increase of $2.8 million, or 44%. Significant variations between periods are as follows:

- a $0.6 million decrease in stock compensation expense in 2022, primarily resulting from the completion of the expense amortization from previously granted stock options;
- a $2.9 million increase in consulting and regulatory expenses in 2022, primarily resulting from expenses relating to the preparations of our Phase 3 registration clinical trial in PRROC.

General and Administrative Expenses

The table below summarizes our general and administrative expenses for the years ended December 31, 2022 and 2021 (in thousands):

General and Administrative Expenses:	December 31, 2022	December 31, 2021
Employee compensation and related expenses	$ 1,520	$ 1,225
Stock compensation, including the cost of stock option modifications	2,047	3,314
Professional services	290	1,719
Facility-related expenses	319	293
Insurance expenses	334	316
Consulting and contract labor expenses	305	1,082
Other expenses	188	345
Total general and administrative expenses	$ 5,003	$ 8,294

General and administrative expenses were $5.0 million and $8.3 million for the years ended December 31, 2022 and 2021, respectively, a decrease of $3.3 million, or 40%. Significant variations between periods are as follows:

- a $0.3 million increase in employee compensation related expenses in 2022, primarily due to hiring during the fourth quarter of 2021 and continuing in 2022;
- a $1.3 million decrease in stock compensation expense in 2022, primarily due to stock option modification costs in 2021;

- a $1.4 million decrease in professional service expenses in 2022, primarily resulting from decreased legal costs related to intellectual property, and to reduced corporate legal costs; and
- a $0.8 million decrease in consulting and contract labor expenses in 2022, primarily related to the decreased cost of accounting and finance consultants and investor relations consultants.

Other Income (Expenses)

Other income (expenses) was a net $(1.1) million and $(1.8) million for the years ended December 31, 2022 and 2021, respectively. During the year ended December 31, 2022, other expenses consisted of interest expense of $1.2 million and debt discount amortization of $0.3 million, while during the same period in 2021, other expenses consisted of interest expense of $1.2 million, debt discount amortization of $0.2 million and financing costs of $0.4 million. During the year ended December 31, 2022, other income consisted of a gain on the forgiveness of a Paycheck Protection Program (PPP) loan payable of $0.3 million, while during the same period in 2021, other income consisted of a gain on the settlement of a convertible note payable of $0.05 million.

Liquidity and Capital Resources

Going Concern

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. During the year ended December 31, 2022, we incurred a net loss of $5.2 million and used cash in operations of $3.6 million and had a shareholders' deficit of $35.8 million as of December 31, 2022. These factors raise substantial doubt about our ability to continue as a going concern. Our ability to continue as a going concern is dependent upon our ability to raise additional funds and implement our strategies, such as executing additional licensing contracts. The financial statements do not include any adjustments that might be necessary if we are unable to continue as a going concern.

As of December 31, 2022, we had cash on hand in the amount of $0.4 million. The ability to continue as a going concern is dependent on us raising additional capital and attaining and maintaining profitable operations in the future to meet our obligations and repay our liabilities arising from normal business operations when they come due. Since inception, we have funded our operations primarily through equity and debt financings and licensing income and we expect to continue to rely on these sources of capital in the future. Subsequent to December 31, 2022, we closed our initial public offering of our common stock (IPO) and received net proceeds of approximately $12.4 million. We expect the proceeds from the IPO, plus our cash on hand, will last for at least 12 months from the closing of the IPO.

No assurance can be given that any future financing will be available or, if available, that it will be on terms that are satisfactory to us. Even if we are able to obtain additional financing, it may contain undue restrictions on our operations, in the case of debt financing, or cause substantial dilution for our stockholders, in the case of equity financing, or grant unfavorable terms in licensing agreements.

Cash Flows

The table below summarizes our cash flow activities for the years ended December 31, 2022 and 2021 (in thousands):

Net cash provided by (used in):	December 31, 2022	December 31, 2021
Operating activities	$ (3,571)	$ (6,585)
Investing activities	(49)	—
Financing activities	(478)	(270)
Net decrease in cash	$ (4,098)	$ (6,855)

Operating Activities

During the year ended December 31, 2022, we used cash from operating activities of $3.6 million, compared to $6.6 million used during the year ended December 31, 2021. During the year ended December 31, 2022, we incurred a net loss of $5.2 million and had non-cash expenses of $3.3 million, compared to a net loss of $16.4 million and non-cash expenses of $5.7 million during the year ended December 31, 2021. The primary non-cash expense during both years was stock compensation, totaling $2.4 million and $1.7 million during the years ended December 31, 2022 and 2021, respectively. The net change in assets and liabilities during the year ended December 31, 2022 used cash of $1.7 million compared to $4.1 million provided during the year ended December 31, 2021. The primary use of cash during the year ended December 31, 2022 was the decrease in deferred revenue of $4.3 million, while the primary source was the increase in accounts payable and accrued expenses of $2.3 million. The primary use of cash during the year ended December 31, 2021 was the increase in prepaid expenses of $1.2 million, while the primary sources were the increase in accounts payable and accrued expenses, accrued compensation and accrued interest payable totaling $1.1 million, and the increase in deferred revenue of $4.5 million.

Investing Activities

Net cash used in investing activities for the year ended December 31, 2022 was $0.05 million, consisting of the purchase of property and equipment. There was no cash used in investing activities for the year ended December 31, 2021.

Financing Activities

Net cash used in financing activities for the years ended December 31, 2022 and 2021 was $0.5 million and $0.3 million, respectively. For the year ended December 31, 2022, cash provided by financing activities consisted of proceeds from the issuance of notes payable-shareholders totaling $1.1 million and proceeds from the exercise of common stock warrants totaling $0.1 million. Cash used in financing activities during the year ended December 31, 2022 related to the repayment of convertible notes payable-shareholders of $0.1 million and the payment of deferred offering costs of $1.6 million. For the year ended December 31, 2021, cash provided by financing activities consisted of proceeds from the issuance of various debt offerings totaling $0.9 million and proceeds from the sale of common stock and warrants and the exercise of stock options and warrants totaling $0.3 million. Cash used in financing activities during the year ended December 31, 2021 related to the repayment of various notes payable totaling $1.5 million.

Funding Requirements

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue our research and development, initiate and conduct preclinical studies and clinical trials, and seek marketing approval for our current and any of our future product candidates. In addition, if we obtain marketing approval for any of our current or our future product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution, which costs we may seek to offset through entry into collaboration agreements with third parties. Furthermore, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on acceptable terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

We believe that our existing cash, together with the net proceeds from our IPO, will enable us to fund our operating expenses and capital expenditure requirements until at least 12 months from the closing of our IPO. We have based this estimate on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Our future capital requirements will depend on a number of factors, including:

- the costs of conducting preclinical studies and clinical trials;
- the costs of manufacturing;
- the scope, progress, results and costs of discovery, preclinical development, laboratory testing, and clinical trials for product candidates we may develop, if any;
- the costs, timing, and outcome of regulatory review of our product candidates;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- the achievement of milestones or occurrence of other developments that trigger payments under any license or collaboration agreements we might have at such time;
- the costs and timing of future commercialization activities, including product sales, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- the amount of revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval;
- the costs of preparing, filing and prosecuting patent applications, obtaining, maintaining and enforcing our intellectual property rights, and defending intellectual property-related claims;
- our headcount growth and associated costs as we expand our business operations and research and development activities; and
- the costs of operating as a public company.

The net proceeds of our IPO, together with our existing cash, will be sufficient to progress our Phase 3 registration trial of development of Olvi-Vec in PRROC, but will not be sufficient to progress registration trials in other indications or the development of any other product candidate. Accordingly, we will be required to obtain further funding to achieve our business objectives.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through public or private equity offerings and debt financings or other sources, such as potential collaboration agreements, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interests may be diluted, and the terms of these securities may include liquidation or other preferences that could adversely affect your rights as a common stockholder. Additional debt financing, if available, may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, that could adversely impact our ability to conduct our business.

If we raise funds through potential collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Critical Accounting Policies and Significant Judgments and Estimates

This Management’s Discussion and Analysis of Financial Condition and Results of Operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States (GAAP). The preparation of these financial statements requires us to make estimates, judgments and

assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities as of the date of the balance sheets and the reported amounts of expenses during the reporting periods. In accordance with GAAP, we base our estimates on historical experience and on various other assumptions that we believe are reasonable under the circumstances at the time such estimates are made. Actual results may differ materially from our estimates and judgments under different assumptions or conditions. We periodically review our estimates in light of changes in circumstances, facts and experience. The effects of material revisions in estimates are reflected in our financial statements prospectively from the date of the change in estimate.

We define our critical accounting policies as those accounting principles that require us to make subjective estimates and judgments about matters that are uncertain and are likely to have a material impact on our financial condition and results of operations, as well as the specific manner in which we apply those principles. While our significant accounting policies are more fully described in Note 2 to our audited financial statements appearing elsewhere in this Annual Report, we believe the following are the critical accounting policies used in the preparation of our financial statements that require significant estimates and judgments.

Prepaid Research and Development Expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued expenses as of each balance sheet date. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf, and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our research and development expenses as of each balance sheet date based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary.

The significant estimates in our prepaid research and development expenses include the costs incurred for services performed by our vendors in connection with research and development activities for which we have not yet been invoiced. We base our expenses related to research and development activities on our estimates of the services received and efforts expended pursuant to quotes and contracts with vendors that conduct research and development on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the research and development expense.

In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid balance accordingly. Non-refundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

Although we do not expect our estimates to be materially different from amounts incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, it could result in us reporting amounts that are too high or too low in any particular period.

Stock-Based Compensation

We measure stock options and other stock-based awards granted to employees and directors based on the fair value of the award on the date of the grant and recognize compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award. We recognize forfeitures as they occur. The reversal of compensation cost previously recognized for an award that is forfeited because of a failure to satisfy a service or performance condition is recognized in the period of the forfeiture. Generally, we issue stock options with only service-based vesting conditions and record the expense for these awards using the straight-line method over the requisite service period.

We classify equity-based compensation expense in our statements of operations in the same manner in which the award recipient's salary and related costs are classified or in which the award recipient's service payments are classified. In future periods, we expect equity-based compensation expense to increase, due in part to our existing unrecognized stock-based compensation expense and as we grant additional stock-based awards to continue to attract and retain employees.

Determination of the Fair Value of Equity-Based Awards

We estimate the fair value of stock option awards granted using the Black-Scholes option-pricing model, which uses as inputs the fair value of our common stock and subjective assumptions we make, including expected stock price volatility, the expected term of the award, the risk-free interest rate, and expected dividends. Due to the lack of a public market for the trading of our common stock and a lack of company-specific historical and implied volatility data, we base the estimate of expected stock price volatility on the historical volatility of a representative group of publicly traded companies for which historical information is available. The historical volatility is generally calculated based on a period of time commensurate with the expected term assumption. We use the simplified method to calculate the expected term for options granted to employees and directors. We utilize this method as we do not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. For options granted to non-employees, we utilize the contractual term. The risk- free interest rate is based on a U.S. treasury instrument whose term is consistent with the expected term of the stock options. The expected dividend yield is assumed to be zero, as we have never paid dividends and do not have current plans to pay any dividends on our common stock. We determine the fair value of restricted common stock awards based on the fair value of our common stock on the date of grant.

As there has been no public market for our common stock, prior to our IPO, the estimated fair value of our common stock had been approved by our board of directors, with input from management, as of the date of each award grant, considering our most recently available sale of our common stock to independent investors and our board of directors' assessment of additional objective and subjective factors deemed relevant that may have changed from the date of the most recent determination through the date of the grant.

The additional objective and subjective factors considered by our board of directors in determining the fair value of our common stock included the following:

- the prices of our common stock and preferred stock sold to outside investors in arm's length transactions, if any, and the rights, preferences and privileges of our preferred stock as compared to those of our common stock, including the liquidation preferences of our preferred stock;
- the progress of our research and development efforts, including the status of preclinical studies and planned clinical trials for our product candidates;
- the lack of liquidity of our equity as a private company;
- our stage of development and business strategy and the material risks related to our business and industry;
- the valuation of publicly traded companies in the biotechnology industry, as well as recently completed mergers and acquisitions of peer companies;
- any external market conditions affecting the biotechnology industry, and trends within the biotechnology industry;
- the likelihood of achieving a liquidity event, such as an IPO or a sale of our company in light of prevailing market conditions; and
- the analysis of IPOs and the market performance of similar companies in the biotechnology industry.

The assumptions underlying our board of directors' valuation determinations represented our board's best estimates, which involved inherent uncertainties and the application of our board's judgment. As a result, if factors or expected outcomes had changed or our board of directors had used significantly different assumptions or estimates, our equity-based compensation expense could have been materially different. Following the completion of this offering, our board of directors will determine the fair value of our common stock based on the quoted market prices of our common stock.

Commitments and Contingencies

From time to time, we may have certain contingent liabilities that arise in the ordinary course of business. We evaluate the likelihood of an unfavorable outcome in legal or regulatory proceedings to which we are a party and record a loss contingency on an undiscounted basis when it is probable that a liability has been incurred and the amount of the loss can be reasonably estimated. These judgments are subjective and based on the status of such legal proceedings, the merits of our defenses, and consultation with legal counsel. Actual outcomes of these legal proceedings may differ materially from our estimates. We estimate accruals for legal expenses when incurred as of each balance sheet date based on the facts and circumstances known to us at that time.

Off-Balance Sheet Arrangements

During the years ended December 31, 2022 and 2021, we did not have, and we do not currently have, any off-balance sheet arrangements (as defined under SEC rules).

Quantitative and Qualitative Disclosures about Market Risk

We are not currently exposed to significant market risk related to changes in foreign currency exchange rates. However, we have contracted with and may continue to contract with foreign vendors that are located in Europe. Our operations may be subject to fluctuations in foreign currency exchange rates in the future.

Inflation generally affects us by increasing our cost of labor. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the years ended December 31, 2022 or 2021.

