ANNUAL REPORT

2025

GENELUX

HOPE

PURPOSE

PATIENTS

SHAREHOLDERS

TRUST

VALUES

CULTURE

CLARITY

TRANSFORMATIVE

RESPECT

CONNECTION

Our **VISION** is to build a pre-eminent immuno-oncology company that addresses serious unmet medical needs.

Our **MISSION** is to develop immunotherapeutics that deliver the full complement of tumor (neo)antigens with the power to stimulate a personalized immune response to fight cancer, individual by individual.

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INTRODUCTION

Dear Stockholders,

As we reflect on 2025, it was a year in which Genelux continued its disciplined execution across clinical development, operations, and corporate governance.

The progress achieved this year underscores our commitment to developing a practice-changing oncolytic immunotherapy that addresses some of the greatest unmet needs in oncology.

Thomas D. Zindrick
President, CEO and Chairman
of Genelux Corporation

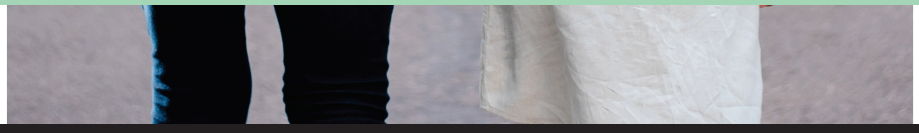
2025 YEAR IN REVIEW

The beginning of 2025 was highly productive, and we carried the momentum throughout the year. We strengthened the organization by welcoming accomplished biopharmaceutical executives to our management team and by completing an underwritten public offering to bolster our balance sheet.

Enrollment continued in our clinical trials, which are designed to build on prior pre-clinical and clinical studies. These include (i) the OnPrime/GOG-3076 Phase 3 registrational trial in ovarian cancer; and (ii) in our systemic administration program, two registration-path trials in lung cancer.

In anticipation of clinical success, we progressed operational and facility readiness activities to support the filing of a Biologics License Application (BLA), as well as the commercial manufacture and launch of Olvi-Vec.

"Platinum-resistant/refractory ovarian cancer remains one of the most challenging areas in oncology. We believe Olvi-Vec has the potential to redefine the treatment paradigm for these patients."



CLINICAL DEVELOPMENT PROGRESS

Our focus is to establish Olvi-Vec as a differentiated immunotherapeutic that favorably modifies the tumor microenvironment and resensitizes tumors to standard-of-care regimens, including frontline platinum-based chemotherapy. The advancements made in 2025 generate momentum toward delivering meaningful data catalysts in 2026 across multiple solid tumor indications that, together, represent a multi-billion-dollar market opportunity.

Genelux continued to advance three sponsored clinical trials in a thoughtfully integrated strategy around its most advanced clinical data:

01 **OnPrime / GOG-3076 (U.S.-based trial):** Phase 3 registrational trial in platinum-resistant/refractory ovarian cancer (PRROC)

02 **Olvi-Vec-SCLC-202 (Greater China-based trial):** Phase 1b/2 trial in recurrent small cell lung cancer (SCLC)

03 **VIRO-25 (U.S.-based trial):** Phase 2 trial in recurrent non-small cell lung cancer (NSCLC)

OnPrime/GOG-3076

Our highest clinical priority remained the OnPrime/GOG-3076 Phase 3 registrational trial in women diagnosed with PRROC. OnPrime is designed based on the positive results achieved in our completed VIRO-15 Phase 2 trial and is being conducted in collaboration with the GOG Foundation (a non-profit gynecologic cancer research group).

It is a U.S.-based, multi-center, randomized, open-label study evaluating the safety and efficacy of intraperitoneally administered Olvi-Vec followed by systemic administration of platinum-doublet chemotherapy and bevacizumab, compared to the active comparator arm of physician's choice chemotherapy and bevacizumab. The trial will enroll a sufficient number of patients to achieve 127 PFS events, with the primary endpoint of progression-free survival (PFS) and with secondary endpoints including overall survival (OS).

Throughout 2025, patient enrollment remained active across our clinical sites. We are pleased to see strong engagement from investigators and site teams, and from patient advocacy groups. Notable achievements included the following:

- The Independent Data Monitoring Committee regularly reviewed safety data and recommended continuation of the trial without modification.

- Genelux achieved alignment with the FDA on key elements of the approval pathway for Olvi-Vec in platinum-resistant/refractory ovarian cancer. Specifically, the agency guided that if a clinically meaningful PFS advantage is demonstrated in the absence of a decrement in OS, this could potentially support traditional approval without the need to conduct a separate confirmatory trial powered to demonstrate an OS benefit. Additionally, the FDA encouraged us to request a meeting prior to filing a BLA upon study completion to discuss next steps.

Systemic Administration Program

In parallel, we are advancing two ongoing registration-path trials in recurrent lung cancer designed to further demonstrate the ability of Olvi-Vec to resensitize multiple solid tumor types after failing frontline platinum-based therapy. Each trial delivers Olvi-Vec via systemic (intravenous) administration, a physician-preferred route of administration.

- The OLVI-VEC-SCLC-202 Phase 1b/2 study in recurrent SCLC is evaluating Olvi-Vec in combination with platinum and etoposide chemotherapy in patients with platinum-resistant or platinum-refractory disease. The trial is co-sponsored by our licensing partner, Newsoara HYK Biopharmaceuticals Co., Ltd., and is being conducted at sites in China.

- The VIRO-25 Phase 2 study in recurrent NSCLC is evaluating Olvi-Vec in combination with platinum-based chemotherapy and an immune checkpoint inhibitor. The trial is being conducted at U.S. sites.

We are enrolling patients into the dose-escalation portion of each open-label study, which will support determination of a systemic dose for future trials.

In March 2025, we reported positive preliminary safety and anti-tumor activity data from the Phase 1b dose-escalation portion of OLVI-VEC-SCLC-202 at the time of data cutoff on February 19, 2025. Initial dose escalation cohorts achieved a 71% disease control rate (5/7 evaluable participants), with (i) two of the five exhibiting partial responses (PRs) and (ii) all five experiencing reductions across all target lesions, including a tumor reduction of approximately 79% in one patient. Additionally, the three remaining patients with disease control, including one individual with three prior lines of treatment, achieved stable disease with tumor size reductions of 24% to 29.2%. Olvi-Vec was generally well tolerated with a favorable safety profile.

BLA Filing and Launch Readiness

To prepare for regulatory filing and launch readiness of Olvi-Vec, we established a detailed framework for BLA filing, progressed manufacturing facility upgrade and process improvement projects for commercial production, and developed initial marketing and sales strategies.



GOVERNANCE AND CULTURE ENHANCED

We remain committed to transparency, ethical leadership, and strong governance standards. The dedication of our employees and the aligned oversight from our Board continued to shape a culture of accountability, innovation, and operational excellence.

With important data milestones on the horizon, we are entering an exciting phase of growth and strengthening our organization with thoughtful additions to our leadership team. We welcomed two accomplished executives with deep industry expertise and strategic acumen to enhance our ability to scale operations and build long-term value for shareholders.

Chief Financial Officer

MATT
PULISIC

In January 2025, Mr. Matt Pulisic joined as our new Chief Financial Officer. Matt brought over 19 years of finance and commercial experience in the biopharmaceutical industry, with a background spanning the United States, Europe, and Asia. Prior to joining Genelux, he served as Vice President of Finance at Arrowhead Pharmaceuticals, Inc. He began his career at Amgen Inc. as a Research Associate before transitioning into finance, eventually holding senior roles including Finance Director of Amgen Worldwide and Head of Capital Finance. Matt earned his M.B.A. in Finance from California Lutheran University and holds a B.S. in Biochemistry and Molecular Biology from the University of California, Santa Cruz.

General Counsel and Head of Business Development

ERIC
GROEN

In July 2025, the Company appointed Mr. Eric Groen as General Counsel, Corporate Secretary, Chief Compliance Officer, and Head of Business Development. Eric brought over 25 years of experience in the life sciences industry and has held senior leadership roles across legal, compliance, and corporate development functions. Prior to joining us, he served as General Counsel at Rani Therapeutics Holdings, Inc. and held a range of senior legal positions at Amgen Inc., supporting business operations across global markets. Eric holds a B.A. in Political Science from the University of California, Santa Barbara and a J.D. from Harvard Law School.

FINANCIAL AND CORPORATE HIGHLIGHTS

Throughout 2025, we maintained disciplined cost management while prioritizing high-value clinical initiatives, and continuing to prepare for future clinical development and commercialization. This cost-effective model reflects our long-standing commitment to building a resilient, execution-focused organization capable of advancing complex oncology programs while efficiently deploying capital and minimizing equity dilution.

Balance Sheet Strength

To support our strategic priorities, we enhanced our capital position and reinforced our financial flexibility through a $10.5 million underwritten public offering in March 2025.

LOOKING AHEAD TO 2026 & BEYOND

2026 is expected to be one of the most consequential years in our Company's history, with the release of potentially major clinical milestones that could bring us closer to delivering a transformative therapy to cancer patients who have limited treatment options.

> *"We are excited to begin a pivotal 2026 with the release of interim data from our systemic lung cancer programs, which reinforce the potential of Olvi-Vec as a platinum-resensitizing agent across multiple platinum-treated solid tumors," said Thomas Zindrick, President, CEO and Chairman of Genelux.*

OLVI-VEC-SCLC-202 PHASE 1B/2

Platinum-relapsed or platinum-refractory advanced SCLC
(Update to the data reported in March 2025)

- 9 evaluable patients
- Overall response rate (ORR) of 33% (3/9 patients), including three partial responses (PRs)
  - Two of the three PRs occurred in Cohort 4, the highest dose cohort tested as of the data review cutoff date, with tumor shrinkage of approximately 55% and 85% from baseline, representing an ORR of 67% (2/3) in Cohort 4 and potentially suggesting a dose-response trend
- Disease control rate (DCR) of 67% (6/9 patients)
  - Tumor shrinkage of 24–85% among the six DCR patients, all of whom experienced a reduction in all target lesions from baseline
- Olvi-Vec generally well tolerated
- Exploratory durability signals:
  Two PR patients across different cohorts have been evaluated in long-term follow-up:
  - A patient with 1 prior line, at last scan, achieved a PR with an ongoing PFS of 12.1 months
  - A patient with 4 prior lines had a PFS of 7.7 months, which exceeds the PFS in the immediately preceding line in the same patient (1.9 months) by 5.8 months

Data review cutoff date: December 23, 2025

VIRO-25 PHASE 2

Advanced or metastatic recurrent NSCLC

- 5 evaluable patients
- DCR of 60% (3/5 patients)
- Tumor size changes among the three DCR patients were +8.9%, -18.9%, and -22.7%, respectively, compared to baseline
- Olvi-Vec generally well tolerated

Data review cutoff date: December 31, 2025

This combined dataset reinforces our commitment to advancing the development of Olvi-Vec in lung cancer.

Leadership Expansion - New Chief Medical Officer

JASON
LITTEN

In January 2026, we were pleased to welcome Dr. Jason Litten as Chief Medical Officer. Jason is a seasoned biopharmaceutical executive with over 20 years of experience spanning academia, large pharmaceutical organizations, and innovative biotechnology companies. He served as Chief Medical Officer at Chimeric Therapeutics, Ltd. and at Artiva Biotherapeutics, Inc. Earlier in his career, Jason held senior leadership roles at Optera Therapeutics Corp., Juno Therapeutics, Inc., Clovis Oncology, Inc., and Amgen Inc., contributing to global development strategies for novel oncology therapeutics.

Jason earned an M.D. from Emory University School of Medicine and a B.S. in Finance and Economics from Cornell University. He completed postdoctoral training in Pediatric Hematology & Oncology at the University of Texas Southwestern Medical Center at Dallas and is licensed as a physician and surgeon in California.

Strengthened Capital Position Heading into Key Milestones

In January 2026, we completed a $20.0 million underwritten public offering. This financing provided additional working capital to extend our operating runway beyond key inflection points across the Olvi-Vec clinical program and to support BLA filing preparation in advance of OnPrime topline readout and commercial readiness activities, including completion of commercial manufacturing upgrades to our facility in San Diego.

UPCOMING MILESTONES

OnPrime/GOG-3076 Phase 3 Results Expected 2H, 2026

The topline data readout of the OnPrime trial remains the most significant near-term milestone. A positive outcome could support a future BLA filing and marketing authorization for Olvi-Vec to treat heavily pretreated platinum-resistant/refractory ovarian cancer patients.