Recent Accounting Pronouncements

For a description of recently issued accounting standards that may have a material impact on our financial statements or will otherwise apply to our operations, please see Note 2 to our audited financial statements appearing elsewhere in this Annual Report.

Emerging Growth Company Status

As an "emerging growth company," the Jumpstart Our Business Startups Act of 2012 permits us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have irrevocably elected to "opt out" of this provision and, as a result, we will comply with new or revised accounting standards when they are required to be adopted by public companies that are not emerging growth companies.

Item 7A. Quantitative and Qualitative Disclosures about Market Risks

We are not currently exposed to significant market risk related to changes in foreign currency exchange rates. However, we have contracted with and may continue to contract with foreign vendors that are located in Europe. Our operations may be subject to fluctuations in foreign currency exchange rates in the future.

Inflation generally affects us by increasing our cost of labor. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the years ended December 31, 2022 and 2021.

Item 8. Financial Statements and Supplementary Data

See the financial statements filed as part of this Annual Report on Form 10-K as listed under Item 15 below.

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

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, refers to controls and procedures 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 such information is accumulated and communicated to a company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures as of December 31, 2022. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at a reasonable assurance level as of December 31, 2022.

In designing and evaluating our disclosure controls and procedures, management recognizes that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a control system, misstatements due to error or fraud may occur and not be detected.

Management's Report on Internal Control Over Financial Reporting

This Annual Report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of our independent registered public accounting firm due to a transition period established by rules of the SEC for newly public companies.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) or 15d-15(f) of the Exchange Act) that occurred during the fourth quarter of 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

Item 9C. Disclosure Regarding Jurisdictions That Prevent Inspections

Not Applicable.

PART III

We will file a definitive Proxy Statement for our 2023 Annual Meeting of Stockholders (the 2023 Proxy Statement) with the SEC, pursuant to Regulation 14A, not later than 120 days after the end of our fiscal year. Accordingly, certain information required by Part III has been omitted under General Instruction G(3) to Form 10-K. Only those sections of the 2023 Proxy Statement that specifically address the items set forth herein are incorporated by reference.

Item 10. Directors, Executive Officers and Corporate Governance.

The text of our Code of Conduct, which applies to our directors and employees (including our principal executive officer, principal financial officer, and principal accounting officer or controller, and persons performing similar functions), is posted in the "Corporate Governance" section of our website, www.genelux.com. A copy of the Code of Conduct, can be obtained free of charge on our website. We intend to disclose on our website any amendments to, or waivers from, our Code of Conduct, that are required to be disclosed pursuant to the rules of the SEC and Nasdaq. The information contained on our website is not considered part of, or incorporated by reference into, this Annual Report on Form 10-K or any other filing that we make with the SEC.

The remaining information required under this item is set forth in our 2023 Proxy Statement, which 2023 Proxy Statement will be filed with the SEC not later than 120 days after the close of our fiscal year ended December 31, 2022, under the sections headed "Proposal 1: Election of Directors," "Information Regarding Director Nominees and Current Directors," "Information Regarding the Board of Directors and Corporate Governance" and "Executive Officers" and all of which is incorporated herein by reference.

Item 11. Executive Compensation.

The information required under this item is set forth in our 2023 Proxy Statement, which 2023 Proxy Statement will be filed with the SEC not later than 120 days after the close of our fiscal year ended December 31, 2022, under the section headed "Executive Compensation" and all of which is incorporated herein by reference.

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

The information required by Item 12 is set forth in our 2023 Proxy Statement under the captions "Security Ownership of Certain Beneficial Owners and Management" and "Securities Authorized for Issuance under Equity Compensation Plans," which 2023 Proxy Statement will be filed with the SEC not later than 120 days after the close of our fiscal year ended December 31, 2022, and all of which is incorporated herein by reference.

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

The information required by Item 13 is set forth in our 2023 Proxy Statement under the captions "Transactions with Related Persons" and "Independence of the Board of Directors," which 2023 Proxy Statement will be filed with the SEC not later than 120 days after the close of our fiscal year ended December 31, 2022, and all of which is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services.

Our independent public accounting firm is Weinberg & Company, P.A., Los Angeles, California (PCAOB Auditor ID: 572). The information required by Item 14 is set forth in our 2023 Proxy Statement under the caption "Ratification of Selection of Independent Registered Public Accounting Firm," which 2023 Proxy Statement will be filed with the SEC not later than 120 days after the close of our fiscal year ended December 31, 2022, under the section headed "Proposal 2: Ratification of Selection of Independent Registered Public Accounting Firm," and all of which is incorporated herein by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a)(1) Financial Statements.

For a list of the financial statements included herein, see Index on page F-1 of this report.

(a)(2) Financial Statement Schedules.

All required information is included in the financial statements or notes thereto.

(a)(3) List of Exhibits.

Item 16. Exhibits and Financial Statement Schedules.

(a) Exhibits.

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-41599), filed with the SEC on January 30, 2023).
3.2	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K (File No. 001-41599), filed with the SEC on January 30, 2023).
4.1	Form of Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-265828), as amended, originally filed with the SEC on August 29, 2022).

4.2	Investors' Rights Agreement, by and among the Registrant and AbbVie, Inc. and Aladar Szalay, Ph.D., dated January 2010 (incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-1 (File No. 333-265828), as amended, originally filed with the SEC on June 24, 2022).
4.3¥	Form of Warrant to Purchase Common Stock issued to WDC Fund I, dated September 2020 (incorporated by reference to Exhibit 4.3 to the Registrant's Registration Statement on Form S-1 (File No. 333-265828), as amended, originally filed with the SEC on June 24, 2022).
4.4	Agreement/Promissory Note, by and among the Registrant and Jillian and Curtis Helmer, dated April 2016, as amended (incorporated by reference to Exhibit 4.4 to the Registrant's Registration Statement on Form S-1 (File No. 333-265828), as amended, originally filed with the SEC on June 24, 2022).
4.5	Form of Umbrella Agreement Regarding Family Investments (incorporated by reference to Exhibit 4.5 to the Registrant's Registration Statement on Form S-1 (File No. 333-265828), as amended, originally filed with the SEC on June 24, 2022).
4.6	Form of Convertible Note Purchase Agreement under the Umbrella Agreement (incorporated by reference to Exhibit 4.5 to the Registrant's Registration Statement on Form S-1 (File No. 333-265828), as amended, originally filed with the SEC on June 24, 2022).
4.7	Form of Representative's Warrant (incorporated by reference to Exhibit 4.7 to the Registrant's Current Report on Form 8-K (File No. 001-41599), filed with the SEC on January 30, 2023).
10.1+	Genelux Corporation 2009 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-265828), as amended, originally filed with the SEC on June 24, 2022).
10.2+	Forms of Grant Notice, Stock Option Agreement and Notice of Exercise under the Genelux Corporation 2009 Equity Incentive Plan (incorporated by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-1 (File No. 333-265828), as amended, originally filed with the SEC on June 24, 2022).
10.3+	Genelux Corporation 2019 Equity Incentive Plan (incorporated by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form S-1 (File No. 333-265828), as amended, originally filed with the SEC on June 24, 2022).
10.4+	Forms of Grant Notice, Stock Option Agreement and Notice of Exercise under the Genelux Corporation 2019 Equity Incentive Plan (incorporated by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-1 (File No. 333-265828), as amended, originally filed with the SEC on June 24, 2022).
10.5+	Genelux Corporation 2022 Equity Incentive Plan (incorporated by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1 (File No. 333-265828), as amended, filed with the SEC on January 10, 2023).
10.6+	Forms of Grant Notice, Stock Option Agreement and Notice of Exercise under the Genelux Corporation 2022 Equity Incentive Plan (incorporated by reference to Exhibit 10.6 to the Registrant's Registration Statement on Form S-1 (File No. 333-265828), as amended, originally filed with the SEC on June 24, 2022).
10.7+	Genelux Corporation 2022 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.7 to the Registrant's Registration Statement on Form S-1 (File No. 333-265828), as amended, filed with the SEC on January 10, 2023).
10.8+	Genelux Corporation Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.8 to the Registrant's Registration Statement on Form S-1 (File No. 333-265828), as amended, originally filed with the SEC on June 24, 2022).
10.9+	Form of Indemnification Agreement by and between the Registrant and its directors and executive officers (incorporated by reference to Exhibit10.9 to the Registrant's Registration Statement on Form S-1 (File No. 333-265828), asamended, originally filed withthe SEC on June 24, 2022).

10.10+	Offer Letter, by and between the Registrant and Sean Ryder, dated September 29, 2021 (incorporated by reference to Exhibit 10.10 to the Registrant's Registration Statement on Form S-1 (File No. 333-265828), as amended, filed with the SEC on January 10, 2023).
10.11+	Offer Letter, by and between the Registrant and Doug Samuelson, dated September 27, 2022 (incorporated by reference to Exhibit 10.11 to the Registrant's Registration Statement on Form S-1 (File No. 333-265828), as amended, filed with the SEC on January 10, 2023).
10.12	Lease Agreement, by and between the Registrant and 1175-1177 Idaho Street, LLC, dated January 2012, as amended (incorporated by reference to Exhibit 10.12 to the Registrant's Registration Statement on Form S-1 (File No. 333-265828), as amended, originally filed with the SEC on June 24, 2022).
10.13	Lease Agreement, by and between the Registrant and Townsgate Property, LLC, dated as of August 2002 (incorporated by reference to Exhibit 10.13 to the Registrant's Registration Statement on Form S-1 (File No. 333-265828), as amended, originally filed with the SEC on June 24, 2022).
10.14	Industrial/Commercial Multi-Tenant Lease, by and between the Registrant and Marindustry Partners, LP, dated July 2018, as amended (incorporated by reference to Exhibit 10.14 to the Registrant's Registration Statement on Form S-1 (File No. 333-265828), as amended, originally filed with the SEC on June 24, 2022).
10.15	Amended and Restated Limited Liability Company Agreement, by and between the Registrant, TVAX Biomedical, Inc. and V2ACT Therapeutics, LLC, dated January 3, 2019 (incorporated by reference to Exhibit 10.15 to the Registrant's Registration Statement on Form S-1 (File No. 333-265828), as amended, originally filed with the SEC on June 24, 2022).
10.16¥#	License Agreement, by and between TVAX Biomedical, Inc. and V2ACT Therapeutics, LLC, dated June 18, 2021, asamended (incorporated by reference to Exhibit10.16 to the Registrant's Registration Statement on Form S-1 (File No. 333-265828), asamended, originally filed with the SEC on June 24, 2022).
10.17¥#	License Agreement, by and between the Registrant and V2ACT Therapeutics, LLC, dated June 18, 2021, as amended (incorporated by reference to Exhibit 10.17 to the Registrant's Registration Statement on Form S-1 (File No. 333-265828), as amended, originally filed with the SEC on June 24, 2022).
10.18¥#	License Agreement, by and between the Registrant and Newsoara BioPharma Co, Ltd., dated September 27, 2021 (incorporated by reference to Exhibit 10.18 to the Registrant's Registration Statement on Form S-1 (File No. 333-265828), as amended, originally filed with the SEC on June 24, 2022).
10.19¥#	License Agreement, by and between the Registrant and ELIAS Animal Health, LLC, dated November 15, 2021, as amended (incorporated by reference to Exhibit 10.19 to the Registrant's Registration Statement on Form S-1 (File No. 333-265828), as amended, originally filed with the SEC on June 24, 2022).
23.1*	Consent of Weinberg & Company, P.A., independent registered public accounting firm.
24.1*	Power of Attorney (included on the signature page hereto).
31.1*	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the-Sarbanes-Oxley Act of 2002.
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.

* Filed with this Annual Report on Form 10-K.
† This certification shall not be deemed filed for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of that Section, nor shall it be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.
\+ Indicates management contract or compensatory plan.
¥ Schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Registrant undertakes to furnish supplemental copies of any of the omitted schedules upon request by the SEC.
\# Pursuant to Item 601(b)(10) of Regulation S-K, certain portions of this exhibit have been omitted (indicated by "[***]") because the Registrant has determined that the information is not material and is the type that the Registrant treats as private or confidential.

Item 16. Form 10-K Summary

None.

SIGNATURES

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

Date: March 29, 2023

GENELUX CORPORATION

By: /s/ Thomas Zindrick
Name: Thomas Zindrick, J.D.
Title: President and Chief Executive Officer

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Thomas Zindrick, J.D. and Doug Samuelson, and each of them, as his or her true and lawful attorneys-in-fact and agents, each with the full power of substitution, for him or her and in his or her name, place or stead, 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 all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or their 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, as amended, this report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Thomas Zindrick Thomas Zindrick, J.D.	President, Chief Executive Officer and Chairman (Principal Executive and Financial Officer)	March 29, 2023
/s/ Doug Samuelson Doug Samuelson	Chief Financial Officer (Principal Accounting Officer)	March 29, 2023
/s/ Mary Mirabelli Mary Mirabelli	Director	March 29, 2023
/s/ James L. Tyree James L. Tyree	Director	March 29, 2023
/s/ John Thomas John Thomas, Ph.D.	Director	March 29, 2023
/s/ Gabe Woodward Gabe Woodward	Director	March 29, 2023

Genelux Corporation
Index to the Financial Statements
For the Years Ended December 31, 2022 and 2021

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders
Genelux Corporation
Westlake Village, California

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Genelux Corporation (the "Company") as of December 31, 2022 and 2021, the related statements of operations, shareholders' deficit, 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, 2022 and 2021, and the results of its operations and its cash flows for the years then ended 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 1, the Company incurred a net loss and used cash in operations during the year ended December 31, 2022, and the Company had a shareholders' deficit at December 31, 2022. These matters 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 1 to the financial statements. These financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

We have served as the Company's auditor since 2021.