Systemic Administration Updates Lung Cancer Updates

Throughout 2026, we anticipate continued updates from our dose-escalation cohorts in the recurrent SCLC and recurrent NSCLC studies. These systemic administration data updates hold the potential to provide deeper insight into the potential of Olvi-Vec to anchor broader commercial opportunities across larger and earlier-line patient populations.

* Pro forma balance sheet as of 12/31/25, plus ~$18.5M in net proceeds raised in January 2026 (after deducting underwriting discounts, commissions and offering expenses).

Looking back, 2025 was a year of substantive progress and foundational strengthening. Looking ahead, 2026 may become one of the most pivotal years in our Company's history with the potential to launch Genelux on a significant growth trajectory.

The oncology landscape is evolving rapidly, with a growing emphasis on therapeutic combinations and personalized approaches. With its clinical tolerability, broad spectrum of activity and *UNIQUE MECHANISM OF ACTION* to favorably modify the tumor microenvironment, *OLVI-VEC* could become a backbone component of combination cancer therapy... a *"DARE-TO-DREAM"* scenario.

None of this would be possible without the steadfast commitment of our Board, the dedication of our employees, and the invaluable partnership of clinicians and investigators. We are also deeply grateful for the continued trust of our stockholders. Above all, we extend our deepest thanks to the patients and their families, whose courage and participation make our work possible.

Together, we remain unwavering in our mission, to bring transformative immunotherapies to cancer patients in need of better options.

Thank you for your continued partnership and trust.

Thomas D. Zindrick
President, CEO and Chairman of Genelux Corporation

On behalf of our Board of Directors, I am pleased to invite you to join the Annual Meeting of Stockholders of Genelux Corporation, which will take place virtually on June 16, 2026 at 8:00 am Pacific Time.

CORPORATE VALUES

We exist to pioneer transformative therapies with the promise of life-changing outcomes, giving patients hope while creating sustainable value for our shareholders.

We succeed by working together with clarity, trust and shared purpose.

Our culture is built on genuine connection, mutual respect, and a willingness to help.

Advance Medicines that Matter.

- We act with urgency and unwavering dedication, considering patients, employees and shareholders at the center of every decision.
- We deliver timely, high-quality, and impactful results to provide innovative therapies.
- We uphold the highest standards of quality, safety and scientific rigor in everything we do.
- We strive to reduce burden and complexity for patients, caregivers, and care teams, empowering healthcare providers to focus fully on the patients in their care.

Say it. Do it. Own it.

- We act with integrity, honesty, and high ethical standards.
- We execute with discipline, managing resources, and driving innovation — understanding that our actions shape the company's performance.
- We take ownership of our commitments and actions, knowing consistent reliability and transparent information-sharing are critical to patient safety, regulatory trust, and responsible stewardship of therapies from clinical trials through commercialization and beyond.
- We build a collaborative environment where people feel free to speak up, seek help, and share hard news without hesitation — actively listening so we can identify, understand, and solve challenges together.

Connection Builds Strength.

- We lead with respect, kindness, and an understanding that our differences make us stronger.
- We create a sense of belonging where people can show up as themselves and feel valued.
- We invest in relationships through everyday interactions and shared moments, in person and across locations.
- We celebrate wins, learn from setbacks, and recognize the effort and sacrifices behind our progress.

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, 2025

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**

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

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

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

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

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

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

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

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

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

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 registrant's voting and non-voting outstanding common stock held by non-affiliates was approximately $89.1 million, based upon the closing price of the registrant's common stock on June 30, 2025.

As of March 16, 2026, 44,805,811 shares of registrant's Common Stock were issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The registrant intends to file a definitive proxy statement pursuant to Regulation 14A within 120 days of the end of the fiscal year ended December 31, 2025. Portions of such definitive proxy statement are incorporated by reference into Part III of this Annual Report on Form 10-K.

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (Annual Report) contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and we intend that such forward-looking statements be subject to the safe harbors created thereby. All statements other than statements of historical facts contained in this Annual Report, 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.

Forward-looking statements contained in this Annual Report include statements regarding:

- the timing, progress and results of clinical studies for our product candidates, including the development of our only clinical-stage product candidate, Olvi-Vec;
- the timing, scope and likelihood of regulatory filings and approvals, including final regulatory approval of our product candidates;
- the potential benefits and market opportunity for our product candidates and CHOICE platform;
- expectations regarding the size, scope and design of clinical studies;
- our manufacturing, commercialization, and marketing plans and strategies;
- our plans to hire additional personnel and our ability to attract and retain such personnel;
- our estimates of the number of patients who suffer from the diseases we are targeting and potential growth in our target markets;
- our expectations regarding the approval and use of our product candidates;
- our competitive position and the development and impact of competing therapies that are or may become available;
- expectations regarding future events under collaboration and licensing agreements, including potential future payments, as well as our plans and strategies for entering into further collaboration and licensing agreements;
- our intellectual property position, including the scope of protection we are able to establish and maintain for intellectual property rights covering product candidates we may develop, including the extensions of existing patent terms where available, the validity of intellectual property rights held by third parties, and our ability not to infringe, misappropriate or otherwise violate any third-party intellectual property rights;
- the rate and degree of market acceptance and clinical utility of product candidates we may develop;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our future financial performance;
- the period over which we estimate our existing cash, cash equivalents, restricted cash and marketable securities will be sufficient to fund our future operations;
- our expected use of net proceeds from our financing transactions;
- the impact of laws and regulations;
- the impact of geopolitical and macroeconomic factors; and
- other risks and uncertainties, including those described under Part I, Item 1A, “Risk Factors” in this Annual Report.

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 “Item 1A. Risk Factors” of Part I and “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations” of Part II of 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. Readers should carefully review these risks, as well as the additional risks described in other documents we file from time to time with the Securities and Exchange Commission (the SEC). Statements made herein are as of the date of the filing of this Annual Report with the SEC and should not be relied upon as of any subsequent date. 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 many risks and uncertainties, as more fully described in under Part I, Item 1A, "Risk Factors" in this Annual Report. Some of these risks and uncertainties are summarized below. The summary below does not contain all of the information that may be important to you, and you should read this summary together with the more detailed discussion of these risks and uncertainties contained in "Risk Factors." 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 Olvi-Vec and any of our future 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.
- 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.
- 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.
- 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 and the third parties with whom we work are subject to stringent and evolving U.S. and foreign laws, regulations, and rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Our (or the third parties with whom we work) actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including class-action claims) and mass arbitration demands; 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.
- 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.

PART I

Item 1. BUSINESS

A. Overview

Genelux is a late clinical-stage biopharmaceutical company focused on developing next-generation oncolytic viral immunotherapies for patients suffering from aggressive and/or difficult-to-treat tumor types. 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. Our lead 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.

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.

We are executing a late-stage clinical program of our lead product candidate, Olvi-Vec, to demonstrate platinum-resensitization in multiple indications. We are currently evaluating Olvi-Vec in three clinical trials:

- a Phase 3 registrational trial in the U.S. to treat patients with platinum-resistant/refractory ovarian cancer (PRROC),
- a Phase 2 clinical trial in the U.S. to treat patients with recurrent non-small cell lung cancer (NSCLC), and
- a Phase 1b/2 clinical trial in China to treat patients with recurrent small cell lung cancer (SCLC).

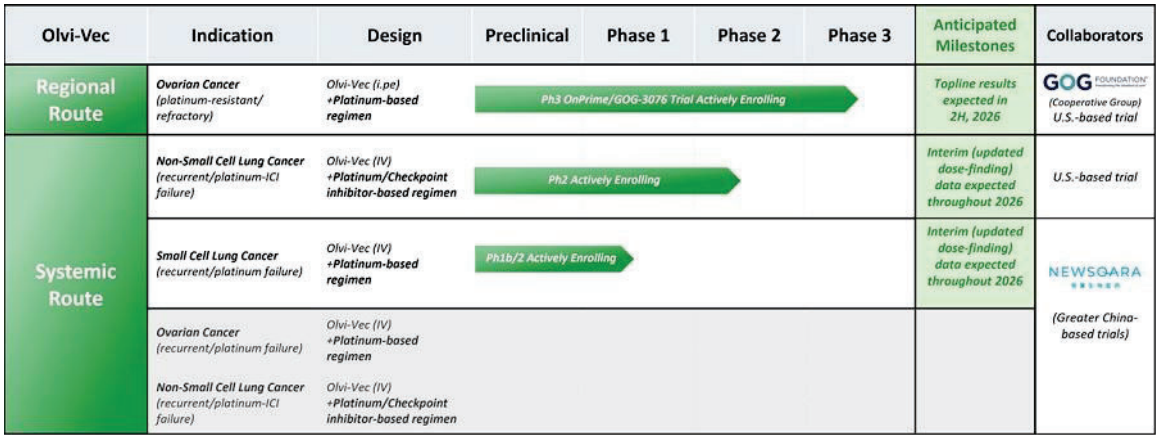
The Phase 3 registrational trial, called the OnPrime/GOG-3076 trial, is evaluating the administration of Olvi-Vec intraperitoneally to treat patients with PRROC. The Phase 2 NSCLC trial, called the VIRO-25 trial, and the Phase 1b/2 SCLC trial are evaluating Olvi-Vec administered systemically (i.e., intravenously) to treat patients with recurrent NSCLC and SCLC, respectively. Our development of Olvi-Vec is discussed in more detail in the *Development Programs* section below.

In September 2021, we entered into a License Agreement (the Newsoara License Agreement) with Newsoara BioPharma Co. Ltd. In October 2025, Newsoara BioPharma Co. Ltd. assigned all of its rights and obligations under the Newsoara License Agreement to an affiliate, Newsoara HYK Biopharmaceuticals Co., Ltd. We refer herein to the counterparty to the Newsoara License Agreement as Newsoara. Pursuant to the Newsoara License Agreement, 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 (the Newsoara Field). The Newsoara License Agreement is discussed in more detail in the *Newsoara License Agreement* section below.

We have a facility in San Diego, California for current Good Manufacturing Practice (cGMP) manufacturing. The facility is producing cGMP material that is being used in our ongoing clinical trials in the U.S. and China and that we intend to use in additional clinical trials of Olvi-Vec and for the initial commercial launch of Olvi-Vec, if approved. We also lease a second building in the same location which, when upgrades are completed, will provide laboratory capabilities and administrative offices.

B. Pipeline

Our pipeline is summarized below:



C. 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, initially 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 a late-stage clinical development program focused on platinum resensitization, and seek regulatory approval.*** Our Phase 3 OnPrime/GOG-3076 registration trial of Olvi-Vec in PRROC and our Phase 2 VIRO-25 trial, which is an open-label, randomized and controlled clinical trial of Olvi-Vec in patients with recurrent NSCLC, are being conducted in the United States and are ongoing.
- ***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.*** Our co-sponsored Phase 1b/2 clinical trial of Olvi-Vec in patients with recurrent SCLC in China is ongoing.
- ***Prepare for U.S. commercial launch in ovarian cancer.*** As our clinical trial program progresses in ovarian cancer, we intend to expand our preliminary commercial strategy initiatives and support corporate development efforts.
- ***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.
- ***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 are positioned to strengthen our leadership in the oncolytic viral immunotherapy field by leveraging the VACV product candidates generated by our CHOICE platform.
- ***Seek additional development and commercial collaborations for Olvi-Vec and our other human therapeutic product candidates, while retaining 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.

The Genelux Approach

Oncolytic VACV

Olvi-Vec utilizes VACV as the backbone of our proprietary CHOICE discovery platform. VACV is a member of the Orthopoxvirus genus and contains a single linear DNA genome.

Our proprietary CHOICE discovery platform 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.).

We have generated an extensive portfolio of oncolytic vaccinia immunotherapy clinical candidates, of which, Olvi-Vec is the furthest along in clinical development. In addition to Olvi-Vec, we have over 500 different versions of the VACV armed with greater than 110 transgenes, having a variety of engineered attributes, including immune modulatory and tumor cell killing properties.

Our oncolytic immunotherapy product candidates are intended to selectively kill tumor cells and induce a robust immune response against a patient's tumor neoantigens. Importantly, these 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.

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).

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, and systemic deliveries, as a monotherapy and in combination with other therapies, in seven completed clinical trials with a variety of cancer types. Those clinical trials have yielded data that has informed our current and future clinical strategy and trial design involving multiple indications and methods of delivery.

In our completed 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 maximum tolerated dose (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; 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 and/or induced anti-vaccinia antibody levels by high and/or extended 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
- Capable of infecting tumor tissues and reducing circulating tumor cells.