/s/ Weinberg & Company, P.A.
Los Angeles, California
March 29, 2023

Genelux Corporation
Balance Sheets
(In thousands, except for share amounts and par value data)

	December 31, 2022	December 31, 2021
ASSETS		
Current Assets		
Cash	$ 397	$ 4,495
Prepaid expenses and other current assets	1,495	1,327
Total Current Assets	1,892	5,822
Property and equipment, net	644	1,148
Right of use asset	1,335	1,064
Deferred offering costs	1,568	—
Other assets	92	92
Total Other Assets	3,639	2,304
TOTAL ASSETS	$ 5,531	$ 8,126
LIABILITIES AND SHAREHOLDERS' DEFICIT		
Current Liabilities		
Accounts payable and accrued expenses	$ 6,775	$ 4,462
Accrued compensation	2,852	2,855
Accrued interest payable	1,178	634
Accrued interest payable—director and shareholders	3,817	3,475
Deferred revenue	170	4,500
Warrant liabilities	169	—
Lease liability, current portion	266	402
Notes payable—shareholders, net of debt discount of $108 in 2022	992	—
Convertible notes payable—shareholders, current portion, including $105 and $235 past due, respectively	15,407	6,155
Total Current Liabilities	31,626	22,483
Long-term Liabilities		
Lease liability, long-term portion	1,164	731
U.S. Small Business Administration PPP loan payable	—	314
Convertible notes payable, net of debt discount of $541 and $738, respectively	8,524	8,327
Convertible notes payable—shareholders, long-term portion	—	9,382
Total Long-term Liabilities	9,688	18,754
Total Liabilities	41,314	41,237
Shareholders' Deficit		
Preferred stock, Series A through K, par value $0.001, 29,927,994 shares authorized; 22,094,889 shares issued and outstanding, respectively;	22	22
Common stock, par value $0.001, 75,000,000 shares authorized; 9,126,726 and 9,110,060 shares issued and outstanding, respectively	9	9
Treasury stock, 433,333 shares, at cost	(433)	(433)
Additional paid-in capital	154,401	151,866
Accumulated other comprehensive income	2	2
Accumulated deficit	(189,784)	(184,577)
Total Shareholders' Deficit	(35,783)	(33,111)
TOTAL LIABILITIES AND SHAREHOLDERS' DEFICIT	$ 5,531	$ 8,126

The accompanying notes are an integral part of these financial statements.

Genelux Corporation
Statements of Operations
(in thousands, except for share amounts and per share data)

	Years Ended December 31,	
	2022	2021
Revenues	$ 11,068	$ —
Operating expenses:		
Research and development	9,078	6,319
General and administrative	5,003	8,294
Total operating expenses	14,081	14,613
Loss from operations	(3,013)	(14,613)
Other income (expenses):		
Interest expense	(1,150)	(1,221)
Debt discount amortization	(258)	(196)
Financing costs	—	(398)
Gain on forgiveness of PPP loan payable	314	—
Gain on settlement of convertible notes payable	—	50
Total other expenses, net	(1,094)	(1,765)
Loss before provision for foreign income taxes	(4,107)	(16,378)
Provision for foreign income taxes	(1,100)	—
NET LOSS	$ (5,207)	$ (16,378)
BASIC AND DILUTED LOSS PER COMMON SHARE	$ (0.57)	$ (1.81)
WEIGHTED-AVERAGE COMMON SHARES OUTSTANDING - BASIC AND DILUTED	9,116,489	9,033,027

The accompanying notes are an integral part of these financial statements.

Genelux Corporation
Statements of Shareholders' Deficit
(in thousands, except share amounts)

	Preferred Stock Series A through K		Common Stock		Treasury Stock			Accumulated Other		
	Shares	Amount	Shares	Amount	Shares	Amount	Additional Paid-in Capital	Comprehensive Income	Accumulated Deficit	Total
Balance, December 31, 2020	22,094,889	$ 22	8,889,434	$ 9	433,333	$ (433)	$ 145,973	$ 2	$ (168,228)	$(22,655)
Adjustment for adoption of ASU 2020-06	—	—	—	—	—	—	(594)	—	29	(565)
Common shares issued for cash, net	—	—	13,571	—			143	—	—	143
Stock compensation	—	—	—	—	—	—	1,663	—	—	1,663
Shares issued upon conversion of note payable from shareholders	—	—	18,687	—	—	—	281	—	—	281
Shares issued upon conversion of convertible note payable	—	—	171,228	—	—	—	1,161	—	—	1,161
Fair value of warrants issued upon conversion of loan payable from shareholder	—	—	—	—	—	—	398	—	—	398
Cost of stock option modifications	—	—	—	—	—	—	2,608	—	—	2,608
Exercise of stock warrants	—	—	17,024	—	—	—	144	—	—	144
Exercise of stock option	—	—	116	—	—	—	1			1
Fair value of stock warrant issued in connection with convertible loan payable	—	—	—	—	—	—	88	—	—	88
Net loss for the year ended December 31, 2021	—	—	—	—	—	—	—	—	(16,378)	(16,378)
Balance, December 31, 2021	22,094,889	22	9,110,060	9	433,333	(433)	151,866	2	(184,577)	(33,111)
Stock compensation	—	—	—	—	—	—	2,415	—	—	2,415
Shares issued upon exercises of stock warrants	—	—	16,666	—	—	—	120	—	—	120
Net loss for the year ended December 31, 2022	—	—	—	—	—	—	—	—	(5,207)	(5,207)
Balance, December 31, 2022	22,094,889	$ 22	9,126,726	$ 9	433,333	$ (433)	$ 154,401	$ 2	$ (189,784)	$(35,783)

The accompanying notes are an integral part of these financial statements.

Genelux Corporation
Statements of Cash Flows
(In thousands)

	Years Ended December 31,	
	2022	2021
Cash Flows from Operating Activities		
Net loss	$(5,207)	$(16,378)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	553	553
Right-of-use asset	415	342
Amortization of debt discount	258	196
Gain on settlement of convertible note payable	—	(50)
Cost of stock option modifications	—	2,608
Fair value of warrants issued upon conversion of loan payable from shareholder	—	398
Stock compensation	2,415	1,663
Gain on forgiveness of PPP loan payable	(314)	—
Changes in Assets and Liabilities		
(Increase) Decrease in:		
Prepaid expenses and other assets	(168)	(1,212)
(Decrease) Increase in:		
Accounts payable and accrued expenses	2,313	754
Accrued compensation	(3)	15
Accrued interest payable	886	310
Deferred revenue	(4,330)	4,500
Lease liability	(389)	(284)
Net cash used in operating activities	(3,571)	(6,585)
Cash Flows from Investing Activities		
Purchases of property and equipment	(49)	—
Net cash used in investing activities	(49)	—
Cash Flows from Financing Activities		
Proceeds from convertible notes payable - shareholders	—	18
Repayment of convertible notes payable - shareholders	(130)	(1,445)
Proceeds from convertible notes payable	—	919
Repayment of convertible note payable	—	(50)
Proceeds from notes payable - shareholders	1,100	—
Payment of deferred offering costs	(1,568)	—
Proceeds from the exercises of stock warrants	120	144
Proceeds from the exercise of stock option	—	1
Proceeds from common stock and warrants issued for cash	—	143
Net cash used in financing activities	(478)	(270)
Net decrease in cash	(4,098)	(6,855)
Cash beginning of period	4,495	11,350
Cash end of period	$ 397	$ 4,495
Supplemental cash flows disclosures:		
Interest paid	$ 264	$ 912
Taxes paid	$ —	$ —
Supplemental non-cash financing disclosures:		
Initial recognition of right-of-use assets and operating lease liabilities upon execution of new leases	$ 686	$ 656
Conversion of convertible note payable and accrued interest into shares of common stock	$ —	$ 1,442
Fair value of warrant recorded as debt discount on issuance of convertible note payable	$ —	$ 88
Effect of adoption of ASU 2020-06	$ —	$ 565

The accompanying notes are an integral part of these financial statements.

GENELUX CORPORATION
NOTES TO FINANCIAL STATEMENTS
FOR THE YEARS ENDED DECEMBER 31, 2022 and 2021
(In thousands, except for share amounts and per share data)

NOTE 1 – BASIS OF PRESENTATION

Organization and Operations

Genelux Corporation ("Genelux" or the "Company"), a Delaware Corporation, incorporated on September 4, 2001, is a biomedical company located in Westlake Village, California. The Company is engaged in the research and development of diagnostic and therapeutic solutions for cancer for which there is no effective treatment today. The Company is focused on the development of therapeutic approaches for cancer that are designed to generate a personalized multi-prong attack to overwhelm a tumor's sophisticated defense mechanisms.

COVID-19 Considerations

During the year ended December 31, 2022, the COVID-19 pandemic did not have a material net impact on our operating results, but did have an impact on our supply chain. In response to the COVID-19 pandemic, a number of governmental orders and other public health guidance measures have been implemented across much of the United States, including in the locations of our office, clinical trial sites and third parties on whom we rely.

Our ability to operate without significant negative operational impact from the COVID-19 pandemic will in part depend on our ability to protect our employees and our supply chain. The Company has endeavored to follow the recommended actions of government and health authorities to protect our employees. Since the onset of the COVID-19 pandemic, we maintained the consistency of our operations. However, the uncertainty resulting from the pandemic could result in an unforeseen disruption to our workforce and supply chain (for example, an inability of a key supplier or transportation supplier to source and transport materials) that could negatively impact our operations. We anticipate that our clinical development timelines could be negatively affected by COVID-19, which could materially and adversely affect our business, financial condition and results of operations.

Through December 31, 2022, the COVID-19 pandemic has not negatively impacted the Company's liquidity position as of such date. During the year ended December 31, 2022, the Company generated cash flows through its licensing agreements to meet its short-term liquidity needs, but it expects to maintain access to the shareholder loans and equity financings, if needed, and potentially future payments under existing and new licensing agreements. The Company has not observed any material impairments of its assets or a significant change in the fair value of its assets due to the COVID-19 pandemic.

Going Concern

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. As reflected in the accompanying financial statements, the Company incurred a net loss of $5,207 and used cash in operations of $3,571 during the year ended December 31, 2022, and had a shareholders' deficit of $35,783 as of December 31, 2022. These factors raise substantial doubt about the Company's ability to continue as a going concern. The ability of the Company to continue as a going concern is dependent upon the Company's ability to raise additional funds and implement its strategies. The financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

At December 31, 2022, the Company had cash on hand in the amount of $397. The ability to continue as a going concern is dependent on the Company attaining and maintaining profitable operations in the future and raising additional capital to meet its obligations and repay its liabilities arising from normal business operations when they come due. Since inception, the Company has funded its operations primarily through equity and debt financings, and licensing income, and it expects to continue to rely on these sources of capital in the future. Subsequent to December 31, 2022, the Company closed its initial public offering (IPO) of its common stock and received net proceeds of approximately $12,400. The Company expects the proceeds from the IPO, plus its cash on hand, will last until at least 12 months from the closing of the IPO.

No assurance can be given that any future financing will be available or, if available, that it will be on terms that are satisfactory to the Company. Even if the Company is able to obtain additional financing, it may contain undue restrictions on our operations, in the case of debt financing, or cause substantial dilution for our stockholders, in case of equity financing, or grant unfavorable terms in licensing future licensing agreements.

Reverse Stock Split

In August 2022, the Company effected a 1-for-3 reverse stock split of its common stock. The par value and the authorized shares of the common stock were not adjusted as a result of the reverse stock split. The reverse stock split resulted in an adjustment to the conversion prices of the convertible preferred stock to reflect a proportional decrease in the number of shares of common stock to be issued upon conversion. The accompanying financial statements and notes to the financial statements give retroactive effect to the reverse stock split for all periods presented.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Use of Estimates

The preparation of the financial statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the financial statement date, and reported amounts of revenue and expenses during the reporting period. Significant estimates are used in the valuation of accruals for potential liabilities, valuations of stock-based compensation, and realization of deferred tax assets, among others. Actual results could differ from these estimates.

Income (Loss) Per Share

Basic loss per share is computed by dividing net loss applicable to common stockholders by the weighted average number of outstanding common shares during the period. Diluted loss per share is computed by dividing the net loss applicable to common stockholders by the weighted average number of common shares outstanding plus the number of additional common shares that would have been outstanding if all dilutive potential common shares had been issued.

For the years ended December 31, 2022 and 2021, the basic and diluted shares outstanding were the same, as potentially dilutive shares were considered anti-dilutive. The potentially dilutive securities consisted of the following:

	December 31, 2022	December 31, 2021
Convertible notes payable	3,394,569	2,730,878
Common stock equivalent of Series A through K convertible preferred stock	7,567,630	7,567,630
Stock options	4,201,019	3,953,233
Stock warrants	725,174	823,124
Stock warrants, issuable upon conversion of notes payable	183,852	183,852
Total	16,072,244	15,258,717

Revenue Recognition

The Company records revenue under the guidance of Accounting Standards Codification (“ASC”) 606, *Revenue from Contracts with Customers (Topic 606)* which requires a company to recognize revenue to depict the transfer of goods or services to a customer at an amount that reflects the consideration it expects to receive in exchange for those goods or services.

The Company determines revenue recognition through the following steps:

- Identification of the contract, or contracts, with a customer
- Identification of the performance obligations in the contract
- Determination of the transaction price
- Allocation of the transaction price to the performance obligations in the contract
- Recognition of revenue when, or as, we satisfy a performance obligation.

Under certain of the Company's licensing, supply and collaboration agreements, it is entitled to receive payment upon the achievement of contingent milestone events or the performance of obligations. The Company recognizes revenue based on guidance in ASC 606. In evaluating revenue recognition under a license agreement, the Company uses a two-step process for determining whether a promised good or service (including a license of intellectual property) is distinct and, therefore, is a performance obligation: (1) consideration of the individual good or service (i.e., whether the good or service is capable of being distinct); and (2) consideration of whether the good or service is separately identifiable from other promises in the contract (i.e., whether the promise to transfer the good or service is distinct in the context of the contract). Amounts received prior to satisfying the revenue recognition criteria are recorded as deferred revenue on the Company's balance sheet. Amounts expected to be recognized as revenue in the next 12 months following the balance sheet date are classified as current liabilities.

Concentration of Credit Risk

Financial instruments, which potentially subject the Company to concentration of credit risk, consist primarily of cash deposits. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. Management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held. The Company has not experienced any losses on deposits since inception.

Deferred Offering Costs

The Company capitalizes certain legal, professional, accounting and other third-party fees that are directly associated with in-process equity issuances as deferred offering costs until such equity issuances are consummated. After consummation of the equity issuance, these costs are recorded as a reduction in the capitalized amount associated with the equity issuance. Should the equity issuance be delayed or abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the Statement of Operations. During the year ended December 31, 2022, the Company incurred $1,568 of deferred offering costs related to the Company's proposed initial public offering ("IPO"). Subsequent to December 31, 2022, the Company closed its IPO and the deferred offering costs will be recorded against the net proceeds received from the IPO during the three months ended March 31, 2023.

Property and Equipment

Property and equipment are recorded at cost, less accumulated depreciation and amortization. Property and equipment is depreciated over the estimated useful life of the asset or the term of the lease using the straight-line method, whichever is shorter. Maintenance and repairs are charged to expense as incurred. At the time depreciable property is retired or otherwise disposed of, the related cost and accumulated depreciation or amortization are removed from the accounts and any resulting gain or loss is reflected in operations. The Company has determined the estimated useful lives of its property and equipment, as follows:

Furniture and office equipment	5 years
Laboratory equipment	5 years
Computer equipment	3 years
Leasehold improvements	Life of lease

Management assesses the carrying value of property and equipment whenever events or changes in circumstances indicate that the carrying value may not be recoverable. If there is indication of impairment, management prepares an estimate of future cash flows expected to result from the use of the asset and its eventual disposition. If these cash flows are less than the carrying amount of the asset, an impairment loss is recognized to write down the asset to its estimated fair value.

Fair Value of Financial Instruments

The Company determines the fair value of its assets and liabilities based on the exchange price in U.S. dollars that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value maximize the use of observable inputs and minimize the use of unobservable inputs. The Company uses a fair value hierarchy with three levels of inputs, of which the first two are considered observable and the last unobservable, to measure fair value:

- *Level 1* — Quoted prices in active markets for identical assets or liabilities.
- *Level 2* — Inputs, other than Level 1, that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- *Level 3* — Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The carrying amount of the Company's warrant liabilities of $169 at December 31, 2022 was based on Level 3 measurements. The carrying amounts of financial instruments such as cash, and accounts payable and accrued liabilities, approximate the related fair values due to the short-term maturities of these instruments. The carrying amounts of the Company's convertible notes payable approximate their fair values as the interest rates of the notes payable are based on prevailing market rates.

Income Taxes

Income tax expense is based on pretax financial accounting income. Deferred tax assets and liabilities are recognized for the expected tax consequences of temporary differences between the tax bases of assets and liabilities and their reported amounts. Valuation allowances are recorded to reduce deferred tax assets to the amount that will more likely than not be realized. The Company recorded a valuation allowance against its deferred tax assets as of December 31, 2022 and 2021.

The Company accounts for uncertainty in income taxes using a two-step approach to recognizing and measuring uncertain tax positions. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50 percent likely of being realized upon settlement. The Company classifies the liability for unrecognized tax benefits as current to the extent that the Company anticipates payment (or receipt) of cash within one year. Interest and penalties related to uncertain tax positions are recognized in the provision for income taxes.

Patents and Patent Application Costs

Although the Company believes that its patents and underlying technology have continuing value, the amount of future benefits to be derived from the patents is uncertain. Patent costs are therefore expensed as incurred and are included in General and administrative expenses on the accompanying Statements of Operations. Patent expenses were $88 and $195 during the years ended December 31, 2022 and 2021, respectively.

Research and Development Costs

Research and development expenses are expensed as incurred. Research and development expenses consist of costs incurred to discover, research and develop drug candidates, including compensation-related expenses for research and development personnel, including stock-based compensation expense, preclinical and clinical activities, costs of manufacturing, overhead expenses including facilities and laboratory expenses, materials and supplies, amounts paid to consultants and outside service providers, and depreciation and amortization.

Payments made pursuant to research and development contracts are initially recorded as advances on research and development contract services in the Company's balance sheet and are then charged to research and development costs in the Company's statement of operations as those contract services are performed. Expenses incurred under research and development contracts in excess of amounts advanced are recorded as research and development contract liabilities in the Company's balance sheet, with a corresponding charge to research and development costs in the Company's statement of operations. The Company reviews the status of its research and development contracts on a quarterly basis.

Stock-Based Compensation

The Company measures all stock options and other stock-based awards granted based on the fair value of the award on the date of the grant and recognizes compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award. The Company has elected to recognize forfeitures as they occur. The reversal of compensation cost previously recognized for an award that is forfeited because of a failure to satisfy a service or performance condition is recognized in the period of the forfeiture. Generally, the Company issues stock options with only service-based vesting conditions and records the expense for these awards using the straight-line method over the requisite service period.

The Company classifies stock-based compensation expense in its statements of operations in the same manner in which the award recipient's payroll costs are classified or in which the award recipients' service payments are classified.

The Company was a private company until the completion of its IPO on January 30, 2023. In 2022 and prior, the Company estimated the fair value of common stock using an appropriate valuation methodology, in accordance with the framework of the American Institute of Certified Public Accountants' Technical Practice Aid, Valuation of Privately-Held Company Equity Securities Issued as Compensation. Each valuation methodology includes estimates and assumptions that require the Company's judgment. These estimates and assumptions include a number of objective and subjective factors, including external market conditions, guideline public company information, the prices at which the Company sold its common stock to third parties in arms' length transactions, the rights and preferences of securities senior to the Company's common stock at the time, and the likelihood of achieving a liquidity event such as an initial public offering or sale. Significant changes to the assumptions used in the valuations could result in different fair values of stock options at each valuation date, as applicable.

The fair value of each stock option grant is estimated using the Black-Scholes option-pricing model. The Company was a private company and lacked company-specific historical and implied volatility information. Therefore, it estimated its expected stock volatility based on the historical volatility of a publicly traded set of peer companies within the biotechnology industry with characteristics similar to the Company. The expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The expected term of stock options granted to non-employees is equal to the contractual term of the option award. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is zero, based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

Leases

The Company accounts for its leases in accordance with the guidance of ASC 842, *Leases*. The Company determines whether a contract is, or contains, a lease at inception. Right-of-use assets represent the Company's right to use an underlying asset during the lease term, and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Right-of-use assets and lease liabilities are recognized at lease commencement based upon the estimated present value of unpaid lease payments over the lease term. The Company uses its incremental borrowing rate based on the information available at lease commencement in determining the present value of unpaid lease payments.

Recent Accounting Pronouncements

In June 2016, the FASB issued ASU No. 2016-13, Credit Losses—Measurement of Credit Losses on Financial Instruments ("ASC 326"). The standard significantly changes how entities will measure credit losses for most financial assets, including accounts and notes receivables. The standard will replace today's "incurred loss" approach with an "expected loss" model, under which companies will recognize allowances based on expected rather than incurred losses. Entities will apply the standard's provisions as a cumulative-effect adjustment to retained earnings as of the beginning of the first reporting period in which the guidance is effective. The standard is effective for the Company beginning January 1, 2023. The adoption of ASU 2016-13 did not have a material impact on the Company's financial position, results of operations, and cash flows.

In August 2020, the FASB issued ASU No. 2020-06 ("ASU 2020-06") "Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40)." ASU 2020-06 reduces the number of accounting models for convertible debt instruments by eliminating the cash conversion and beneficial conversion accounting models. As a result, the Company's convertible debt instruments will be accounted for as a single liability measured at its amortized cost as long as no other features require bifurcation and recognition as derivatives. For contracts in an entity's own equity, the type of contracts primarily affected by this update are freestanding and embedded features that are accounted for as derivatives under the current guidance due to a failure to meet the settlement conditions of the derivative scope exception. The Company early adopted ASU No. 2020-06 effective January 1, 2021 using the modified retrospective approach. Upon adoption, the following changes resulted: (i) the intrinsic value of the beneficial conversion feature recorded in 2020 was reversed as of the effective date of adoption, thereby resulting in an increase in the convertible notes payable with an offsetting adjustment to additional paid in capital and (ii) debt discount amortization recorded in 2020 that related to the beneficial conversion feature was reversed against opening accumulated deficit. Accordingly, the adoption of ASU 2020-06 resulted in a decrease to accumulated deficit of $29 and a decrease in additional paid in capital of $594.

The Company accounted for convertible notes payable (when it has determined that the embedded conversion options should not be bifurcated from their host instruments) in accordance with ASC 470-20, Debt with Conversion and Other Options up through December 31, 2020. Accordingly, the Company recorded, when necessary, discounts to convertible notes payable for the intrinsic value of conversion options embedded in debt instruments based upon the differences between the fair value of the underlying common stock at the commitment date of the note transaction and the effective conversion price embedded in the note. Debt discounts under these arrangements were amortized over the term of the related debt to their earliest date of redemption. The Company determined that the embedded conversion options in its issued convertible notes payable do not meet the definition of a derivative liability.

In May 2021, the FASB issued ASU 2021-04, Earnings Per Share (Topic 260), Debt—Modifications and Extinguishments (Subtopic 470-50), Compensation—Stock Compensation (Topic 718), and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options. ASU 2021-04 provides clarification and reduces diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options (such as warrants) that remain equity classified after modification or exchange. An issuer measures the effect of a modification or exchange as the difference between the fair value of the modified or exchanged warrant and the fair value of that warrant immediately before modification or exchange. ASU 2021-04 introduces a recognition model that comprises four categories of transactions and the corresponding accounting treatment for each category (equity issuance, debt origination, debt modification, and modifications unrelated to equity issuance and debt origination or modification). ASU 2021-04 is effective for all entities for fiscal years beginning after December 15, 2021. The adoption of ASU 2021-04 did not have a material impact on the Company's financial statements or disclosures.

Other recent accounting pronouncements issued by the FASB, including its Emerging Issues Task Force, the American Institute of Certified Public Accountants, and the Securities and Exchange Commission did not or are not believed by management to have a material impact on the Company's present or future consolidated financial statements.

NOTE 3—PROPERTY AND EQUIPMENT

Property and equipment consisted of the following at December 31, 2022 and 2021:

	December 31, 2022	December 31, 2021
Furniture and office equipment	$ 148	$ 148
Laboratory equipment	2,762	2,713
Computer equipment	127	127
Leasehold improvements	557	557
	3,594	3,545
Less: accumulated depreciation and amortization	(2,950)	(2,397)
Property and equipment, net	$ 644	$ 1,148

Depreciation expense for each of the years ended December 31, 2022 and 2021 was $553.

NOTE 4 – ACCRUED COMPENSATION

As of December 31, 2022 and 2021, the Company had accrued compensation owed to the Company's Chief Executive Officer, another employee and two former employees that had accrued over a several year period. As of December 31, 2022 and 2021, a total of $2,852 and $2,855, respectively, was owed to employees for these past due balances and for current accrued payroll and other compensation related benefits.

NOTE 5 – LEASE LIABILITIES

Operating Leases

The Company accounts for leases in accordance with ASC 842, which requires a lessee to record a right-of-use asset and a corresponding lease liability at the inception of the lease initially measured at the present value of the lease payments. In July 2018, the Company entered into a long-term non-cancellable lease agreement for its manufacturing facility that requires aggregate average monthly payments of $10 beginning October 2018. The lease terminates in September 2023, with a Company option to extend for an additional five years. The Company classified the lease as an operating lease and determined that the value of the right of use asset and lease liability at the adoption date was $518 and $519, respectively, using a discount rate of 4.00%. Effective April 2022, the Company extended the lease for the additional five-year period, with no changes to any of the other terms of the lease, and has the option to extend the lease for an additional five years. Prior to the extension, the remaining lease liability amounted to $174. On the date of the extension, the Company determined that the value of the new right of use asset and lease liability was $860, respectively, using a discount rate of 4.00%. As such, the Company recorded an increase in lease liability of $686 as a result of the lease extension.

In December 2020, the Company entered into a long-term non-cancellable lease agreement for a laboratory facility that requires aggregate average monthly payments of $18 beginning January 2021. The lease terminates in February 2023. The Company classified the lease as an operating lease and determined that the value of the right of use asset and lease liability at the adoption date was $439, respectively, using a discount rate of 4.00%.

In July 2021, the Company entered into a long-term non-cancellable lease agreement for its new corporate headquarters that requires aggregate average monthly payments of $10 beginning August 2021. The lease terminates in July 2027. The Company classified the lease as an operating lease and determined that the value of the right of use asset and lease liability at the adoption date was $656, respectively, using a discount rate of 4.00%.

During the years ended December 31, 2022 and 2021, the Company made combined aggregate payments of $389 and $284, respectively, towards the lease liabilities. As of December 31, 2022 and 2021, the combined lease liability amounted to $1,430 and $1,133, respectively.

ASC 842 requires recognition in the statement of operations of a single lease cost, calculated so that the cost of the lease is allocated over the lease term, generally on a straight-line basis. During the years ended December 31, 2022 and 2021, the Company reflected combined amortization of the right of use assets of $415 and $342, respectively, related to the leases, resulting in a combined net asset balance of $1,335 and $1,064 as of December 31, 2022 and 2021, respectively.

The maturities of the Company's lease liabilities are as follows as of December 31, 2022:

Years ending	
2023	$ 266
2024	247
2025	266
2026	286
2027	241
2028	124
	1,430
Less: current portion	(266)
Long-term portion	$ 1,164

Other Leases

In November 2019, the Company entered into a short-term lease agreement for one of its office facilities, extending the lease until December 2020, and in October 2020, it was extended until December 2021. In November 2021, it was extended again for one year until December 2022. The lease for this facility is currently on a month-to-month basis. Rent expense was $36 during the years ended December 31, 2022 and 2021.