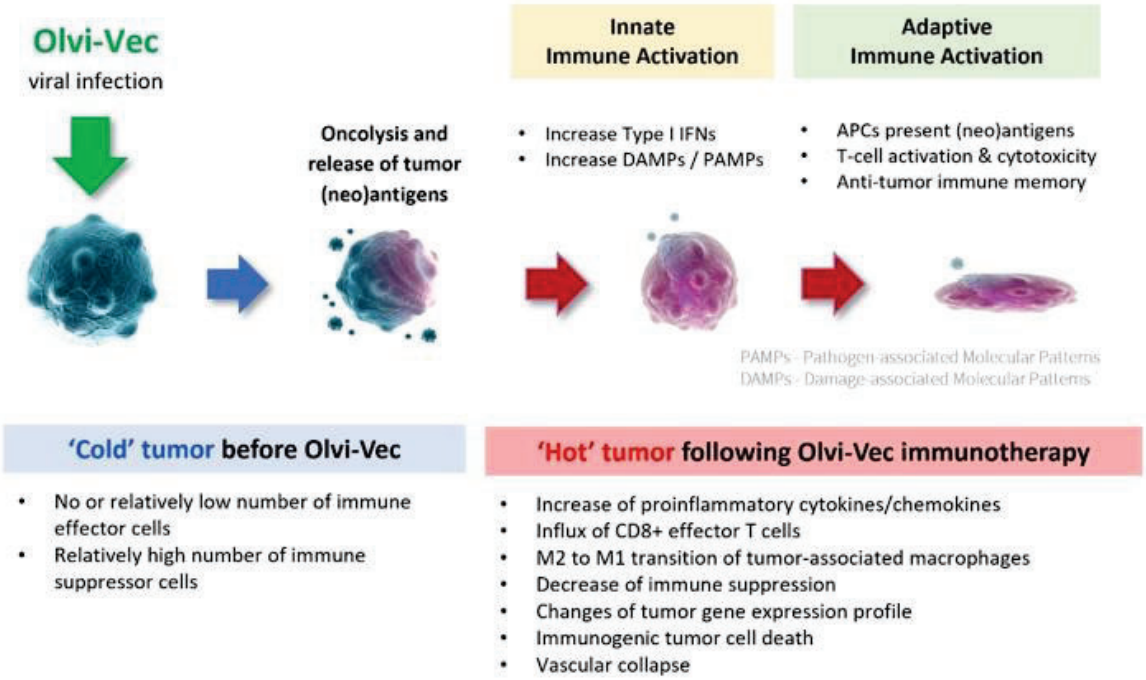
Mechanism of Action

Olvi-Vec is a robust immune modulator that selectively replicates in tumor cells, unleashing the body's immune system to mount a personalized attack against cancer cells throughout the body. Olvi-Vec is believed to accomplish this by the following processes:

- 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 tumor cell killing and viral-changes in tumor-associated vasculature;

- Infection enhances the neoantigen presentation and stimulates a tumor-specific immune response which results in the body's immune system attacking and killing tumor cells; and
- Infection converts the tumor microenvironment from immunosuppressive (cold state) to immunoreactive (hot state).

The following diagram sets forth Olvi-Vec's proposed mechanism of action.



D. Development Programs

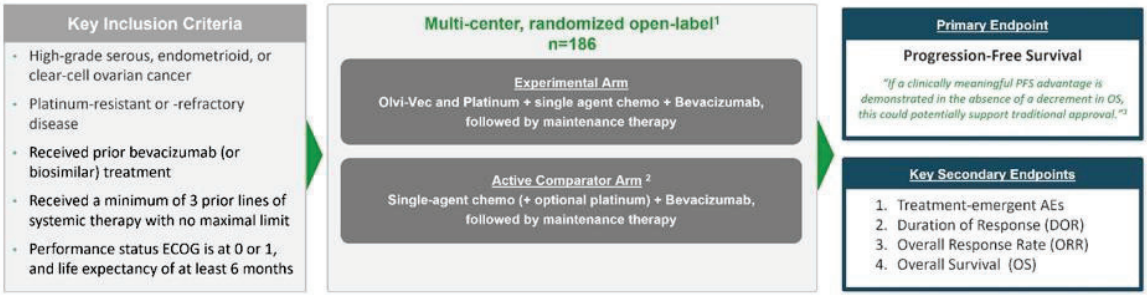
Platinum Resistant/Refractory Ovarian Cancer

We envision that Olvi-Vec-primed immunochemotherapy may overcome chemotherapy resistance for patients with end-stage ovarian cancer that would otherwise consider palliative care or use of drugs with historically poor response rates. We initiated a Phase 3 OnPrime/GOG-3076 registration trial in PRROC in 2022. The trial is an open-label, randomized control design (2:1 randomization), enrolling patients who are platinum resistant/refractory by standard definitions and received a minimum of 3 prior lines of therapy. The trial is designed to address a broad and underserved pool of patients and the inclusion criteria allows patients to enroll regardless of (i) tumor biomarkers, (ii) platinum refractory tumors or (iii) the maximum number of prior lines of treatments (i.e., no cap on previous treatments).

Patients in the experimental arm of the trial 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.

Patients in the active comparator arm of the trial receive a regimen of single agent chemotherapy with optional platinum, plus bevacizumab followed by maintenance therapy. Total trial enrollment will be a number of patients sufficient to achieve a primary progression-free survival analysis (PFS) of 127 events. We anticipate reporting topline results in the second half of 2026. Additionally, in communication regarding the Phase 3 OnPrime/GOG-3076 registrational trial in March 2025, the FDA stated that an interim analysis of overall survival (OS) should be planned at the time of the primary PFS analysis and confirmed that if a clinically meaningful PFS advantage is demonstrated in the absence of a decrement in OS, this could potentially support traditional approval. The FDA further recommended us to request a pre-Biologics License Application (BLA) meeting with the FDA with topline safety and efficacy data following completion of the trial so that the FDA may discuss next steps.

The following graphic summarizes the study design for the Phase 3 OnPrime/GOG-3076 registration trial.



Previously, we conducted a Phase 1b/2 clinical trial of Olvi-Vec, which was administered intraperitoneally in a single round of treatment consisting of a bolus infusion on two consecutive days. In the Phase 1b portion of the clinical trial, patients were treated with Olvi-Vec alone, in three dose escalation cohorts. 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). Patients enrolled into the trial were heavily pretreated (with a median of four prior lines of therapy), with confirmed progressive disease (PD) at the time of enrollment, and had PRROC, with poor responses to conventional chemotherapies. The topline data of the Phase 2 portion was published in JAMA Oncology in May 2023.

In the Phase 1b portion of the clinical trial, no virus- related severe organ toxicity was observed by clinical or serologic parameters, and a maximum tolerated dose was not reached. Olvi-Vec treatment was observed to be well tolerated.

In the Phase 2 portion of the clinical trial, data from patients who received Olvi-Vec-primed immunochemotherapy supported that there was demonstrated responsiveness to platinum- based therapy, to which they previously were deemed resistant or refractory, leading to the hypothesis that treatment with Olvi-Vec may re-sensitize patients to platinum-based therapies. As shown in the following figure, this was documented by multiple efficacy evaluation endpoints (based on pre-chemotherapy baseline), such as overall response rate (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, the heavily pretreated patients with median 4 prior lines receiving Olvi-Vec-primed immunochemotherapy generally showed marked clinical benefits, particularly with respect to ORR per RECIST 1.1 (54%: 19% CRs; 35% PRs) with durable response, median PFS (11.0 months) and median OS (15.7 months). Historically, for such patients the expected ORR per RECIST 1.1 would be < 20%, median PFS < 4 months, and median OS < 12 months. Of note, an ORR by RECIST 1.1 of 54% and median PFS of 11.4 months were achieved in patients with platinum-refractory disease versus the historically expected ORR per RECIST 1.1 of < 10%, median PFS < 3 months; prior to joining our trial, these patients progressed during, or within one month after, receiving their most recent prior platinum-based therapy.

With 13 objective responders per RECIST 1.1 out of 24 evaluable patients, the trial results exceeded the pre-defined threshold of 43%, and after our discussions with the FDA, supported moving into a Phase 3 trial.

Overall Response Rate (ORR), including Complete Responses (CR) & Partial Responses (PR), and Progression-Free Survival (PFS)*

	ORR by RECIST1.1**	Duration of Response	ORR by CA-125	Median PFS	Median Overall Survival (OS)
All patients (n= 27) (95% CI)	**54%** (13◊/24◊◊) (33 - 74) **CR=8% PR=46%**	**7.6 mos** (3.7 - 9.6)	**85%** (22/26◊◊◊) (65 - 96)	**11.0 mos** (6.7 - 13.0)	**15.7 mos** (12.3 - 23.8)
Platinum-resistant (n=14) (95% CI)	**55%** (6/11) (26 - 84) **CR=18% PR=36%**	**7.6 mos** (3.7 - NA)	**85%** (11/13) (55 - 98)	**10.0 mos** (6.4 - NA)	**18.5 mos** (11.3 – 23.8)
Platinum-refractory (n=13) (95% CI)	**54%** (7/13) (27 - 81) **CR=0% PR=54%**	**8.0 mos** (3.7 - NA)	**85%** (11/13) (55 - 98)	**11.4 mos** (4.3 -13.2)	**14.7 mos** (10.8 – 33.6)

*Baseline for ORR & PFS evaluation is the timepoint immediately prior to starting post-Olvi-Vec carboplatin doublet +/- bevacizumab to allow direct comparison to historical data or patients' own previous line of chemotherapy
**Eligible for evaluation: with at least 1 measurable target lesion at baseline; including 2 patients without post-chemo scan after virotherapy, and therefore are assigned to the 'inevaluable for response' category per RECIST1.1
◊Including 3 unconfirmed; 2 in resistant and 1 in refractory groups
◊◊Three of 27 patients were not evaluable as defined by RECIST 1.1 criteria due to no measurable disease. However, these 3 patients were evaluable by the Gynecological Cancer InterGroup (GCIG) CA-125 criteria, showing 2 partial responses and 1 complete response as best response.
◊◊◊One of 27 patents was not evaluable by GCIG CA-125 criteria. However, this patient was evaluable by RECIST 1.1, showing stable disease as best response.

The majority of patients treated with Olvi-Vec-primed immunochemotherapy showed clinical benefits exceeding their own last prior line of therapy (median PFS of 11.0 months versus 4.5 months) with preserved or improved performance status. Additionally, 20% of patients were long-term survivors, which is generally regarded as a hallmark of clinically beneficial immunotherapies.

Systemic Administration

We selected recurrent lung cancers (recurrent SCLC and recurrent NSCLC) as our initial registration-path indications for intravenous delivery of Olvi-Vec-primed immunochemotherapy because of the promising preclinical and clinical data generated in patients with lung disease (primary or metastatic) in our prior clinical trials. We believe intravenous delivery of Olvi-Vec to the lung, unlike other viruses that are administered locally, 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. In a previous Phase 1b trial, Olvi-Vec demonstrated a dose-dependent overall survival benefit in heavily pre-treated solid tumor patients.

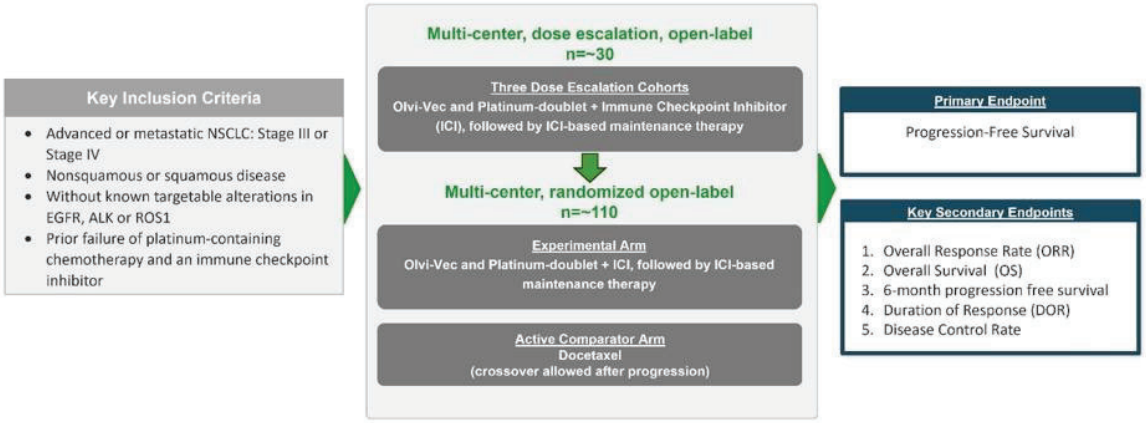
In addition, we selected recurrent patients because of the promising preclinical and clinical data generated in recurrent ovarian cancer patients in our Phase 2 VIRO-15 trial. Each of these trials is designed to enroll and re-challenge patients who have failed prior platinum therapy (and, in the case of the NSCLC re-challenge patients who also failed a prior immune checkpoint inhibitor).

The Phase 1b/2 SCLC trial and Phase 2 VIRO-25 trial are actively enrolling in dose escalation cohorts to inform dose selection for the subsequent portion of the studies.

Non-Small Cell Lung Cancer

In 2024, we initiated enrollment in the dose escalation portion of our Phase 2 VIRO-25 trial in the United States, prior to selecting a dose to potentially move into an open-label, randomized, and controlled clinical trial of Olvi-Vec in patients with recurrent NSCLC (after progression on a front-line maintenance Immune Checkpoint Inhibitor-based regimen).

The following graphic summarizes the study design for the Phase 2 VIRO-25 trial:



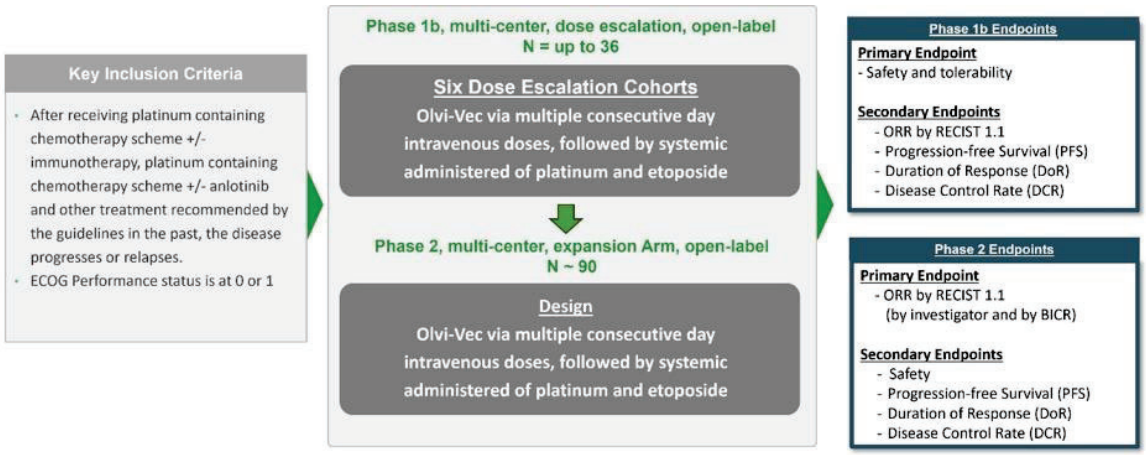
In January 2026, we announced initial interim results from the VIRO-25 trial. As of the data review cutoff date of December 31, 2025, systemic administration of Olvi-Vec in the initial dose escalation cohorts of the trial achieved the following preliminary results:

- 5 evaluable patients
- Disease control response (DCR) of 60% (3/5 patients)
- Tumor size changes among the three DCR patients were 8.9%, -18.9%, and -22.7%, respectively, as compared to baseline
- Olvi-Vec was generally well tolerated

We expect to report additional updated dose-finding data from this trial throughout 2026.

Small Cell Lung Cancer

We sponsor with Newsoara an ongoing Phase 1b/2 clinical trial of Olvi-Vec in patients with recurrent SCLC in China. The following graphic summarizes the study design for the Phase 1b/2 trial.



A readout of interim results in the Phase 1b portion of this trial was disclosed in the first quarter of 2025. In January 2026, we announced additional interim results from the SCLC trial. As of the data review cutoff date of December 23, 2025, systemic administration of Olvi-Vec in the initial dose escalation cohorts in this trial achieved the following preliminary results:

- 9 evaluable patients
- Overall response rate (ORR) of 33% (3/9 patients), including three partial responses (PRs)
    - Two of the three PRs occurred in Cohort 4, the highest dose cohort tested as of the data review cutoff date, with tumor shrinkage of approximately 55% and 85% from baseline, representing an ORR of 67% (2/3) in Cohort 4 and potentially suggesting a dose-response trend

- Disease control rate of 67% (6/9 patients)
    - Tumor shrinkage of 24–85% among the six DCR patients, all of whom experienced a reduction in all target lesions from baseline
- Olvi-Vec was generally well tolerated
- Exploratory durability signals: Two PR patients across different cohorts have been evaluated in long-term follow-up:
    - A patient with 1 prior line, at last scan, achieved a PR with an ongoing PFS of 12.1 months
    - A patient with 4 prior lines had a PFS of 7.7 months, which exceeds the PFS in the immediately preceding line in the same patient (1.9 months) by 5.8 months

Notably, this SCLC trial is primarily evaluating safety and tolerability and, as such, patients who achieved objective responses from Olvi-Vec immunochemotherapy in this trial do not receive any subsequent standard maintenance immunotherapy to extend durability of response.

We expect to report additional updated dose-finding data from this trial throughout 2026.

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. 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.

Indications for development 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.

Newsoara License Agreement

In September 2021, we entered into the Newsoara License Agreement, 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 on 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 mainland China, Taiwan, Hong Kong and Macau (the Newsoara Territory) in the field of 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 Agreement, Newsoara granted us an exclusive and royalty bearing license to develop, commercialize and exploit outside the Newsoara Territory any derived products developed by Newsoara.

Under the terms of the Newsoara License Agreement and to date, we have received from Newsoara an aggregate of $11.0 million ($5.0 million as an upfront payment and $6.0 million as a milestone payment) associated with the Newsoara License Agreement. 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 10th 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.

Pursuant to the Newsoara License Agreement, Newsoara is required to use commercially reasonable efforts to research, develop, manufacture and commercialize the licensed products in the Newsoara Territory in the 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, which is the VIRO-25 clinical trial. Newsoara is generally obligated under the Newsoara License Agreement to fund the costs of the VIRO-25 clinical trial in the United States and China. In November 2023, we and Newsoara agreed that we would engage a clinical research organization (CRO) to conduct certain start-up activities for the trial in the United States only, with Newsoara to reimburse us for the costs and expenses. Pursuant to a letter of understanding (the LOU), in September 2025, we agreed with Newsoara that the CRO would conduct additional study activities beyond startup for the VIRO-25 clinical trial in the United States and Newsoara would reimburse us for costs and expenses related to such additional activities; however, Newsoara is permitted to defer reimbursement of the foregoing costs and expenses until the earlier of: (i) completion of its next round of financing, or (ii) December 31, 2026.

In November 2022, we entered into a Clinical Supply Agreement with Newsoara to manufacture and supply Olvi-Vec for Newsoara's clinical trials in the Newsoara Territory. We are responsible for supplying Olvi-Vec to Newsoara, and Newsoara will pay us the cost of manufacturing.

E. Operations

Manufacturing and Distribution

We lease a 7,569 square-foot building in San Diego, California where we have established and equipped our own manufacturing facility in order to secure supplies for clinical trials and commercial launch. The facility includes laboratories, production cleanrooms, and installed equipment, to accept and prepare raw materials, and produce drug substance and drug product in accordance with cGMP and all other applicable laws and regulations.

We also lease a 6,755 square-foot building in the same location which, when upgrades are completed, will provide laboratory capabilities and administrative offices.

We maintain agreements with our raw material and component 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 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 raw material and component suppliers.

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 protecting and enhancing our proprietary technologies, inventions and improvements that are believed to be important to our business. 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 brand.

Patents

The U.S. patent system permits the filing of provisional and non-provisional patent applications. A provisional patent application is not examined for patentability by the U.S. Patent and Trademark Office (USPTO), and automatically expires 12 months after its filing date. As a result, a provisional patent application cannot mature into an issued patent. Provisional patent applications are often used, among other things, to establish an early effective filing date for a later-filed non-provisional patent application. A non-provisional patent application is examined by the USPTO and can mature into a patent once the USPTO determines that the claimed invention meets the standards of patentability.

Individual patents extend for varying periods of time depending on the date of filing of the patent application, the priority date claimed, and the legal term of patents as determined by the applicable law in the countries in which those patents are obtained. Generally, patents issued from applications filed in the United States are effective for 20 years from the earliest non-provisional filing date. In addition, in certain instances, a patent term can be extended to recapture a portion of the term effectively lost as a result of the FDA regulatory review period; however, the restoration period cannot be longer than five years and the total patent term including the restoration period must not exceed 14 years following FDA approval. Additionally, patent term adjustments can extend the term to account for certain delays by the USPTO during prosecution before that office. The duration of non-U.S. patents varies in accordance with provisions of applicable local law, but typically, the life of a non-U.S. patent is 20 years from the earliest international filing date, not inclusive of any patent term extension that may be available. 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 extensions of patent term, the availability of legal remedies in a particular country and the validity and enforceability of the patent.

National and international patent laws concerning protein-based biologics such as our products remain highly unsettled. No consistent policy regarding the patent eligibility or the breadth of claims allowed in patents in this field has emerged to date among the United States, Europe or other countries. Changes in either the patent laws or in interpretations of patent laws in the United States or other countries can diminish our ability to protect our inventions and enforce our intellectual property rights. Accordingly, we cannot predict the breadth or enforceability of claims that may be granted in our patents or in third party patents. The biotechnology and pharmaceutical industries are characterized by extensive intellectual property litigation. Our ability to maintain and solidify a proprietary position for our product candidates and technology will depend on our success in obtaining effective claims in our patents and enforcing those claims once a patent is granted. We do not know whether any of our patent applications will result in the issuance of any patents. Our issued patents may be challenged, invalidated or circumvented, and the rights granted under any issued patents may not provide us with sufficient protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop and commercialize similar drugs or duplicate our technology, business model or strategy without infringing our patents. Because of the extensive time required for clinical development and regulatory review of any drug we may develop from our product candidates, it is possible that, before any of our drugs can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of any such patent.

As of December 31, 2025, our patent portfolio consisted of 12 issued U.S. patents, 9 issued foreign patents, and 7 pending foreign patent applications, which relate generally to the composition of our current and potential future products, their methods of use and methods of manufacture. Our issued patents are expected to expire between 2026 and 2038.

Trade Secrets

We rely, in part, 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, invention assignment agreements with our employees, and contractual protections in agreements with third party vendors and collaborators. 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.

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 European Union, the United Kingdom, China and in several other countries.

Our unregistered trademarks include “CHOICE”.

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. 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 of cancer therapies. Many of our potential competitors, alone or with their strategic partners, 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.

Competition in cancer therapeutics comes in many forms, where different technologies are employed against different molecular targets or biological systems. These therapies include oncolytic viral immunotherapies, immunotherapy antibodies (including monoclonal antibodies, bi-specific antibodies, and antibody-drug conjugates), cancer vaccines, cell-based therapies, therapies aimed at activating innate immunity, and traditional cancer therapies like chemotherapy and radiation. We are developing next-generation oncolytic 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.

We believe that our product candidates, if and when marketed, would largely complement rather than compete directly with existing treatment options.

PRROC

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

- Currently marketed products for ovarian cancer include brand and generic chemotherapies, along with the following brand products (some of which are also manufactured as generic products): Abbvie's ELAHERE, Eisai Inc.'s HEXALEN, Roche/Genentech, Inc.'s AVASTIN, Merck & Co.'s KEYTRUDA, GSK's ZEJULA, AstraZeneca's LYNPARZA, Pharma& and Tolmar's RUBRACA, and Verstem Oncology's combination of AVMAPKI+FAKZYNJA.
- Product candidates that have completed a registration trial and filed for U.S. regulatory approval for PRROC include: Relacorilant, an anti-glucocorticoid, by Corcept Therapeutics Inc.

NSCLC

We are conducting a Phase 2 clinical trial of Olvi-Vec for the treatment of recurrent NSCLC, and have not yet initiated a registrational trial for Olvi-Vec in NSCLC. If we complete one or more registrational trials and achieve regulatory approval of Olvi-Vec for recurrent NSCLC, we will face competition. Besides brand and generic chemotherapies used to treat NSCLC, there are many companies already marketing competing products for NSCLC, including large pharmaceutical and biotechnology companies like Roche/Genentech, Inc., Merck & Co., Astrazeneca, Novartis Pharmaceuticals Corporation, Pfizer, Inc., Johnson & Johnson, Eli Lilly & Co., and Bristol Myers Squibb. In addition, if Olvi-Vec completes one or more registrational trials and achieves regulatory approval, we expect there to be additional product candidates approved for NSCLC by that time which would compete with Olvi-Vec.