NOTE 6 – NOTES PAYABLE – SHAREHOLDERS

During the year ended December 31, 2022, the Company, in anticipation of closing its IPO, entered into note payable agreements with several shareholders totaling $1,100. The notes accrue interest at 12% per annum, are unsecured and are due at the earlier of June 15, 2023 or the month after the closing of the IPO. During the year ended December 31, 2022, the notes accrued interest of $5 and no principal and interest payments were made on the notes. As of December 31, 2022, the outstanding principal and accrued and unpaid interest balances on the notes were $1,100 and $5, respectively. Subsequent to December 31, 2022, the Company borrowed an additional $500 from its shareholders prior to the closing of the IPO (see Note 15).

In consideration for the notes, the Company issued the note holders stock warrants to purchase up to an aggregate total of 30,553 shares of its common stock with an exercise price per share equal to 90% of the IPO price, or $5.40 per share, based on the IPO closing price (see Note 15). The issuance of the warrants was contingent upon the closing of the IPO, and as such, were not formally granted until the closing of the IPO in January 2023. The warrants expire in December 2025. The Company determined the warrants should be accounted for as a liability on the date of issuance. The Company calculated the fair value of the warrants issued to the noteholders to be $169 using a Black Scholes option pricing model with the following assumptions:

Exercise price	$6.00
Expected dividends	—
Expected volatility	96.0%
Risk free interest rate	3.50%
Life of the warrants	3.0

The Company recognized a liability and recorded a debt discount at the date of issuance in the amount of $169. The Company recorded the fair value of the warrants as warrant liabilities as of December 31, 2022. The notes' discounts are being amortized over the term of the notes and the unamortized portion is recognized as a reduction to the carrying amount of the notes (a valuation debt discount). During the year ended December 31, 2022, the Company amortized $61 of debt discount, leaving an unamortized balance of $108 at December 31, 2022.

The following table sets forth a summary of the changes in the estimated fair value of the warrant liabilities during the years ended December 31, 2022 and 2021:

	Years Ended December 31,	
	2022	2021
Beginning balance	$ —	$ —
Recognition of warrant liabilities	169	—
Change in fair value	—	—
Extinguishment	—	—
Ending balance	**$ 169**	**$ —**

NOTE 7 – CONVERTIBLE NOTES PAYABLE – SHAREHOLDERS

Convertible notes payable to shareholders consisted of the following as of December 31, 2022 and 2021:

	December 31, 2022	December 31, 2021
Convertible notes payable – shareholders (a)	$ 7,838	$ 7,968
Convertible note payable – shareholder (b)	1,500	1,500
Convertible notes payable – shareholders (c)	700	700
Convertible notes payable – shareholders (d)	5,369	5,369
	15,407	15,537
Less: current portion	(15,407)	(6,155)
Convertible notes payable – shareholders – long—term portion	$ —	$ 9,382

(a) During the years ended December 31, 2011 through 2016, the Company entered into convertible note payable agreements with individuals aggregating to a total amount of $7,988. The notes accrued interest at 8% per annum, are unsecured, had an initial maturity of November 2016 and are convertible into the Company's Series K preferred stock at $25.73 per share. In December 2016, the Company entered into amended agreements with certain of the individuals holding notes with an aggregate balance of $7,733 to convert into common stock at $6.78 per share and to accrue interest at 0.61% per annum. In November 2019, the notes with those individuals were amended again, extending the maturity date to November 2022 and updating the interest rate to 1.68% per annum. As of December 31, 2021, the principal amount due on the amended notes aggregated to $7,733 and the amount due on the notes that were not amended and extended aggregated to $235. At December 31, 2021, total accrued and unpaid interest of $2,857 was owed on the notes. During the year ended December 31, 2021, several of the amended notes, totaling $2,923, were amended again, extending the maturity date to December 31, 2023. During the year ended December 31, 2022, the notes accrued interest of $140 and the Company made principal and interest payments of $130 and $107, respectively. As of December 31, 2022, the principal amount due on the amended notes aggregated to $7,733 and the amount due on the notes that were not amended and extended aggregated to $105. At December 31, 2022, total accrued and unpaid interest of $2,890 was owed on the notes. In the event the Company closes an underwritten public offering of its common stock pursuant to an effective registration statement, then the principal amount of $7,733, plus accrued and unpaid interest relating to that amount, will automatically convert into 1,553,245 shares of the Company's common stock based on the principal and accrued interest due as of December 31, 2022. Subsequent to December 31, 2022, the Company closed its underwritten public offering of its common stock pursuant to an effective registration statement and all of the principal and accrued interest due at the closing was converted into 1,554,814 shares of the Company's common stock (see Note 15).

(b) In April 2016, the Company entered into a convertible note payable agreement with a shareholder in the amount of $2,661. The note accrued interest at 11.51% per annum, was unsecured, had an initial maturity date of May 2018 and was convertible into the Company's common stock at the price of $6.78 per share. Interest payments are due monthly. In consideration for the loan, the Company issued the shareholder a stock warrant to purchase up to 177,395 shares of its common stock with an exercise price of $9.00 per share. The warrant expires ten years

from the date of grant. As an inducement to convert, the agreement also contains a provision that in the case the shareholder converts the note into shares of the Company's common stock, the shareholder will receive a warrant to purchase up to 25% of the shares converted at the exercise price of $9.00 per share, as long as the amount converted was $1,000 or more. The warrant, if issued, will expire ten years from the date of grant. In May 2018, the note was amended. The amended agreement extended the maturity date to May 2021 and included a provision under which the loan will accrue $10 per month of loan fees through the date the loan is repaid or is converted into the Company's common stock. The loan fees can be converted into shares of the Company's common stock at $6.78 per share. In December 2020, the note was amended again, extending the maturity date to May 2022 and reducing the interest rate to 10.5%.

During the year ended December 31, 2021, the shareholder entered into an amendment to his agreement under which the shareholder agreed to modify the shareholder's loan agreement that in the event the Company closes an underwritten public offering of its common stock pursuant to an effective registration statement, then all of the principal of $2,661 plus accrued and unpaid loan fees will automatically convert into shares of the Company's common stock at the conversion prices of $6.78 per share. The shareholder also agreed to convert a portion of the principal of his loan in the amount of $1,161 into 171,228 shares of the Company's common stock. In connection with the conversion of the loan payable, the Company issued the shareholder a warrant to purchase 42,807 shares of common stock. The warrants have an exercise price of $9.00 per share and expire ten years from the date of grant. The fair value of the warrants of $398 was recorded as a financing cost during the year ended December 31, 2021 and was based on a probability affected Black-Scholes pricing model with a stock price of $10.50, volatility of 95.7% and a risk-free rate of 0.82%. As of December 31, 2021, a total of $1,500 of principal and $440 of accrued loan fees were owed on the note, and no unpaid and accrued interest. During the year ended December 31, 2021, the note was amended, extending the maturity date to December 31, 2023. During the year ended December 31, 2022, the Company made interest payments totaling $158 relating to the notes and at December 31, 2022, a total of $1,500 of principal and $560 of accrued loan fees were owed on the note, and no accrued and unpaid interest. In the event the Company closes an underwritten public offering of its common stock pursuant to an effective registration statement, then all of the principal plus accrued and unpaid interest and loan fees will automatically convert into 303,835 shares of the Company's common stock based on the principal and accrued interest due as of December 31, 2022. Subsequent to December 31, 2022, the Company closed its underwritten public offering of its common stock pursuant to an effective registration statement and all of the principal and accrued loan fees due at the closing were converted into 305,308 shares of the Company's common stock (see Note 15).

(c) In April 2018, the Company entered into two convertible note payable agreements with a shareholder under which the Company borrowed an aggregate total of $700. The notes accrue interest at 5.0% per annum, are unsecured, and are convertible into the Company's common stock at the price of $12.00 per share. One of the notes totaling $200 had an initial maturity date of March 2019, while the other note totaling $500, had an initial maturity date of April 2021. The agreements also contain a provision that in the case the shareholder converts the notes into shares of the Company's common stock, the shareholder will receive a warrant to purchase up to 25% of the shares converted, at the exercise price of $10.50 per share. The warrant, if issued, will expire three years from the date of grant. During the year ended December 31, 2020, the notes were amended, which extended the maturity dates to December 31, 2021. As of December 31, 2021, total principal of $700 and total accrued and unpaid interest of $129 was owed on the notes. During the year ended December 31, 2021, the notes were amended, extending the maturity date to December 31, 2023. During the year ended December 31, 2022, the notes accrued interest of $35, and at December 31, 2022, total principal of $700 and total accrued and unpaid interest of $164 was owed on the notes. In the event the Company closes an underwritten public offering of its common stock pursuant to an effective registration statement, then all of the principal plus accrued and unpaid interest will automatically convert into 72,038 shares of the Company's common stock based on the principal and accrued interest due as of December 31, 2022, and the conversion price would be the lower of 90% of the IPO price or the stated price of $12.00 per share. Subsequent to December 31, 2022, the Company closed its underwritten public offering of its common stock pursuant to an effective registration statement and all of the principal and accrued interest due at the closing was converted into 160,563 shares of the Company's common stock (see Note 15).

(d) During the year ended December 31, 2019, the Company entered into convertible note payable agreements with several shareholders under which the Company borrowed an aggregate amount of $1,900. The notes accrue interest at 5.0% per annum, are unsecured, have a maturity date of December 31, 2021 and are convertible into the Company's common stock at the price of $12.00 per share. The agreements contain a provision under which each investing "family" (as defined by the agreements) must invest at least $500 in the aggregate in order to participate in these agreements. The agreements also contain a provision that in the case a shareholder converts the notes into shares of the Company's common stock, the shareholder will receive a warrant to purchase up to 25% of the shares converted, at the exercise price of $10.50 per share. The warrant, if issued, will expire three years from the date of grant. During the years ended December 31, 2020 and 2021, the Company entered into the same convertible note payable agreements with several families under which the Company borrowed a net aggregate amount of $3,469. The notes entered into during the years ended December 31, 2020 and 2021 have the same terms and conditions as the notes entered into during the year ended December 31, 2019, except that they have maturity dates ranging from December 31, 2021 to December 31, 2023. As of December 31, 2021, total principal of $5,369 and total accrued and unpaid interest of $489 was owed on the notes. During the year ended December 31, 2021, several of the notes due prior to December 31, 2022, totaling $1,690, were amended again, extending the maturity date to December 31, 2023. During the year ended December 31, 2022, the notes accrued interest of $268, and at December 31, 2022, total principal of $5,369 and total accrued and unpaid interest of $758 was owed on the notes. In the event the Company closes an underwritten public offering of its common stock pursuant to an effective registration statement, then all of the principal plus accrued and unpaid interest will automatically convert into 510,462 shares of the Company's common stock based on the principal and accrued interest due as of December 31 2022, and the conversion price would be the lower of 90% of the IPO price or the stated price of $12.00 per share. Subsequent to December 31, 2022, the Company closed its underwritten public offering of its common stock pursuant to an effective registration statement and all of the principal and accrued interest due at the closing was converted into 1,134,063 shares of the Company's common stock (see Note 15).

NOTE 8 – CONVERTIBLE NOTES PAYABLE

Convertible notes payable consisted of the following as of December 31, 2022 and 2021:

	December 31, 2022	December 31, 2021
Convertible note payable	$ 9,065	$ 9,065
Less: debt discount	(541)	(738)
Convertible notes payable, net	$ 8,524	$ 8,327

During the year ended December 31, 2020, the Company entered into convertible note payable agreements with an investing group under which the Company borrowed $8,146. The notes accrue interest at 6.0% per annum, are unsecured, have a maturity date of September 2025 and are convertible into the Company's common stock at the price of $10.50 per share, which was the fair value of the common stock on the date of the agreement. In consideration for the note, the Company issued the note holder stock warrants to purchase up to 133,847 shares of its common stock with an exercise price of $10.50 per share. The warrants expire in September 2025.

The Company calculated the fair value of the warrants issued to the noteholder to be $864 using a Black Scholes option pricing model and performed a relative fair value allocation. The Company then made a calculation to determine if a beneficial conversion feature (BCF) existed. The beneficial conversion was based upon the effective conversion price based on the proceeds received that were allocated to the convertible instrument. Based upon the Company's calculation, it was determined that a beneficial conversion feature existed amounting to $594 and was recorded as a debt discount. As such the Company recognized a debt discount at the date of issuance in the aggregate amount of $1,485 consisting of the $27 fees paid relating to the loan, the relative value of the warrants and the BCF. The note discount is being amortized over the term of the notes and the unamortized portion is recognized as a reduction to the carrying amount of the notes (a valuation debt discount). As of December 31, 2020, the Company had amortized $74 of debt discount, leaving an unamortized balance of $1,411 at December 31, 2020. During the year ended December 31, 2021, the Company adopted ASU 2020-06 (see Note 2), which had the effect of reversing out $565 of the debt discount existing at December 31, 2020.

The notes above, all executed as of December 31, 2020, include a note in the amount of $1,100, of which $146 was funded through December 31, 2020. During the year ended December 31, 2021, the Company was advanced an additional $919 under the 2020 agreement, no payments were made on the notes and the notes accrued interest of $537. As of December 31, 2021, the Company owed $9,065 of principal on the notes and $634 of accrued and unpaid interest. During the year ended December 31, 2022, the notes accrued interest of $544, and at December 31, 2022, total principal of $9,065 and total accrued and unpaid interest of $1,178 was owed on the notes.

In consideration for the note, the Company issued the note holder a stock warrant to purchase up to 13,128 shares of its common stock with an exercise price of $10.50 per share. The warrant expires in September 2025. The Company calculated the relative fair value of the warrant issued to the noteholder to be $88 using a Black Scholes option pricing model and recognized a debt discount at the date of issuance in the amount of $88. The note discount is being amortized over the term of the note and the unamortized portion is recognized as a reduction to the carrying amount of the note (a valuation debt discount). During the year ended December 31, 2021, the Company amortized $196 of debt discount, leaving an unamortized balance of $738 at December 31, 2021. During the year ended December 31, 2022, the Company amortized $197 of debt discount, leaving an unamortized balance of $541 at December 31, 2022.