SCLC

We are conducting a Phase 1b/2 clinical trial of Olvi-Vec for the treatment of recurrent SCLC, and have not yet initiated a registrational trial for Olvi-Vec in SCLC. If we complete one or more registrational trials and achieve regulatory approval of Olvi-Vec for recurrent SCLC, we will face competition. Besides brand and generic chemotherapies used to treat SCLC, there are many companies already marketing competing products for SCLC, including large pharmaceutical and biotechnology companies like Amgen, Roche/Genentech, Inc., Merck & Co., Astrazeneca and Bristol Myers Squibb. In addition, if Olvi-Vec completes one or more registrational trials and achieves regulatory approval, we expect there to be additional product candidates approved for SCLC by that time which would compete with Olvi-Vec.

Generic Competition

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 data exclusivity for each of our biological product candidates that is subject to its own BLA for 12 years in the United States, up to 11 years in Europe and varying durations in other markets.

GOVERNMENT REGULATION AND PRODUCT APPROVAL

In the United States, the FDA regulates biological products under the Federal Food, Drug, and Cosmetic Act (FDCA), the Public Health Service Act (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 and/or other applicable regulations;
- Submission to the FDA of an Investigational New Drug application IND), which allows human clinical trials to begin unless the FDA objects within 30 calendar days;
- Approval by an independent IRB, reviewing each clinical site before each clinical trial may be initiated at such site; Institutional Biosafety Committee (IBC) approval is also required for viral products
- 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 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 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 (if applicable) and FDA review and approval, of the BLA (e.g. product licensure).

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 are required to 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 (potency), 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. For later stage studies, in addition to a safety concern, the FDA may place a study on hold for faulty design issues. 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 or study design (later phase studies) 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, or addition of new studies to an existing 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 criteria, 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 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 is intended to generate, together with previously generated data, sufficient data for the FDA or other relevant regulatory agency 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 specifications.

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 Chemistry, Manufacturing, and Controls (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 generally requires payment of 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, under the FDA Reauthorization Act of 2017, 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 the process consistently results in a product candidate with appropriate 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 may also inspect the laboratories where pre-clinical studies were conducted. 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 and other 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.

Expedited Development and Review Programs

The FDA offers a number of programs intended to expedite the development or review of a marketing application for a product candidate. For example, the Fast Track designation program is intended to expedite or facilitate the process for developing and reviewing product candidates that are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast Track designation applies to the combination of the product candidate and the specific indication for which it is being studied. The sponsor of a Fast Track product candidate has opportunities for more frequent interactions with the applicable FDA review team during development and, once a BLA is submitted, the application may be eligible for priority review. A BLA for a Fast Track product candidate may also be eligible for rolling review, where the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA.

A product candidate intended to treat a serious or life-threatening disease or condition may also be eligible for Breakthrough Therapy designation to expedite its development and review. A product candidate can receive Breakthrough Therapy designation if preliminary clinical evidence indicates that the product candidate, alone or in combination with one or more other drugs, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the Fast Track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product candidate, including involvement of senior managers.

Any marketing application for a drug submitted to the FDA for approval, including a product candidate with a Fast Track designation and/or Breakthrough Therapy designation, may be eligible for other types of FDA programs intended to expedite the development and review processes, such as priority review and accelerated approval. The FDA may designate an application for priority review if it is for a drug or biologic that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness over existing therapy. The FDA determines at the time that the marketing application is submitted, on a case- by-case basis, whether the proposed drug or biologic represents a significant improvement in treatment, prevention or diagnosis of disease when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting drug reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, or evidence of safety and effectiveness in a new subpopulation. A priority review designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on an original marketing application from ten months to six months from the date of filing.

Additionally, product candidates studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may be eligible for accelerated approval upon a determination that the product candidate has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefits, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of continued approval, the FDA will generally require the sponsor of a drug receiving accelerated approval to perform adequate and well-controlled confirmatory clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefits, and may require that such confirmatory trials be underway prior to granting accelerated approval. Products receiving accelerated approval may be subject to expedited withdrawal procedures if the sponsor fails to conduct the required confirmatory studies in a timely manner or if such studies fail to verify the predicted clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Fast Track designation, Breakthrough Therapy designation, priority review, and accelerated approval do not change the standards for approval, but may expedite the development or approval process. Even if a product candidate qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Post-Approval Requirements

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

Additionally, products approved under accelerated approval regulations may require a "confirmatory" study which is designed to verify the clinical benefits of the product. FDA may also require other post approval commitments as a condition of approval.

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, 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 False Claims Act, 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.

- The Health Insurance Portability and Accountability Act (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 FDCA, 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 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 obtain certain regulatory licenses to manufacture or distribute pharmaceutical products commercially and/or the registration of pharmaceutical sales representatives in the jurisdiction; 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; and state laws that require the reporting of information related to drug pricing.

Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government-funded healthcare programs, such as Medicare and Medicaid, disgorgement, additional reporting requirements or oversight if we become subject to a corporate integrity agreement or similar agreement, and the curtailment or restructuring of our operations.

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 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. For example, HHS imposes rebates on many Medicare Part B and Medicare Part D products to penalize price increases that outpace inflation on an annual basis. In addition, HHS has been empowered to negotiate the price of certain single-source biologics that have been on the market for at least 11 years covered under Medicare as part of the Medicare Drug Price Negotiation Program. Each year up to 20 products will be selected by HHS for the Medicare Drug Price Negotiation Program. Products subject to the Medicare Drug Price Negotiation Program are expected to experience a significant reduction in reimbursement from the Medicare program on a per unit basis.

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.

There have been executive, judicial and Congressional challenges and amendments to certain aspects of the ACA. For example, on July 4, 2025, the One Big Beautiful Bill Act (the OBBBA) was signed into law, which narrowed access to ACA marketplace exchange enrollment and declined to extend the ACA enhanced advanced premium tax credits that expired at the end of 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. The OBBBA also is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. Congress is considering proposed legislation intended to further reduce healthcare costs with alternatives to replace the expired ACA subsidies.

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 Build Back Better Act and the Infrastructure Investment and Jobs Act, will remain in effect until 2032 unless additional Congressional action is taken.

The current Trump administration is pursuing policies to reduce regulations and expenditures across government including at HHS, the FDA, CMS and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. For example, the current administration has announced agreements with pharmaceutical companies that require the drug manufacturers to offer, through a direct-to-consumer platform (TrumpRx), U.S. patients and Medicaid programs prescription drug Most-Favored-Nation pricing equal to or lower than those paid in other developed nations, with additional mandates for direct-to-patient discounts and repatriation of foreign revenues. Other recent actions may, for example, include directives to reduce agency workforce; directing HHS and other agencies to lower prescription drug costs through a variety of initiatives; imposing tariffs on imported pharmaceutical products; and as part of the Make America Healthy Again Commission's Strategy Report released in September 2025, working across government agencies to increase enforcement on direct-to-consumer pharmaceutical advertising. Additionally, the current administration recently called on Congress to enact "The Great Healthcare Plan," to codify and expand Most-Favored Nation pricing, lower government subsidies to private insurance companies, increase healthcare price transparency, expand pharmaceutical drugs available for over-the-counter purchase, and enact restrictions on pharmacy benefit manager payment methodologies, among other things. These actions and policies may significantly reduce U.S. drug prices, potentially impacting manufacturers' global pricing strategies and profitability, while increasing their operational costs and compliance risks. In June 2024, in Loper Bright Enterprises v. Raimondo, the U.S. Supreme Court greatly reduced judicial deference to regulatory agencies, which could increase successful legal challenges to federal regulations affecting our operations. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program.

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 it from being able to generate revenue, attain profitability or commercialize our product candidates.

Data Privacy and Security

In the ordinary course of 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 us or other third parties. Accordingly, we are 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 the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), imposes specific requirements on covered entities, which include certain healthcare providers, health plans and healthcare clearinghouses, and their business associates and covered subcontractors that receive or obtain protected health information in connection with providing a service on behalf of a covered entity relating to the privacy, security, and transmission of individually identifiable health information. In addition, numerous U.S. states 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 fines and allows private litigants affected by certain data breaches to recover significant statutory damages. Furthermore, U.S. federal and state consumer protection laws 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.

Compliance with these and any other applicable data privacy and security obligations is a rigorous and time-intensive process, and we may be required to put in place additional mechanisms to ensure compliance.

See the section titled "Risk Factors – Risk Related to Government Regulation – ***We and the third parties with whom we work are subject to stringent and evolving U.S. and foreign laws, regulations, and rules, contractual obligations, policies and other obligations related to data privacy and security. Our (or the third parties with whom we work) actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including class-action claims) and mass arbitration demands; 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.

Moreover, cyber-attacks, malicious internet-based activity and other similar activities threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties with whom we work. Such threats are prevalent and continue to rise. 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. For more information regarding risks relating to data security, see "Risk Factors – Risks Related to Our Business and Operations – *If our information technology systems or those third parties with whom we work or its data, 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*."

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

As of December 31, 2025, we had 25 full-time employees and 1 part-time employee, including 16 employees engaged in research and development and manufacturing and 10 engaged in management and administrative functions. Our human capital strategy is designed to enable successful execution of our business objectives, while fostering a collaborative and innovative culture. We monitor our success with insights across human capital metrics such as employee engagement, vacancy rates, time to hire, and retention. To attract qualified applicants to the Company, we offer a total compensation package consisting of base salary and cash target bonus, a comprehensive benefit package and equity compensation to every employee. Bonus opportunity and equity compensation increase as a percentage of total compensation based on level of responsibility. Actual bonus payout is based on performance.

CORPORATE INFORMATION

Genelux Corporation was incorporated in Delaware in September 2001. Its principal executive office is located at 2625 Townsgate Road, Suite 230, Westlake Village, California 91361, and its telephone number is (805) 267-9889. The Company completed its initial public offering (IPO) in January 2023, and its common stock is listed on the Nasdaq Capital Market under the symbol “GNLX.”

The Company is an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012 (JOBS Act). The Company will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of its IPO (i.e. December 31, 2028), (b) in which the Company has total annual gross revenue of at least $1.235 billion or (c) in which the Company is deemed to be a large accelerated filer, which means the market value of its common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th and (2) the date on which the Company has issued more than $1.0 billion in non-convertible debt during the prior three-year period.

AVAILABLE INFORMATION

Our website address is http://www.genelux.com. Our website address is not intended to function as a hyperlink and the information contained on its website is not, and should not be considered part of, and is not incorporated by reference into, this Annual Report. The Company’s reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (the Exchange Act), including its Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, Proxy Statements, and amendments to such periodic reports and Proxy Statements, are accessible through its website, free of charge, as soon as reasonably practicable after these reports are filed electronically with, or otherwise furnished to, the SEC. These SEC reports can be accessed through the “Investors” section of the Company’s website. The SEC maintains an Internet website that contains reports, proxy and information statements, and other information regarding the Company and other issuers that file electronically with the SEC. The SEC’s Internet website address is http://www.sec.gov.

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 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 marketable securities. 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 losses were $32.1 million and $29.9 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of $283.5 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' equity 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 studies 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 Olvi-Vec and any of our future 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 impact of geopolitical and macroeconomic events, including future bank failures, new or increased tariffs and other trade measures, funding shortages at governmental and regulatory agencies on which we rely, geopolitical tensions between the United States and China, the Russia/Ukraine conflict, conflicts in the Middle East and global pandemics on U.S. and global economic conditions including changes in monetary and fiscal policy, U.S. political developments and other sources of instability.

Besides the obligations by Newsoara to provide clinical trial funding under the Newsoara License Agreement, 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, debt and/or other capital sources such as milestone payments, royalties or other payments or funding from existing or potential collaborations, strategic alliances, licensing arrangements and other arrangements. Based on our research and development plans, we expect that our existing cash, cash equivalents, restricted cash and marketable securities will fund our planned operations into the first quarter of 2027. 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. The failure to receive all or some of the committed proceeds would exhaust our available capital resources sooner than expected and will require us 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, 2025 and 2024 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 study and clinical trial 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 of our Phase 2 clinical trial, an open-label, single-arm study, of our lead product candidate, Olvi-Vec, in patients with PRROC, was completed in September 2019, and we reported multiple data readouts in 2020, 2021, 2022 and 2023 for our Phase 2 PRROC clinical trial. We expect the final readout, reported on May 25, 2023 and published in JAMA Oncology in May 2023, to remain essentially unchanged in the final study report. Our Phase 3 registration trial of Olvi-Vec in PRROC initiated enrollment in the third quarter of 2022. We continue to enroll patients in this Phase 3 trial with topline results anticipated in the second half of 2026.

Newsoara is generally obligated under the Newsoara License Agreement to fund our ongoing Phase 2, open-label, randomized, and controlled NSCLC clinical trial in its entirety in the United States and China, known as the VIRO-25 Trial. In November 2023, we agreed with Newsoara that we would directly engage a CRO on mutually agreeable terms to conduct certain startup activities for the VIRO-25 Trial in the United States only, with Newsoara reimbursing us for the costs and expenses of such agreed-upon startup activities. In September 2025 and pursuant to the LOU, we agreed with Newsoara that the CRO would conduct study activities beyond startup for the VIRO-25 Trial in the United States and Newsoara would reimburse us for costs and expenses related to such additional activities. Under the agreed upon terms, Newsoara is permitted to defer reimbursement of the foregoing costs and expenses until the earlier of: (i) completion of its next round of financing, or (ii) December 31, 2026. Subject to regulatory authorization in China, Newsoara may eventually add sites in China and the parties would then conduct this study as a multi-regional clinical trial.

We and Newsoara co-sponsor a Phase 1b/2 clinical trial of Olvi-Vec in patients with recurrent SCLC in China, which Newsoara is conducting, and initiated the Phase 1 portion in the first half of 2023. A readout of interim results in the Phase 1b portion of this trial was disclosed in the first quarter of 2025 and additional interim results were disclosed in January 2026. We expect to report additional interim results from the Phase 1b portion of this trial throughout 2026. Data are supportive of Olvi-Vec being a platinum resensitizing agent beyond ovarian cancer and underscore the current clinical development strategy. In addition to expecting Newsoara to join our ongoing Phase 2 NSCLC trial, as discussed above, we anticipate they will initiate a trial in recurrent ovarian cancer in China.

Additionally, we have a portfolio of oncolytic VACV constructs that are in early-to- late stages of discovery and preclinical development that 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 studies 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 IND applications or 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 and continues to enroll patients. Our co-sponsored Phase 1b/2 clinical trial in recurrent SCLC continues to enroll patients in China. Our ongoing Phase 2, open-label, randomized, and controlled clinical trial designed to evaluate the efficacy and safety of intravenously delivered Olvi-Vec oncolytic VACV in patients with recurrent NSCLC continues to enroll patients in the U.S. In January 2026, we disclosed interim results for the SCLC and NSCLC trials and expect to disclose additional interim readouts for these trials throughout 2026. 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. We have not previously submitted a 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. 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 study 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. 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. Additionally, 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, 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 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 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, or flaws in the design of the trial;
- 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 existing or future manufacturing processes or facilities of our company or of third-party manufacturers with which we contract for clinical and commercial supplies;
- we may decide, or regulatory authorities may require us, to conduct or gather, as applicable, additional clinical trials, analyses, reports, data, or preclinical studies, or we may abandon product development programs;

- we may fail to reach an agreement with regulatory authorities 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;
- Regulatory authorities 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, we previously modified our manufacturing process and had to demonstrate analytical comparability to the FDA in order to use Olvi-Vec manufactured by this process in our ongoing Phase 3 PRROC trial. Any future changes to our manufacturing process may similarly require comparability assessments by the FDA and could delay clinical trials or, if the modified manufacturing process is not comparable, result in inconsistencies in trial results that may be difficult to explain.

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 studies or clinical trials beyond what we currently have planned will be required, will begin as planned, will need to be redesigned, 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, which would 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 or contracting health conditions;
- 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;
- the timely initiation of clinical trial sites;
- 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;
- withdrawal of consent for any reason;
- imbalance in withdrawals between the comparator and treatment arms;
- 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.

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

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, in which Olvi-Vec 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 FDA's analysis and interpretation of the data may also differ from ours.

For our lead product candidate, Olvi-Vec, we completed enrollment, and we reported multiple data readouts in 2020, 2021, 2022 and 2023 for our Phase 2 PRROC clinical trial. Our Phase 3 registration trial of Olvi-Vec in PRROC initiated enrollment in the third quarter of 2022. We expect to report topline results from the trial in the second half of 2026. In January 2026, we disclosed interim results for our ongoing SCLC and NSCLC trials and expect to disclose additional interim readouts for these trials throughout 2026.

The results of previous clinical trials of Olvi-Vec and interim readouts from ongoing 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 or subsequent data readouts from ongoing 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 successfully completing a registration-stage clinical trial and may be unable to 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 trials 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.

In January 2026, we disclosed interim results for our ongoing SCLC and NSCLC trials and expect to disclose additional interim readouts for these trials throughout 2026. 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.

Fast track designation by the FDA for Olvi-Vec may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that Olvi-Vec or any future product candidate which may receive fast track designation will receive marketing approval.

The FDA has granted a fast track designation for Olvi-Vec for the treatment of patients with PRROC, and we may seek fast track designations for other indications or future product candidates. The fast track program is intended to expedite or facilitate the process for reviewing new product candidates that meet certain criteria. Specifically, biologics are eligible for fast track designation if they are intended, alone or in combination with one or more drugs or biologics, to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product candidate and the specific indication for which it is being studied. The sponsor of a fast track product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and, once a BLA is submitted, the application may be eligible for priority review. A BLA submitted for a fast track product candidate may also be eligible for rolling review, where the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA.

The FDA has broad discretion whether or not to grant this designation. Even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Although we have received fast track designation for Olvi-Vec for the treatment of patients with PRROC, and even if we receive additional fast track designations for other indications or any future product candidates, such product candidates may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may also withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program. Furthermore, such a designation does not increase the likelihood that Olvi-Vec or any future product candidate that may be granted fast track designation will receive marketing approval in the United States. Many product candidates that have received fast track designation have ultimately failed to obtain approval.

We may attempt to secure approval from the FDA through the use of the accelerated approval pathway. If we are unable to obtain such approval, we may be required to conduct additional clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary regulatory approvals. Even if we receive accelerated approval from the FDA, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA may seek to withdraw any accelerated approval we have obtained.

We may in the future seek an accelerated approval for Olvi-Vec or our future product candidates. Under the accelerated approval program, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that such product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit.

The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. If such confirmatory studies fail to confirm the drug's clinical benefit or are not completed in a timely manner, the FDA may withdraw its approval of the drug on an expedited basis. In addition, in December 2022, the Food and Drug Omnibus Reform Act of 2022 was enacted, which, among other things, provided the FDA new statutory authority to mitigate potential risks to patients from continued marketing of ineffective drugs previously granted accelerated approval, and additional oversight over confirmatory trials. Under these provisions, the FDA may, among other things, require a sponsor of a product seeking accelerated approval to have a confirmatory trial underway prior to such approval being granted.

Prior to seeking approval for Olvi-Vec or any future product candidate we intend to seek feedback from the FDA and will otherwise evaluate our ability to seek and receive accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit a BLA for accelerated approval or obtain any other form of expedited development, review, or approval. Furthermore, if we decide to submit an application for accelerated approval for Olvi-Vec or any future product candidate, there can be no assurance that such submission or application will be accepted or that any expedited development, review, or approval will be granted on a timely basis, or at all. The FDA could also require us to conduct further studies prior to considering our application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development, review, or approval for Olvi-Vec or any future product candidate would result in a longer time period to commercialization of such product candidate, if any, could increase the cost of development of such product candidate, and could harm our competitive position in the marketplace.

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 with enrollment completed 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, 2021, 2022 and 2023 for our Phase 2 PRROC clinical trial. We expect the final readout, reported on May 25, 2023 and published in JAMA Oncology in May 2023, to remain essentially unchanged in the final study report. Additionally, we previously conducted five Phase 1 clinical trials and one Expanded Access Program 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, vomiting, 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 the drug is 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 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 from 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 inability 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 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 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 a serious safety issue becomes known 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 are currently conducting our Phase 2 clinical trial for Olvi-Vec in recurrent NSCLC in the United States and may conduct this trial in China as part of a multi-regional clinical trial with our collaboration partner, Newsoara, pending approval to proceed. We may conduct additional clinical trials in China. However, the FDA and other comparable foreign regulatory authorities may not accept data from such trial, in which case our development plans will be delayed, which could materially harm our business.

Newsoara is generally obligated under the Newsoara License Agreement to fund a Phase 2, open-label, randomized, and controlled clinical trial designed to evaluate the efficacy and safety of intravenously delivered Olvi-Vec oncolytic VACV for patients with recurrent NSCLC in the United States, which VIRO-25 trial is now ongoing with the first patient dosed in October 2024. In November 2023, we agreed with Newsoara that we would directly engage a CRO on mutually agreeable terms to conduct certain startup activities for the NSCLC trial in the United States only, with Newsoara reimbursing us for the costs and expenses of such agreed-upon startup activities. In September 2025, we agreed with Newsoara that the CRO would conduct additional study activities beyond startup for the VIRO-25 clinical trial in the United States and Newsoara would reimburse us for costs and expenses related to such additional activities; however, Newsoara is permitted to defer reimbursement of the foregoing costs and expenses until the earlier of: (i) completion of its next round of financing, or (ii) December 31, 2026.

We dosed our first patient in the trial in the United States in 2024 and, subject to regulatory authorization, may launch the NSCLC trial in China with Newsoara. Newsoara initiated a Phase 1 clinical trial of Olvi-Vec in patients with recurrent SCLC in China in 2023, and may initiate further 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 International Conference on Harmonization (ICH), and 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 comparable foreign regulatory 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 comparable foreign regulatory authorities will accept data from our Phase 2 clinical trial in Olvi-Vec, which is currently ongoing in the United States. If the FDA or comparable foreign regulatory 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.

Approval by the FDA or comparable foreign regulatory authorities to market a product candidate will be 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, the U.S. Department of Justice, the U.S. 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 to market 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 announced and 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 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. For example, the U.S. Supreme Court's June 2024 decision in Loper Bright Enterprises v. Raimondo overturned the longstanding Chevron doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The Loper decision could result in additional legal challenges to regulations and decisions issued by federal agencies, including the FDA, on which we rely. Any such legal challenges, if successful, could have a material impact on our business. Additionally, the Loper decision may result in increased regulatory uncertainty, inconsistent judicial interpretations, and other impacts to the agency rulemaking process, any of which could adversely impact our business and operations. In addition, changes in medical practice and standard of care may also impact the marketability of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad.

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, 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 cGMP manufacturing facility in order to supply clinical product for development. We are in the process of renovating the facility to support scale-up 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 recently leased a second building in the same location which, when upgrades are completed, will provide laboratory capabilities and administrative offices.

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, improving product quality or for 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 non-clinical 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, we previously modified our manufacturing process and had to demonstrate analytical comparability to the FDA in order to use Olvi-Vec manufactured by this process in our ongoing Phase 3 PRROC trial. Any future changes to our manufacturing process may similarly require comparability assessments by the FDA and could delay clinical trials or, if the product of the modified manufacturing process is not comparable, result in inconsistencies in trial results that may be difficult to explain.

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 may 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, which 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 unsatisfactory quality or may be unavailable 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, and to package and distribute our products.

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;
- variability of properly released raw materials between batches from a single supplier or between suppliers;
- 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;
- the inability to provide adequate supplies of our product;
- 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, raw materials 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 studies are conducted in accordance with the FDA's Good Laboratory Practice 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 comply 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 collaboration with Newsoara, 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 collaborator's 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 development or 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.

For example, Newsoara is generally obligated under the Newsoara License Agreement to fund a Phase 2, open-label, randomized, and controlled clinical trial designed to evaluate the efficacy and safety of intravenously delivered Olvi-Vec oncolytic VACV for patients with recurrent NSCLC in the United States, which VIRO-25 trial is now ongoing with the first patient dosed in October 2024. Newsoara has also agreed to reimburse us for the costs and expenses of a CRO to conduct activities for the NSCLC trial in the United States, but is permitted to defer such reimbursement payments until the earlier of: (i) completion of its next round of financing, or (ii) December 31, 2026. If Newsoara is unable or unwilling to provide funding and/or reimbursement of costs for the NSCLC trial in a timely manner or at all, we would need to obtain the funding on our own and/or scale back or discontinue these clinical development activities.