In the event the Company closes an underwritten public offering of its common stock pursuant to an effective registration statement, then all of the principal plus accrued and unpaid interest will automatically convert into 975,364 shares of the Company's common stock based on the principal and accrued interest due as of December 31, 2022. Subsequent to December 31, 2022, the Company closed its underwritten public offering of its common stock pursuant to an effective registration statement and all of the principal and accrued interest due at the closing was converted into 979,619 shares of the Company's common stock (see Note 15).

NOTE 9 – U.S. SMALL BUSINESS ADMINISTRATION LOAN PAYABLE

During the year ended December 31, 2020, the Company entered into a loan agreement with the United States Small Business Administration (SBA) under which the Company borrowed $314. The loan is unsecured, accrues interest at 1.0% and is due on April 23, 2022. The loan term may be extended to April 2025 if mutually agreed to by the Company and lender. The Company applied ASC 470, Debt, to account for the PPP loan. The PPP loan may be prepaid at any time prior to maturity with no prepayment penalties. Funds from the PPP loan may only be used for qualifying expenses as described in the CARES Act, including qualifying payroll costs, qualifying group health care benefits, qualifying rent and debt obligations, and qualifying utilities. The Company used the entire loan amount for qualifying expenses. Under the terms of the PPP, certain amounts of the loan may be forgiven if they are used for qualifying expenses. The Company is entitled to apply for forgiveness of the PPP loan with respect to these qualifying expenses, however, it cannot assure that such forgiveness of any portion of the PPP loan will occur. As for the potential loan forgiveness, once the PPP loan is, in part or wholly, forgiven and a legal release is received, the liability would be reduced by the amount forgiven and a gain on extinguishment would be recorded. The terms of the PPP loan provide for customary events of default including, among other things, payment defaults, breach of representations and warranties, and insolvency events. The Company was in compliance with the terms of the PPP loan as of December 31, 2021. During the year ended December 31, 2021, the Company applied for forgiveness of the loan and the loan was forgiven by the SBA during the year ended December 31, 2022. The forgiveness of the loan was recorded as a gain on forgiveness of debt during the same period. No amounts are due under the loan as of December 31, 2022.

NOTE 10 – AGGREGATE ANNUAL MATURITIES OF DEBT

The aggregate annual maturities of all of the Company's debt as of December 31, 2022 are as follows:

Years ending	
2023	$ 16,507
2025	9,065
Total	$ 25,572

NOTE 11 – LICENSE AGREEMENTS

Agreement with Newsoara BioPharma Co. Ltd

In September 2021, the Company entered into a collaboration and exclusive license with Newsoara BioPharma Co. Ltd (Newsoara) for the development and commercialization of the Company's primary product (Olvi-Vec). According to the terms of the agreement, Newsoara shall have exclusive rights in Greater China to Olvi-Vec, for which the Company currently is planning a US-based Phase 3 registration trial in ovarian cancer. Newsoara also shall have exclusive rights in Greater China to the Company's proprietary oncolytic virus platform (with the exception of V-VET1, described below), and the parties will collaborate on the development of novel oncolytic immune therapeutics. Newsoara, at its cost and expense, will be responsible for development and commercialization and will have the future right to manufacture licensed products in Greater China. Subject to FDA authorization, the Company and Newsoara anticipate initiating a Phase 2, open-label, randomized, and controlled clinical trial designed to evaluate the efficacy and safety of intravenously delivered Olvi-Vec oncolytic VACV followed by treatment as per the National Comprehensive Cancer Network (NCCN) Guidelines for patients with recurrent NSCLC in the United States in the first half of 2023, which will be funded in its entirety by Newsoara.

Under terms of the agreement, the Company has received up-front and near-term payments totaling $9,900, net of a 10% Chinese income tax, and will be eligible to receive additional per product payments of up to $160.5 million, contingent on certain development, regulatory, and commercial milestones, plus tiered royalties on net sales ranging from mid-single digit to mid-teens percentages. The Company shall have an exclusive license outside of Greater China to oncolytic virus products derived by Newsoara and will pay Newsoara milestones and royalties on sales of any such products which Genelux elects to develop. As of December 31, 2021, the Company had received a $4,500 up front payment (net of a 10% foreign income tax). During the year ended December 31, 2022, the Company received the remaining $5,400 of the upfront payments (net of the 10% foreign income tax).

The allocation of the transaction price to the Company's primary performance obligations in the agreement includes payments related to each of the following obligations (or events):

1) Signing of the agreement and transfer of rights to its technology—$5.0 million.

2) Approval from the U.S. Food and Drug Administration to begin the phase 3 trial of the Company's primary product—$6.0 million, net of a 10% income tax owed to the Chinese government.

3) Manufacture and distribute product, or the transfer of its manufacturing technology – the manufactured cost of the product as determined by the Company and approved by the customer upon completion of a production batch.

At December 31,2021, the Company performed an analysis of revenue recognition in accordance with guidance of ASC 606 and determined that since the Company did not complete obligation 3) above prior to December 31, 2021, that revenue would be recognized at such time as the Company met that performance obligation. As such, as of December 31, 2021, the Company delayed recognition of any revenue under this contract and the cash received of $4,500 was recorded as deferred revenue. During the year ended December 31, 2022, the Company completed the transfer of its manufacturing technology, at which point the Company completed its performance obligation 3) above, and thus recognized the related revenue of $11,000, with the 10% foreign income tax of $1,100 being recorded as a provision for foreign income taxes. Under no circumstances would the Company be required to repay the $9,900 received under the license agreement.

Agreement with ELIAS Animal Health, LLC

In November 2021, the Company entered into an exclusive worldwide licensing agreement for V-VET1, its clinical stage animal health product candidate, with ELIAS Animal Health, LLC (ELIAS), a biotechnology company advancing its novel cell-based immunotherapies for the treatment of cancer in veterinary medicine. V-VET1 is a vaccinia viral strain which selectively replicates in cancer cells causing cell death (apoptosis). ELIAS plans future clinical trials to evaluate and develop V-VET1 as a potential new immunotherapy option for veterinary oncologists. Under the terms of the agreement, Genelux will receive an upfront payment of $60 and will receive further payments under development and sales milestones, and royalties on product sales. No payments were received as of December 31, 2021.

The allocation of the transaction price to the Company's primary performance obligations in the agreement includes payments related to each of the following obligations (or events):

1) Signing of the agreement and transfer of rights to its technology—$60.

2) Manufacture and distribute product, or the transfer of its manufacturing technology – the manufactured cost of the product as determined by the Company and approved by the customer upon completion of a production batch.

The Company performed an analysis of revenue recognition in accordance with guidance of ASC 606 and determined that since the Company did not complete obligation 2) above prior to December 31, 2021, that revenue recognition would be recognized at such time as the Company met that performance obligation. During the year ended December 31, 2022, the Company received payment of $68 and completed the transfer of its manufacturing technology, at which point the Company completed its performance obligation 2) above, and thus recognized the related revenue of $68. Under no circumstances would the Company be required to repay the $60 received under the license agreement.

NOTE 12—SHAREHOLDERS' EQUITY

Preferred Stock

Authorized shares and shares issued and outstanding of the Company's preferred stock by series as of December 31, 2022 and 2021 are as follows:

	Authorized Shares	Issued and Outstanding	Par Value
Series A Preferred Stock	4,500,000	4,500,000	4,500
Series B Preferred Stock	608,000	608,000	608
Series C Preferred Stock	5,000,000	5,000,000	5,000
Series D Preferred Stock	3,000,000	3,000,000	3,000
Series E Preferred Stock	1,591,994	1,591,994	1,592
Series F Preferred Stock	953,000	953,000	953
Series H Preferred Stock	5,000,000	536,000	536
Series I Preferred Stock	2,775,000	2,757,442	2,757
Series J Preferred Stock	2,500,000	1,281,600	1,282
Series K Preferred Stock	4,000,000	1,866,853	1,867
Total	29,927,994	22,094,889	22,095

Convertible Series A Preferred Stock

In August 2002, the Company entered into an asset purchase agreement to purchase specific assets and issued 1,500,000 shares of Series A preferred stock ("Series A") to the founder of the Company. In August 2002, the Company also entered into a credit agreement with a single investor, whereas the investor provided an unsecured line of credit to the Company of $50,000 and the Company issued 1,500,000 shares of the Company's Series A as consideration. In December 2009, the Board of Directors approved the issuance of 1,500,000 shares of Series A to the founder of the Company in exchange for 1,500,000 of common stock.

Convertible Series B Preferred Stock

In December 2002, the Company issued 608,000 shares of convertible Series B preferred stock ("Series B") at $1.00 per share for gross proceeds of $608.

Convertible Series C Preferred Stock

From September 2004 to June 2005, the Company issued 5,000,000 shares of convertible Series C preferred stock ("Series C") at $1.00 per share for gross proceeds of $5,000.

Convertible Series D Preferred Stock

From December 2005 to July 2006, the Company issued 3,000,000 shares of convertible Series D preferred stock ("Series D") at $3.00 per share for gross proceeds of $9,000.

Convertible Series E Preferred Stock

In November 2006, the Company offered up to $5,000 principal amount of 8% convertible notes. Each note was sold with an attached warrant to purchase 110,000 shares of common stock at an exercise price of $4.55 per share. Each warrant was exercisable immediately upon its issuance date and had a seven-year term. The amount allocated to the fair value of the warrants was insignificant. In the period from November 2006 to October 2007, a total amount of $4,985 was issued to various investors with a convertible Series E preferred stock ("Series E") conversion price of $3.50 per share. On June 9, 2008, outstanding principal and interest in the amount of $4,985 and $475 were converted to 1,591,994 shares of Series E, respectively.

Convertible Series F Preferred Stock

In June 2008, the Company issued 953,000 shares of convertible Series F preferred stock ("Series F") at $5.00 per share for gross proceeds of $4,765.

Convertible Series H Preferred Stock

In February 2009, the Company issued 536,000 units at $5.00 per unit for gross proceeds of $2,680. Each unit consisted of one share of Series H preferred stock ("Series H") and one warrant which entitled the holder to acquire a half share of the Company's common stock at an exercise price of $5.00 per share. In May 2010, 236,000 warrants were exercised by investors and 118,000 shares of common stock were purchased at a price of $5.00 per share. The remaining warrants expired as of December 31, 2010.

Convertible Series I Preferred Stock

From May 2009 to February 2010, the Company issued 2,757,442 shares of convertible Series I preferred stock ("Series I") at $6.00 per share for gross proceeds of approximately $16,545.

Convertible Series J Preferred Stock

From 2010 through 2012, the Company issued 1,281,600 shares of convertible Series J preferred stock ("Series J") at $10.00 per share for gross proceeds of $12,816.

Convertible Series K Preferred Stock

From April 1, 2012 to December 31, 2017, the Company sold 1,866,853 shares of Series K convertible preferred ("Series K") stock resulting in gross proceeds of approximately $22,402.

The significant terms of the Convertible Preferred Stock are as follows*:*

Dividends

Each share is entitled to dividends on a pari passu basis with Series A, Series B, Series C, Series D, Series E, Series F, Series I, Series J and Series K as and when declared by the Board. Series H dividends are payable in cash or in kind at the election of the Company at such time as dividends may lawfully be declared and paid thereon by the Company, in an amount equal to 9% per annum There have been no dividends declared or paid to date. As of December 31, 2022 and 2021, earned but undeclared and unpaid Series H dividends were $3,423 and $3,184, respectively. In addition, if the Company closes a firmly underwritten public offering of common stock, the earned but undeclared and unpaid dividends as of those dates will be converted automatically into 270,537 and 251,627 shares of the Company's common stock, respectively. Subsequent to December 31, 2022, the Company closed its underwritten public offering of its common stock pursuant to an effective registration statement and all of the earned but undeclared and unpaid Series H dividends due at the closing was converted into 272,101 shares of the Company's common stock (see Note 15).

Voting

Holders of the Series A, Series B, Series C, Series D, Series E, Series F, Series H, Series I, Series J and Series K generally have one vote for each full share of common stock into which such holder's shares would be convertible on the record date for any vote of the stockholders. Holders of the Series A are entitled to elect two members to the Board of Directors; holders of the Series B are entitled to elect one member to the Board of Directors; holders of the Series C are entitled to elect one member to the Board of Directors; holders of common stock voting together with the holders of the Series D, Series E, Series F, Series I, Series J and Series K are entitled to elect one director to the Board of Directors; and holders of all issued shares of common stock and preferred stock voting together as a class are entitled to elect two members to the Board of Directors.

Conversion

Holders of the Series A, Series B, Series C, Series D, Series E, Series F, Series H, Series I, Series J and Series K may convert their shares at any time into shares of our Common Stock at the effective conversion rate for each such series on date of conversion. The conversion rate is initially $1.00 per share for the Series A and Series C, $0.50 per share for the Series B, $3.00 per share for the Series D, $3.50 per share for the Series E, $5.00 per share for the Series F, $5.00 per share for the Series H, $6.00 per share for the Series I, $10.00 per share for the Series J and $12.00 per share for Series K. Pursuant to these conversion prices, the Series A, Series C, Series D, Series E, Series F, Series H, Series I, Series J and Series K are convertible into common stock on a one-for-one basis and the Series B is convertible into common stock on a two-for-one basis. The conversion prices are subject to adjustment according to a weighted-average anti-dilution formula. In addition, if the Company closes a firmly underwritten public offering of common stock, the outstanding shares of preferred stock will be converted automatically into 8,355,610 shares of the Company's common stock, of which 991,172 shares are attributable to conversion price adjustments based on a weighted-average anti-dilution formula. Subsequent to December 31, 2022, the Company closed its underwritten public offering of its common stock pursuant to an effective registration statement and all of the outstanding shares of preferred stock was converted into shares of the Company's common stock (see Note 15).