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 to the operations of the FDA, the SEC, other U.S. governmental agencies or comparable foreign regulatory authorities caused by funding shortages, leadership changes, staffing cuts or other staffing shortages, along with uncertainty regarding the potential for new initiatives, laws, regulations, policies and guidance affecting our product candidates or other aspects of our business, could materially and adversely affect our business.

The ability of the FDA or other comparable foreign regulatory authorities to review and approve new products or take action with respect to other regulatory matters can be affected by a variety of factors, including government budget and funding levels, leadership changes, the ability to hire and retain key personnel and accept payment of user fees, the availability of personnel and other resources, changes in statutes, regulations and policies that affect the FDA's or comparable foreign regulatory authorities' ability to perform routine functions, and other business disruptions. Average review times at the FDA and comparable foreign regulatory authorities have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Over the last several years, the U.S. government has shut down several times, including in the fourth quarter of 2025 and first quarter of 2026, and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. In addition, there have recently been terminations of large numbers of federal employees at various federal agencies, including the FDA. Changes and cuts in FDA staffing could result in delays in the FDA's responsiveness or in its ability to review IND submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion, or at all. A prolonged government shutdown and/or employee terminations or resignations could significantly impact the ability of the FDA or other federal agencies to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, current and future government shutdowns and/or employee terminations or resignations at the SEC could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

There is substantial uncertainty as to whether and how the current administration will seek to modify or revise the requirements and policies of the FDA and other regulatory agencies with jurisdiction over our product candidates and any products for which we obtain approval. This uncertainty could present new challenges as we navigate development and approval of our product candidates. Some of these efforts have manifested to date in the form of personnel cuts and measures that could impact the FDA's ability to hire and retain key personnel, which could result in delays or limitations on our ability to obtain guidance from the FDA on our product candidates in development and obtain the requisite regulatory approvals in the future. There is uncertainty as to whether we will be materially and negatively impacted by governmental orders, regulations, policies or guidance, or disruptions to the normal operations of government agencies.

International trade policies, including tariffs, sanctions and trade barriers may adversely affect our business, financial condition, results of operations and prospects.

We operate in a global economy, which includes utilizing third-party suppliers in several countries outside the United States. There is inherent risk, based on the complex relationships among the U.S. and the countries in which we conduct our business, that political, diplomatic, and national security factors can lead to global trade restrictions and changes in trade policies and export regulations that may adversely affect our business and operations. The current international trade and regulatory environment is subject to significant ongoing uncertainty. The U.S. government has recently announced substantial new tariffs affecting a wide range of products and jurisdictions and has indicated an intention to continue developing new trade policies, including with respect to the pharmaceutical industry. In response, certain foreign governments have announced or implemented retaliatory tariffs and other protectionist measures. Further, the Bureau of Industry and Security, U.S. Department of Commerce, has initiated an investigation to determine whether pharmaceutical ingredients, including finished drug product, manufactured outside the United States pose a national security risk and should be subject to additional tariffs. These developments have created a dynamic and unpredictable trade landscape, which may adversely impact our business, results of operations, financial condition and prospects.

We rely on specialized laboratory equipment, supplies, and materials, all or part of which we believe may be ultimately sourced from multiple countries outside the United States, to advance our research and development efforts.

Current or future tariffs will result in increased research and development expenses, including with respect to increased costs associated with specialized laboratory equipment used in the manufacture of Olvi-Vec. In addition, such tariffs will increase our supply chain complexity and could also potentially disrupt our existing supply chain. Unlike consumer goods, pharmaceuticals face unique regulatory constraints that make rapid supply chain adjustments particularly difficult and costly. Trade restrictions affecting the import of materials necessary for clinical trials could result in delays to our development timelines. Increased development costs and extended development timelines could place us at a competitive disadvantage compared to companies operating in regions with more favorable trade relationships and could reduce investor confidence, negatively impacting our ability to secure additional financing on favorable terms or at all. In addition, as we advance toward commercialization in the future, tariffs and trade restrictions could hinder our ability to establish cost-effective production capabilities, negatively impacting our growth prospects.

The complexity of announced or future tariffs may also increase the risk that we or our suppliers may be subject to civil or criminal enforcement actions in the United States or foreign jurisdictions related to compliance with trade regulations. Foreign governments may also adopt non-tariff measures, such as procurement preferences or informal disincentives to engage with, purchase from or invest in U.S. entities, which may limit our ability to compete internationally and attract non-U.S. investment, employees, customers and suppliers. Foreign governments may also take other retaliatory actions against U.S. entities, such as decreased intellectual property protection, increased enforcement actions, or delays in regulatory approvals, which may result in heightened international legal and operational risks. In addition, the United States and other governments have imposed and may continue to impose additional sanctions, such as trade restrictions or trade barriers, which could restrict us from doing business directly or indirectly in or with certain countries or parties and may impose additional costs and complexity to our business.

Trade disputes, tariffs, restrictions and other political tensions between the United States and other countries may also exacerbate unfavorable macroeconomic conditions including inflationary pressures, foreign exchange volatility, financial market instability, and economic recessions or downturns. The ultimate impact of current or future tariffs and trade restrictions remains uncertain and could materially and adversely affect our business, financial condition, and prospects. While we actively monitor these risks, any prolonged economic downturn, escalation in trade tensions, or deterioration in international perception of U.S.-based companies could materially and adversely affect our business, ability to access the capital markets or other financing sources, results of operations, financial condition and prospects. In addition, trade developments have and may continue to heighten the risks related to the other risk factors described in this Annual Report.

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 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.

Any viral immunotherapies that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

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

- Currently marketed products for ovarian cancer include brand and generic chemotherapies, along with the following brand products (some of which are also manufactured as generic products): Abbvie's ELAHERE, Eisai Inc.'s HEXALEN, Roche/Genentech, Inc.'s AVASTIN, Merck & Co.'s KEYTRUDA,, GSK's ZEJULA, AstraZeneca's LYNPARZA, Pharma& and Tolmar's RUBRACA, and Verstem Oncology's combination of AVMAPKI+FAKZYNJA.

- Product candidates that have completed a registration trial and filed for U.S. regulatory approval for PRROC include: Relacorilant, an anti-glucocorticoid, by Corcept Therapeutics Inc.

With respect to NSCLC, we are conducting a Phase 2 clinical trial of Olvi-Vec for the treatment of recurrent NSCLC and have not yet initiated a registrational trial for Olvi-Vec in NSCLC. If we complete one or more registrational trials and achieve regulatory approval of Olvi-Vec for recurrent NSCLC, we will face competition. Besides brand and generic chemotherapies used to treat NSCLC, there are many companies already marketing competing products for NSCLC, including large pharmaceutical and biotechnology companies like Roche/Genentech, Inc., Merck & Co., Astrazeneca, Novartis Pharmaceuticals Corporation, Pfizer, Inc., Johnson & Johnson, Eli Lilly & Co., and Bristol Myers Squibb. In addition, if Olvi-Vec completes one or more registrational trials and achieves regulatory approval, we expect there to be additional product candidates approved for NSCLC by that time which would compete with Olvi-Vec.

With respect to SCLC, we are conducting a Phase 1b/2 clinical trial of Olvi-Vec for the treatment of recurrent SCLC and have not yet initiated a registrational trial for Olvi-Vec in SCLC. If we complete one or more registrational trials and achieve regulatory approval of Olvi-Vec for recurrent SCLC, we will face competition. Besides brand and generic chemotherapies used to treat SCLC, there are many companies already marketing competing products for SCLC, including large pharmaceutical and biotechnology companies like Amgen, Roche/Genentech, Inc., Merck & Co., Astrazeneca and Bristol Myers Squibb. In addition, if Olvi-Vec completes one or more registrational trials and achieves regulatory approval, we expect there to be additional product candidates approved for SCLC by that time which would compete with Olvi-Vec.

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 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 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 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.

For the core technology in our CHOICE platform and Olvi-Vec and our other product candidates, patents have issued and applications are pending. As of December 31, 2025, our patent portfolio consisted of 12 issued U.S. patents, 9 issued foreign patents, and 7 pending foreign patent applications, which relate generally to the composition of our current and potential future products, their methods of use and methods of manufacture. 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 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 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 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 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 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 data 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.
- The Health Insurance Portability and Accountability Act (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 obtain certain regulatory licenses to manufacture or distribute our products commercially and/or the registration of pharmaceutical sales representatives in the jurisdiction; 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; and state laws that require the reporting of information related to drug pricing.

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. Additionally, coverage policies and third-party payor reimbursement rates may change at any time. Therefore, even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future.

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. In addition, HHS imposes rebates on many Medicare Part B and Medicare Part D products to penalize price increases that outpace inflation on an annual basis. In addition, HHS has been empowered to negotiate the price of certain single-source biologics that have been on the market for at least 11

years covered under Medicare as part of the Medicare Drug Price Negotiation Program. Each year up to 20 products will be selected by HHS for the Medicare Drug Price Negotiation Program. Products subject to the Medicare Drug Price Negotiation Program are expected to experience a significant reduction in reimbursement from the Medicare program on a per unit basis. 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 and amendments to certain aspects of the ACA. For example, on July 4, 2025, the One Big Beautiful Bill Act (the OBBBA) was signed into law, which narrowed access to ACA marketplace exchange enrollment and declined to extend the ACA enhanced advanced premium tax credits that expired at the end of 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. The OBBBA also is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. Congress is considering proposed legislation intended to further reduce healthcare costs with alternatives to replace the expired ACA subsidies. 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 second Trump 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, due to subsequent legislative amendments, will remain in effect until 2032 unless additional Congressional action is taken.

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 American Rescue Plan Act of 2021 eliminated the statutory Medicaid drug rebate cap, previously set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, effective January 1, 2024. The current Trump administration is pursuing policies to reduce regulations and expenditures across government including at HHS, the FDA, CMS and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. For example, the current administration has announced agreements with pharmaceutical companies that require the drug manufacturers to offer, through a direct-to-consumer platform (TrumpRx), U.S. patients and Medicaid programs prescription drug Most-Favored-Nation pricing equal to or lower than that paid in other developed nations, with additional mandates for direct-to-patient discounts and repatriation of foreign revenues. Other recent actions may, for example, include directives to reduce agency workforce, directing HHS and other agencies to lower prescription drug costs through a variety of initiatives; imposing tariffs on imported pharmaceutical products; and as part of the Make America Healthy Again Commission's Strategy Report released in September 2025, working across government agencies to increase enforcement on direct-to-consumer pharmaceutical advertising. Additionally, the current administration recently called on Congress to enact "The Great Healthcare Plan," to codify and expand Most-Favored-Nation pricing, lower government subsidies to private insurance companies, increase healthcare price transparency, expand pharmaceutical drugs available for over-the-counter purchase, and enact restrictions on pharmacy benefit manager payment methodologies, among other things. These actions and policies may significantly reduce U.S. drug prices, potentially impacting manufacturers' global pricing strategies and profitability, while increasing their operational costs and compliance risks. In June 2024, in Loper Bright Enterprises v. Raimondo, the U.S. Supreme Court greatly reduced judicial deference to regulatory agencies, which could increase successful legal challenges to federal regulations affecting our operations. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program.

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 and the third parties with whom we work are subject to stringent and evolving U.S. and foreign laws, regulations, and rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Our (or the third parties with whom we work) actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including class-action claims) and mass arbitration demands; 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 ordinary course of our business, we collect, receive, process, generate, use, transfer, make accessible, protect, secure, dispose of, transmit and store (collectively, process) personal data and other sensitive information, including proprietary and confidential business data, intellectual property, trade secrets, data we collect about trial participants in connection with clinical trials and sensitive third-party data. Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements and other obligations relating to data privacy and security.

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 protected health information. Numerous U.S. states have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services.

Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the CCPA applies to the personal data of consumers, business representatives and employees who are California residents, and requires covered businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. The CCPA provides for fines and allows private litigants affected by certain data breaches to recover significant statutory damages. The CCPA and other comprehensive U.S. state privacy laws exempt some data processed in the context of clinical trials, but these developments may further complicate compliance efforts, and increase legal risk and compliance costs for us, the third parties with whom we work and our customers. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. We may also be subject to new U.S. state laws governing the privacy of consumer health data.