Liquidation

In the event of any liquidation, dissolution or winding up of the Company, whether voluntary or involuntary, the holders of Series B, Series C, Series D, Series E, Series F, Series H, Series I, Series J and Series K shall be entitled to receive, prior and in preference to any distribution of any of the assets or funds of the Company to the holders of Series A or common stock, on a pari passu basis, an amount equal to the Original Issue Price for each such series as set forth in the Company's Certificate of Incorporation, as amended. Prior to any distribution of the remaining assets and funds to the holders of the Company's common stock, if the distribution to the holders of the Series B through Series K has been paid in full, then the holders of record of Series A shall be entitled to a distribution equal to its Original Issue Price per share. If any assets are remaining following the distributions, prior to any distribution being made on the common stock, the holders of Series A through K shall also be entitled to receive upon liquidation, on a pari passu basis, an additional liquidation amount equal to such holder's Original Issue Price per share of preferred stock owned of record by such holder as of the date of liquidation. Following such distributions on the Series A through Series K, all remaining amounts of assets and funds shall be distributed to the holders of common stock and Series A through Series K, pari passu, as if only shares of common stock were then outstanding as of the date of such distribution. To the extent that there are not sufficient assets or funds remaining in the Company at the date of liquidation after payment of all other debts and obligations of the Company through such date, then the holders of the capital stock of the Company shall receive whatever amounts are then available for distribution in the same proportion as if there were sufficient assets and funds upon liquidation to satisfy the entire distribution contemplated above, with the Series A and common stock ranking junior in right of payment to the shares of Series B through Series K outstanding as of such date of liquidation. The Original Issue Price for each series of preferred stock is subject to equitable adjustment for any combinations, consolidations, stock distributions, stock splits or stock dividends with respect to such series.

Common Stock

Authorized shares

The Company's Certificate of Incorporation authorizes the Company to issue up to 75,000,000 of its common shares. Holders of shares of common stock have full voting rights, one vote for each share held of record. Shareholders are entitled to receive dividends as may be declared by the Board out of funds legally available therefore and share pro rata in any distributions to shareholders upon liquidation. Shareholders have no conversion, pre-emptive or subscription rights. All outstanding shares of common stock are fully paid and non-assessable. As of December 31, 2022 and 2021, there were 9,126,726 and 9,110,060 shares of common stock issued and outstanding, respectively.

Shareholders' Equity Transactions for the Year Ended December 31, 2021

Common Shares Issued for Cash

During the year ended December 31, 2021, the Company received $143 from the sale of 13,571 shares of its common stock at $10.50 per share under agreements dated prior to December 31, 2020.

Shares Issued upon Conversion of Note Payable from Shareholders

During the year ended December 31, 2021, the Company entered into an omnibus amendment and conversion election agreement with a loan holder. On the date of the agreement, total principal of $1,500 and total accrued and agreed-upon unpaid interest of $225 was due on the note. Under the agreement, the Company agreed to issue the note holder 18,687 shares of its common stock, with a fair value of $281 ($5.00 per share), and to pay them $1,445.

Shares Issued upon Conversion of Loan Payable from Shareholder and Fair Value of Warrants Issued upon Conversion

During the year ended December 31, 2021, a shareholder agreed to convert a portion of the principal of his loan in the amount of $1,161 into 171,228 shares of the Company's common stock. In connection with the conversion of the loan payable, the Company issued the shareholder a warrant to purchase 42,807 shares of common stock. The fair value of the warrant of $398 was recorded as a financing cost during the year ended December 31, 2021.

Cost of Stock Option Modifications

In May 2021, the Company entered into "transition agreements" with four former Directors. Under the agreements, the Company agreed to modify their option agreements such that upon termination, the options would remain exercisable for the lesser of five years from the date of transition, or their ten-year expiration term, rather than the 90-day period as documented in their original option agreement.

In accounting for the modification, the Company calculated for the fair value of the options before modification using current valuation inputs including the Company's stock price of $10.50, a volatility metric of 95.7%, a risk-free interest rate of 0.82% and an expected life of 0.25 years. The Company also calculated the fair value of the options after modification using the extended term of five years. The incremental fair value of the options resulting from the modifications was $2,608 that was recognized as an expense during the year ended December 31, 2021.

Fair Value of Stock Warrant Issued in Connection with Convertible Loan Payable

During the year ended December 31, 2021, an investing group loaned the Company $919, and in connection with the loan, the Company issued the note holder a stock warrant to purchase up to 13,128 shares of its common stock with an exercise price of $10.50 per share. The Company calculated the relative fair value of the warrant issued to the noteholder to be $88 using a Black Scholes option pricing model and recognized a debt discount at the date of issuance in the amount of $88.

Stock Options

In August 2009, the Company's Board of Directors approved the adoption of the 2009 Equity Incentive Plan ("the 2009 Plan"). The 2009 Plan was initiated to encourage and enable employees, directors and consultants of the Company to acquire and retain a proprietary interest in the Company by ownership of its common stock. A total of 6,166,666 of the authorized shares of the Company's common stock may be subject to, or issued pursuant to, the terms of the plan. As of December 31, 2021 and 2022, no shares were available for grant under the 2009 plan.

In September 2018, the Company's Board of Directors approved the adoption of the 2019 Equity Incentive Plan ("the 2019 Plan"). The 2019 Plan was initiated to encourage and enable employees, directors and consultants of the Company to acquire and retain a proprietary interest in the Company by ownership of its common stock. The 2019 Plan allows for the following types of awards: (i) Incentive Stock Options; (ii) Nonstatutory Stock Options; (iii) Stock Appreciation Rights; (iv) Restricted Stock Awards; (v) Restricted Stock Unit Awards; (vi) Other Stock Awards. The maximum number of shares of our common stock that may be issued under our 2019 Plan is 2,059,073 shares. Outstanding stock awards granted under the 2009 Plan that (i) expire or terminate for any reason prior to exercise or settlement; (ii) are forfeited because of failure to meet a contingency or condition required to vest such shares or otherwise return to us; or (iii) are required or withheld (or not issued) to satisfy a tax withholding obligation in connection with an award or to satisfy the purchase price or exercise price of a stock award can be added to the authorized shares as Returning Shares, not to exceed 3,774,260 shares. The maximum number of shares of our common stock under our 2019 Plan that may be issued is 5,833,333 shares. As of December 31, 2022, a total of 1,632,315 shares were available for grant under the 2019 plan.

Option exercise prices are set forth in the Grant Notice, without commission or other charge, provided however, that the price per share of the shares subject to the option shall not be less than the greater of (i) 100% of the fair market value of a share of stock on the grant date, or (ii) 110% of the fair market value of a share of stock on the grant date in the case of a Participant then owning more than 10% of the total combined voting power of all classes of stock of the Company or any "subsidiary corporation" of the Company or any "parent corporation" of the Company. Options to employees, directors and consultants generally vest and become exercisable over a period not exceeding four years. Options typically expire ten years after date of grant.

The Company's policy is to recognize compensation cost for awards with only service conditions on a straight-line basis over the requisite service period for the entire award. Additionally, the Company's policy is to issue new shares of common stock to satisfy stock option exercises. The Company applied fair value accounting for all share-based payments awards. The fair value of each option granted is estimated on the date of grant using the Black-Scholes option-pricing model.

The table below summarizes the Company's stock option activities for the years ended December 31, 2022 and 2021:

	Number of Option Shares	Exercise Price Range Per Share	Weighted Average Exercise Price
Balance, December 31, 2020	3,922,150	$9.00 - 10.50	$ 10.11
Granted	150,000	10.50	10.50
Cancelled	(118,800)	10.50	10.50
Exercised	(116)	9.00	9.00
Expired	—	—	—
Balance, December 31, 2021	3,953,234	9.00 -10.50	10.11
Granted	247,785	10.50	10.40
Cancelled	—	—	—
Exercised	—	—	—
Expired	—	—	—
Balance, December 31, 2022	4,201,019	$ 9.00 -10.50	$ 10.12
Vested and exercisable, December 31, 2022	3,970,079	$ 9.00 -10.50	$ 10.10
Unvested, December 31, 2022	230,940	$ 10.50	$ 10.50

The following table summarizes information concerning outstanding and exercisable options as of December 31, 2022:

	Options Outstanding			Options Exercisable		
Range of Exercise Prices	Number Outstanding	Average Remaining Contractual Life (in years)	Weighted Average Exercise Price	Number Exercisable	Average Remaining Contractual Life (in years)	Weighted Average Exercise Price
$ 9.00	1,064,698	2.64	$ 9.00	1,064,698	2.64	$ 9.00
10.50	3,136,321	6.34	10.50	2,905,381	6.14	10.50
$ 9.00 - 10.50	4,201,019	5.41	$ 10.12	3,970,079	5.20	$ 10.10

Stock Option Grants during the Year Ended December 31, 2022

During the year ended December 31, 2022, under its 2019 Plan, the Company granted options to certain employees and directors, and a consultant, to purchase 247,785 shares of its common stock with exercise prices of $9.00 and $10.50 per share. The options vest over various periods, but none longer than four years, expire ten years from the date of grant and had an aggregate fair value of $1,969 at the date of grant. The Company valued the options using a Black-Scholes option pricing model. During the year ended December 31, 2022, the Company recorded $2,415 of stock compensation for the value of all options vesting during the period.

The assumptions used for all of the options granted during the year ended December 31, 2022 are as follows:

Exercise price	$9.00 - 10.50
Expected dividends	—
Expected volatility	94.6% -96.1%
Risk free interest rate	0.34%
Expected life of options	5.0 - 5.9

Stock Option Grants during the Year Ended December 31, 2021

During the year ended December 31, 2021, the Company granted an employee an option under the 2019 Incentive Plan to purchase 150,000 shares of its common stock with an exercise price of $10.50 per share. The option vests over four years, expires ten years from the date of grant and had an aggregate fair value of $1,209 at the date of grant. The Company valued the option using a Black-Scholes option pricing model. During the year ended December 31, 2021, the Company recorded $1,663 of stock compensation for the value of all options vesting during the period.

The assumptions used for all of the options granted during the year ended December 31, 2021 are as follows:

Exercise price	$ 10.50
Expected dividends	—
Expected volatility	96.4%
Risk free interest rate	1.1%
Expected life of options	5.9

As of December 31, 2022, unvested compensation of $1,978 remained that will be amortized over the remaining vesting period, through September 2026. The weighted average grant-date fair value per share of options granted during the years ended December 31, 2022 and 2021 was $7.68 and $8.07, respectively. The aggregate intrinsic value for option shares outstanding at December 31, 2022 was $1,597.

At the time of the issuances of stock options, the Company believed the Company’s estimates of the fair value for financial reporting purposes of the Company’s common stock were reasonable and consistent with the Company’s understanding of how similarly situated companies in the industry were valued.

The following table summarizes the stock-based compensation expense, for stock options only, by line item in the statements of operations for the years ended December 31, 2022 and 2021, respectively.

	December 31, 2022	December 31, 2021
Research and development	$ 368	$ 957
General and administrative	2,047	706
Total stock-based compensation expense	$ 2,415	$ 1,663

Stock Warrants

The table below summarizes the Company's warrants activities for the years ended December 31, 2022 and 2021:

	Number of Warrant Shares	Exercise Price Range Per Share	Weighted Average Exercise Price
Balance, December 31, 2020	784,224	$0.03 – 10.50	$ 7.44
Granted	55,935	9.00 – 10.50	9.36
Cancelled	(12)	10.50	10.50
Exercised	(17,024)	0.03 – 10.50	8.46
Expired	—	—	—
Balance, December 31, 2021	823,123	0.03 -10.50	7.56
Granted	—	—	—
Cancelled	—	—	—
Exercised	(16,666)	0.03 -9.00	7.21
Expired	(81,283)	0.03 -10.50	1.56
Balance, December 31, 2022	725,174	$ 3.00 -10.50	$ 8.24
Vested and exercisable, December 31, 2022	725,174	$ 3.00 -10.50	$ 8.24

The following table summarizes information concerning outstanding and exercisable warrants as of December 31, 2022:

	Warrants Outstanding			Warrants Exercisable		
Range of Exercise Prices	Number Outstanding	Average Remaining Contractual Life (in years)	Weighted Average Exercise Price	Number Exercisable	Average Remaining Contractual Life (in years)	Weighted Average Exercise Price
$ 3.00	133,333	4.17	$ 3.00	133,333	4.17	$ 3.00
9.00	425,201	2.72	9.00	425,201	2.72	9.00
10.50	166,640	2.50	10.50	166,640	2.50	10.50
$ 0.03 – 10.50	725,174	2.94	$ 8.24	725,174	2.94	$ 8.24

During the year ended December 31, 2021, in connection with the issuance of and conversion of convertible notes payable, the Company issued warrants to purchase 55,935 shares of the Company's common stock with exercise prices of $9.00 and $10.50 per share. The warrants expire five to ten years from the date of grant. Also, four stock warrant holders exercised their warrants totaling 17,024 shares with exercise prices of $0.03 and $10.50 per share, for proceeds of $144.

The Company has entered into convertible debt agreements with various lenders under which the agreements contain a provision that in the case the lender converts the notes into shares of the Company's common stock, the lender will receive a warrant to purchase up to 25% of the shares converted, with exercise prices ranging from $9.00 to $12.00 per share. The warrants, if issued, will expire over various periods from the date of grant, but none exceeding ten years. The maximum total number of warrant shares that could be granted upon conversion of all convertible debt agreements containing this provision is 183,852 as of December 31, 2022 and 2021. Subsequent to December 31, 2022, the Company closed its underwritten public offering of its common stock pursuant to an effective registration statement and in connection with the closing, the Company granted the warrant shares to the lenders (see Note 15).

The aggregate intrinsic value for warrant shares outstanding at December 31, 2022 was $1,638.

NOTE 13—INCOME TAXES

Significant components of the provision for income taxes for the years ended December 31, 2022 and 2021 are as follows:

	December 31, 2022	December 31, 2021
Current		
Federal	$ 258	$ (2,308)
State	93	(987)
Total	351	(3,295)
Deferred		
Federal	3,448	(3,611)
State	538	(725)
Total	3,986	(4,336)
Total income tax expense before change in valuation allowance	4,335	(7,631)
Change in valuation allowance	(4,335)	7,631
Total income tax expense	$ —	$ —

The reconciliation of income tax attributable to income before provision for income taxes at the U.S. federal statutory tax rate to income tax expense for the years ended December 31, 2022 and 2021 is as follows:

	December 31, 2022	December 31, 2021
Statutory federal income tax rate of 21% applied to loss before income taxes	$ (1,093)	$ (3,439)
State income tax rate of 7%, net of federal benefit	(364)	(1,146)
Convertible note interest	12	12
Other temporary differences	1,339	1,120
Change in valuation allowance	106	3,453
Total income tax expense	$ —	$ —

Significant components of the Company's deferred tax assets and liabilities as of December 31, 2022 and 2021 were as follows:

	December 31, 2022	December 31, 2021
Deferred tax assets		
Stock-based compensation	$ 9,181	$ 8,083
Accruals	4,388	3,427
Fixed assets	67	67
Net operating losses	34,921	36,333
Tax credits	4,549	4,549
Total deferred tax assets	53,106	52,459
Deferred tax liabilities		
State taxes	(2,623)	(2,789)
Prepaid expenses	(446)	—
Fixed assets	75	(168)
Total deferred tax liabilities	(2,994)	(2,957)
Net deferred tax assets before valuation allowance	50,112	49,502
Valuation allowance	(50,112)	(49,502)
Net deferred tax assets	$ —	$ —

Deferred income tax assets and liabilities are recorded for differences between the financial statement and tax basis of the assets and liabilities that will result in taxable or deductible amounts in the future based on enacted laws and rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized.

The Company has evaluated the available evidence supporting the realization of its gross deferred tax assets, including the amount and timing of future taxable income, and has determined it is more likely than not that the assets will not be realized. Due to uncertainties surrounding the realizability of the deferred tax assets, the Company has recorded a full valuation allowance against its deferred tax assets at December 31, 2022 and 2021.

At December 31, 2022 and 2021, the Company had federal income tax net operating loss carryforwards of approximately $132,000, respectively. At December 31, 2022 and 2021, the Company had California income tax net operating loss carryforwards of approximately $106,000, respectively. Of the total federal net operating loss, $22,330 has an indefinite carryforward period as of December 31, 2022. The remaining federal and California net operating loss carryforwards will expire through December 31, 2039, unless previously utilized. At December 31, 2022, the Company also has federal and California research and development tax credits of $2,579 and $1,970, respectively. The federal credits will expire through 2040 unless previously utilized. The California credits carryforward indefinitely. The utilization of net operating loss and tax credit carryforwards may be subject to limitation under the provisions of the Internal Revenue Code Section 382 and similar state provisions.

The Company has adopted the provisions in ASC 740 relating to the accounting for uncertain tax positions. This provision requires that the Company recognize the impact of a tax position in its financial statements if the position is more likely than not to be sustained upon examination and on the technical merits of the position. The Company's also has a policy to recognize interest and/or penalties on the income tax expense related to uncertain tax positions. The Company had no material uncertain tax positions as of December 31, 2022 and 2021, respectively, and consequently, no interest or penalties have been accrued by the Company.

The Company is subject to taxation in the United States and state jurisdictions. The Company's tax years for 2009 and forward are subject to examination by the United States and California tax authorities due to the carry forward of unutilized net operating losses.

NOTE 14—LEGAL MATTERS

We are currently involved in one pending litigation. Although the results of the pending legal proceeding in which we currently are involved cannot be predicted with certainty, we do not believe that there is a reasonable possibility that the final outcome of this matter will have a material adverse effect on our business or financial results. Regardless of the final outcome, however, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources, harm to our reputation and brand, and other factors.

We are not currently a party, nor have we received threat or notice that we will be a party, to any other legal proceedings. In the future, we may be involved in additional actual and/or threatened legal proceedings, claims, investigations and government inquiries arising in the ordinary course of our business, including legal proceedings, claims, investigations and government inquiries involving intellectual property, data privacy and data protection, privacy and other torts, illegal or objectionable content, consumer protection, securities, employment, contractual rights, civil rights infringement, false or misleading advertising, or other legal claims relating to our business.

NOTE 15—SUBSEQUENT EVENTS

Initial Public Offering and Conversions of Notes Payable and Preferred Stock

On January 30, 2023, the Company completed its underwritten IPO of its common stock, in which the Company issued and sold 2,500,000 shares of its common stock at a public offering price of $6.00 per share. In February 2023, the Company sold an additional 153,000 shares of common stock at $6.00 per share pursuant to the underwriters' partial exercise of their option to purchase additional shares of common stock. The total gross proceeds of the IPO were $15,918 and the Company raised approximately $12,400 in net proceeds after deducting underwriting discounts and commissions and offering expenses payable by the Company. In addition, upon the closing of the IPO, all of the Company's outstanding shares of Series A through Series K preferred stock, and certain convertible notes payable and accrued interest and loan fees, automatically converted into shares of common stock.

The accompanying unaudited pro forma balance sheet below as of December 31, 2022 has been prepared to give effect to (i) the sale of the 2,653,000 IPO shares and the automatic conversion of all outstanding shares of preferred stock into an aggregate of 8,355,610 shares of common stock, and the automatic conversion of certain convertible notes payable, accrued interest and loan fees into an aggregate of 4,134,367 shares of common stock based on the Company's proposed public offering on January 30, 2023, (ii) the issuance of 272,101 shares of common stock upon satisfaction of earned and unpaid dividends on our Series H preferred stock as of January 30, 2023, and (iii) the reclassification of the Company's warrant liabilities, totaling $169 as of December 31, 2022, to additional paid-in-capital, each in connection with the closing of our IPO.

On the date of the IPO closing on January 30, 2023, a total of 24,541,804 shares of common stock were outstanding.

The effects of these transactions on our historical December 31, 2022 financial statements are reflected in the pro forma Balance Sheet below.

Genelux Corporation
Balance Sheets
(In thousands, except for share amounts and par value data)

	December 31, 2022	Pro Forma December 31, 2022 (Unaudited)
ASSETS		
Current Assets		
Cash	$ 397	$ 12,797
Other current assets	1,495	1,495
Total Current Assets	1,892	14,292
Deferred offering costs	1,568	—
Other assets	2,071	2,071
Total Other Assets	3,639	2,071
TOTAL ASSETS	$ 5,531	$ 16,363
LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIT)		
Current Liabilities		
Accrued interest payable	$ 1,178	$ —
Accrued interest payable—director and shareholders	3,817	92
Warrant liabilities	169	—
Convertible notes payable—shareholders, current portion, including $105 past due	15,407	105
Other current liabilities	11,055	11,055
Total Current Liabilities	31,626	11,252
Long-term Liabilities		
Convertible notes payable, net of debt discount of $541	8,524	—
Other long-term liabilities	1,164	1,164
Total Long-term Liabilities	9,688	1,164
Total Liabilities	41,314	12,416
Shareholders' Equity (Deficit)		
Preferred stock, Series A through K, par value $0.001, 29,927,994 shares authorized; 22,094,889 shares issued and outstanding, respectively; no shares issued and outstanding pro forma (unaudited)	22	—
Common stock, par value $0.001, 75,000,000 shares authorized; 9,126,726 shares issued and outstanding 24,541,804 shares issued and outstanding pro forma (unaudited)	9	25
Treasury stock, 433,333 shares, at cost	(433)	(433)
Additional paid-in capital	154,401	194,137
Accumulated other comprehensive income	2	2
Accumulated deficit	(189,784)	(189,784)
Total Shareholder's Equity (Deficit)	(35,783)	3,947
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIT)	$ 5,531	$ 16,363

Other IPO-Related Transactions

Upon the closing of the IPO, the Company agreed to issue to the underwriters, warrants entitling them to purchase up to 175,000 shares of the Company's common stock. The warrants have an exercise price of $6.00 per share and expire on the fifth anniversary of the closing date of the IPO, or January 2028.

On January 30, 2023, upon the closing of the IPO, the Company filed an amended and restated certificate of incorporation (the "Restated Certificate") with the Secretary of State of the State of Delaware in connection with the closing of the IPO.

Effective as of January 30, 2023, upon the closing of the IPO, the Company adopted amended and restated bylaws (the "Restated Bylaws") in connection with the closing of the IPO.

Upon the closing of the IPO, the Company granted warrants to certain of its lenders to purchase up to 183,852 shares of the Company's common stock (see Note 12 – Stock Warrants). The warrants were granted in connection with certain convertible debt agreements with various lenders under which the agreements contained a provision that in the case the lender converts the notes into shares of the Company's common stock, the lender will receive a warrant to purchase up to 25% of the shares converted, with exercise prices ranging from $9.00 to $12.00 per share. The warrants will expire over various periods from the date of grant, but none exceeding ten years.

Other Subsequent Events

Adoption of Equity Incentive Plan and Employee Stock Purchase Plan

In June 2022, the Board of Directors adopted the 2022 Equity Incentive Plan (the "2022 Plan"). The stockholders approved the 2022 Plan in August 2022, and it became effective upon its approval by the Company's stockholders, but no grants could be made under the 2022 Plan until immediately prior to the execution of the underwriting agreement related to the IPO. Under the 2022 Plan, the Company may grant incentive stock options to employees, including employees of any parent or subsidiary, and nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance awards and other forms of stock awards to employees, directors, and consultants, including employees and consultants of the Company's affiliates. The 2022 Plan is a successor to the 2019 Plan. A total of 2,800,00 shares of common stock were approved to be initially reserved for issuance under the 2022 Plan. In addition, the number of shares of the Company's common stock reserved for issuance under the 2022 Plan will automatically increase on January 1 of each calendar year, starting on January 1, 2024 and continuing through and including January 1, 2032, in an amount equal to 5% of the total number of shares of the Company's common stock outstanding on the last day of the calendar month before the date of each automatic increase, or a lesser number of shares determined by the Company's Board of Directors.

In June 2022, the Board of Directors adopted the 2022 Employee Stock Purchase Plan (the "ESPP"). The stockholders approved the ESPP in August 2022, and it became effective immediately prior to the execution of the underwriting agreement for the IPO. A total of 770,000 shares of common stock were approved to be initially reserved for issuance under the ESPP. In addition, the number of shares of common stock reserved for issuance under the ESPP will automatically increase on January 1 of each calendar year, beginning on January 1, 2024 and continuing through, and including, January 1, 2032, by the lesser of (1) 1% of the total number of shares of the Company's common stock outstanding on the last day of the calendar month before the date of the automatic increase, and (2) 2,100,000 shares; provided, that before the date of any such increase, the Company's Board of Directors may determine that such increase will be less than the amount set forth in clauses (1) and (2).

Stock Option Repricing

In September 2022, the Company's board of directors approved a stock option repricing whereby the exercise prices of previously granted and unexercised options held by certain employees, directors and key advisers with exercise prices between $9.00 and $10.50 per share, would be adjusted (the "Stock Option Repricing") to equal the initial offering price, contingent and effective upon the completion of the Company's IPO. In cnnection with the closing of the IPO, the Stock Option Repricing was completed and the options to purchase 4,092,886 shares of the Company's common stock, with exercise prices previously between $9.00 and $10.50, were repriced to the initial offering price of $6.00 per share, of which a total of 2,796,400 shares of Common Stock are held by executive officers and directors. The total cost of the repricing was $12,741.

Bridge Loans

Subsequent to December 31, 2022, the Company borrowed an additional $500 from one of its shareholders under its bridge loan financing (see Note 6). The note accrues interest at 12% per annum, is unsecured, includes a warrant to purchase up to 13,988 shares of the Company's common stock with an exercise price per share equal to 90% of the IPO price ($5.40 per share), and is due at the earlier of June 15, 2023 or the month after the closing of the IPO (February 2023). In connection with the bridge loan financing, warrants were granted to the lenders to purchase up to an aggregate total of 44,441 shares, all of which were formally granted upon the closing of the IPO.

Sale of Product to Newsoara

Subsequent to December 31, 2022, the Company, under its Newsoara agreement (see Note 9), invoiced and collected $170 relating to supplying product for Newsoara to use in their clinical trials. As the product did not ship during the year ended December 31, 2022, the Company recorded the cash received as deferred revenue until the product is shipped. Subsequent to December 31, 2022, the Company shipped the product to Newsoara and thus recognized the revenue during the three months ending March 31, 2023.

Restricted Stock Grant

Subsequent to December 31, 2022, the Company's board of directors approved the granting of restricted stock units to its directors and employees. A total of 113,500 shares of the Company's common stock was granted. The total value of the shares on the grant date was $746.

Lease Extension

Subsequent to December 31, 2022, the Company extended its laboratory facility lease until December 2024 (see Note 5). The lease was set to expire in February 2023. The average monthly rent payment on the extended lease is approximately $30 per month. The Company will account for the lease extension during the three months ended March 31, 2023.

Exercise of Stock Warrant

Subsequent to December 31, 2022, a shareholder completed a cashless exercise of their stock warrant, under which they exercised their warrant to purchase 16,666 shares of the Company's common stock. The shareholder received 11,666 shares of the Company's common stock upon the exercise of their warrant.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statement on Form S-8 (Registration No. 333-269427) pertaining to the 2009 Equity Incentive Plan, the 2019 Equity Incentive Plan, the 2022 Equity Incentive Plan, and the 2022 Employee Stock Purchase Plan of Genelux Corporation of our report dated March 29, 2023, relating to the financial statements for the year ended December 31, 2022 (modified for a going concern uncertainty) which appears in this Form 10-K.

/s/Weinberg & Company, P.A.
Los Angeles, California
March 29, 2023

Exhibit 31.1

CERTIFICATION PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED

PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Thomas Zindrick, J.D., certify that:

1. I have reviewed this Annual Report on Form 10-K of Genelux Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)):

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me by others within those entities, particularly during the period in which this report is being prepared;

(b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report my conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 29, 2023

By: /s/Thomas Zindrick
Thomas Zindrick, J.D.
President, Chief Executive Officer and Chairman
(*Principal Executive and Financial Officer*)

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,

AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Genelux Corporation (the "Company") for the fiscal year ended December 31, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Thomas Zindrick, J.D., President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 29, 2023

By: /s/ Thomas Zindrick
Thomas Zindrick, J.D.
President, Chief Executive Officer and Chairman
(*Principal Executive and Financial Officer*)

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Genelux Corporation under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.