Outside the United States, an increasing number of laws, regulations, and industry standards govern data privacy and security. For example, the EU GDPR and the UK GDPR (collectively, GDPR), and the Swiss Federal Act on Data Protection impose strict requirements for processing personal data. For example, under the GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million euros under the EU GDPR, 17.5 million pounds sterling under the UK GDPR or, in each case, 4% of annual global revenue, whichever is greater; or 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 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 they generally believe are inadequate.

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 standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), 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 (such as Europe) 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, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR's cross-border data transfer limitations. Other jurisdictions may adopt or have already adopted similarly stringent data localization and cross-border data transfer laws.

Additionally, the U.S. Department of Justice issued a rule entitled the Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons, which places additional restriction on certain data transactions involving countries of concern (e.g., China, Russia, Iran) and covered persons (i.e., individuals and entities who are designated as such by the U.S. Attorney General or considered "foreign persons" and are majority owned by, organized under the laws of, a primary resident in, or a contractor of, a covered person or country of concern, as applicable) that may impact certain business activities such as vendor engagements, sale or sharing of data, employment of certain individuals, and investor agreements. Violations of the rule could lead to significant civil and criminal fines and penalties. The rule applies regardless of whether data is anonymized, key-coded, pseudonymized, de-identified or encrypted, which presents particular challenges for companies like ours and may impact our ability to engage in transactions or agreements with certain third parties in the future.

In addition to data privacy and security laws, we are contractually subject to industry standards adopted by industry groups and, we are and may become in the future, subject to such obligations. We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. For example, certain privacy laws, such as the GDPR, and the CCPA, require our customers to impose specific contractual restrictions on their service providers. Additionally, some of our customer contracts require us to host personal data locally.

Our employees and personnel use generative artificial intelligence (AI) technologies to perform their work, and the disclosure and use of personal data in generative AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating AI technologies. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and lawsuits. If we are unable to use AI technologies, it could make our business less efficient and result in competitive disadvantages.

We may publish privacy policies, marketing materials, and other statements, such as statements related to compliance with certain certifications or self-regulatory principles, concerning data privacy and security. Regulators in the United States are increasingly scrutinizing these statements, and if these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, misleading, 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 (and consumers' data privacy expectations) are quickly changing, becoming increasingly stringent, and creating 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, which may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf.

We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties with whom we work may fail to comply with such obligations, which could negatively impact our business operations. If we or the third parties with whom we work fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans or restrictions on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. 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 substantial changes to our business model or 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, will also 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 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, 2025, we had 25 full-time employees and 1 and part-time employee, including 16 employees engaged in research and development and manufacturing. As our development and commercialization plans and strategies develop, 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 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 could materially and adversely affect our preclinical studies and clinical trials, business, financial condition and results of operations.

As a result of 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 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 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.

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 those third parties with whom we work or our data 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 and the third parties with whom we work process proprietary, confidential, and sensitive data, including personal data, de-identified 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 with whom we work. Such threats are prevalent and continue to rise, are becoming increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors, "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 with whom we work 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 with whom we work are subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks, credential stuffing attacks, 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, attacks enhanced or facilitated by AI, and other similar threats. In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, ability to provide our products or services, disruption of clinical trials, loss of sensitive data 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.

It may be difficult and/or costly to detect, investigate, mitigate, contain, and remediate a security incident. Our efforts to do so may not be successful. Actions taken by us or the third parties with whom we work to detect, investigate, mitigate, contain, and remediate a security incident could result in outages, data losses, and disruptions of our business. Threat actors may also gain access to other networks and systems after a compromise of our networks and systems. For example, threat actors may use an initial compromise of one part of our environment to gain access to other parts of our environment, or leverage a compromise of our networks or systems to gain access to the networks or systems of third parties with whom we work, such as through phishing or supply chain attacks.

Remote work has increased risks to our information technology systems and data, as 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 on third parties to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, cloud-based infrastructure, data center facilities, encryption and authentication technology, employee email, 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 the third parties with whom we work experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if the third parties with whom we work 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' infrastructure in our supply chain or that of the third parties with whom we work have not been compromised.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps designed to detect, mitigate and remediate vulnerabilities in our information technology systems (such as our hardware and/or software, including that of third parties with whom we work). We have not and may not in the future, however, detect and remediate all such vulnerabilities including on a timely basis. Further, we have (and may in the future) experienced delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident.

Certain of the previously identified or similar threats have in the past and may in the future cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information or our information technology systems or those of the third parties with whom we work. A security incident or other interruption could disrupt our ability (and that of third parties with whom we work) to provide our products and/or to conduct our clinical trials. Our current security measures may be insufficient to prevent or deter such incidents or interruptions. 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 have required us to implement and maintain specific security measures, industry-standard or reasonable security measures to protect our information technology systems and sensitive information.

Applicable data privacy and security obligations may require us, or we may voluntarily choose, to notify relevant stakeholders, including affected individuals, customers, regulators, and investors, of security incidents, or to take other actions, such as providing credit monitoring and identity theft protection services. Such disclosures and related actions can be costly, and the disclosure or the failure to comply with such applicable requirements could lead to adverse consequences. If we (or a third party with whom we work) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences, such as 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-action claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; diversion of management attention; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences 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.

Additionally, sensitive information of the Company or our customers could be leaked, disclosed, or revealed as a result of or in connection with our employees', personnel's, or vendors' use of generative AI technologies.

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 an 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, 2025, we had federal and state NOL carryforwards of approximately $192.2 and $190.5 on, 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 $93.7 million, may be carried forward indefinitely, but the utilization of such U.S. federal NOLs is limited. As of December 31, 2025, we also had federal and state R&D credit carryforwards of $3.9 million and $3.0 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 Internal Revenue Code of 1986, as amended, 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 a company's 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. For example, California recently imposed limits on the usability of California state NOL carryforwards and certain state tax credits in tax years beginning after 2023 and before 2027.

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, 2025, 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 of 2002, as amended (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 current 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;
- ineffectiveness of our internal controls;
- changes in the variables used as a basis for valuing these stock-based awards, resulting in changes in the magnitude of the expense that we must recognize;
- general geopolitical and macroeconomic conditions, including as a result of bank failures, new or increased tariffs, funding shortages at governmental and regulatory agencies on which we rely, global pandemics, changes in monetary and fiscal policy, U.S. political developments and other sources of instability that may impact our ability to access capital on acceptable terms, if at all, geopolitical tensions between the U.S. and China, the Russia/Ukraine conflict or conflicts in the Middle East; 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;
- negative public perception of us, our competitors, or the biopharmaceutical and biotechnology industries; 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, the daily closing market price for our common stock has varied significantly since the commencement of trading of our common stock on Nasdaq on January 26, 2023, ranging between a high price of $40.98 on June 20, 2023, and a low price of $1.60 on August 5, 2024. Since the closing of our IPO, 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 trials for Olvi-Vec, our preclinical studies and any other future clinical development programs;
- 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;
- 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 bank failures, new or increased tariffs, global pandemics, changes in monetary and fiscal policy, geopolitical tensions between the U.S. and China, the Russia/Ukraine conflict or conflicts in the Middle East; 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.

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. 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.

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 and Rule 144 and Rule 701 under the Securities Act of 1933, as amended (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.

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.

In January 2026, we completed an underwritten follow-on public offering of 6,666,667 shares of our common stock at an offering price of $3.00 per share. The total net proceeds from the offering were $18.5 million, after deducting underwriting discounts and commissions and offering expenses payable by us.

In March 2025, we completed an underwritten offering of 3,000,000 shares of our common stock at an offering price of $3.50 per share. We also issued to the underwriter a warrant to purchase 120,000 shares of our common stock with an exercise price of $4.20 per share and which may be exercised until March 25, 2030. The total net proceeds from the offering were $9.6 million, after deducting underwriting discounts, commissions and offering expenses payable by us.

In May 2024, we completed an underwritten follow-on public offering of 7,500,000 shares of our common stock and accompanying warrants to purchase 7,500,000 shares of our common stock, including the partial exercise of the underwriters' option to purchase additional shares, at a combined offering price of $4.00 per share. The total net proceeds from the offering were $27.7 million, after deducting underwriting discounts, commissions and offering expenses payable by us.

In February 2024, we entered into a sales agreement with Guggenheim Securities, LLC (Guggenheim) (the 2024 Sales Agreement) implementing an "at-the-market" offering program (the ATM). In the ATM, we had the ability to offer and sell, from time to time and at our option, up to an aggregate of $100.0 million of shares of our common stock through Guggenheim, acting as sales agent. Guggenheim was entitled to a fixed commission rate of up to 3.0% of the gross sales proceeds of shares sold under the ATM. As of December 31, 2025, we had sold an aggregate of 5,460 shares of common stock under the ATM. In March 2026, we terminated the 2024 Sales Agreement. We may put in place a similar program in the future.

Pursuant to our 2022 Equity Incentive Plan (the 2022 Plan) and the 2023 Inducement Plan (the Inducement Plan), we are authorized to grant equity awards 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, 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 Employee Stock Purchase Plan, the number of shares of our common stock reserved for issuance will automatically increase on January 1 of each calendar year, continuing through and including January 1, 2032, by the lesser of (i) 1% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year, and (ii) 2,100,000 shares of common stock; 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 Jumpstart our Business Startups Act of 2012 (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. December 31, 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 provides that the Court of Chancery of the State of Delaware and the U.S. federal district courts are 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 provides 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 does 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 incur significantly increased costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, we incur significant legal, accounting, and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Exchange Act, which 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 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 SEC, 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, 2025, 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 Annual Report on 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 Cuts and Jobs Act, the Coronavirus Aid, Relief, and Economic Security Act, the IRA, and the OBBA 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 Cuts and Jobs 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 1C. Cybersecurity

Risk management and strategy

We have implemented and maintain various information security processes designed to identify, assess and manage material risks from cybersecurity threats to our critical computer networks, third-party hosted services, communications systems, hardware and software, and our critical data, including intellectual property, confidential information that is proprietary, strategic or competitive in nature, and clinical trial data (Information Systems and Data).

We engage an external information technology company to operate information technology systems for us. This vendor works with us, including our general counsel, to help identify, assess and manage our cybersecurity threats and risks. This group works to identify and assess risks from cybersecurity threats by monitoring and evaluating our threat environment using various methods, including, for example: manual and automated tools, subscribing to reports and services that identify cybersecurity threats, analyzing reports of threats and actors, evaluating threats reported to us, conducting vulnerability assessments, evaluating our and our industry's risk profile, and conducting third-party threat assessments.

Depending on the environment, we implement and maintain various technical, physical, and organizational measures, processes, standards and policies designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data, including, for example: an incident response plan, a vulnerability management policy, disaster recovery and business continuity plans, risk assessments, implementation of security standards or certifications, encryption of certain data, network security controls and data segregation (for certain systems), physical security, asset management, tracking and disposal, systems monitoring, employee training, and cybersecurity insurance.

Our assessment and management of material risks from cybersecurity threats are integrated into our overall risk management processes. Cybersecurity risk is addressed as a component of the our enterprise risk management program and senior management prioritizes our risk management processes and reports to the Audit Committee of the Board of Directors, which evaluates our overall enterprise risk.

We use third-party service providers to assist us from time to time to identify, assess, and manage material risks from cybersecurity threats, including, for example managed cybersecurity service providers and professional services firms (including legal counsel).

We also use third-party service providers to perform a variety of other functions throughout our business, such as application providers, hosting companies, contract research organizations, contract manufacturing organizations, and distributors. We have a vendor management program to manage cybersecurity risks associated with our use of these providers. The program may include, depending on the provider, a security questionnaire, security audit, a risk assessment for certain vendors, and imposition of information security contractual obligations on certain vendors.

For a description of the risks from cybersecurity threats that may materially affect the Company and how they may do so, see our risk factors under Part 1. Item 1A. Risk Factors in this Annual Report on Form 10-K, including "*If our information technology systems or those third parties with whom we work or our data 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*."

Governance

Our Board of Directors addresses our risk management as part of its general oversight function. The Audit Committee is responsible for overseeing our cybersecurity risk management processes, including oversight of mitigation of risks from cybersecurity threats.

Our cybersecurity risk assessment and management processes are implemented and maintained by our Cybersecurity Risk Management Team, which includes our General Counsel and an external information technology vendor.

Our Chief Executive Officer is responsible for hiring appropriate personnel, helping to integrate cybersecurity risk considerations into our overall risk management strategy, and communicating key priorities to relevant personnel. Our Cybersecurity Risk Management Team is responsible for developing budgets, helping prepare for cybersecurity incidents, approving cybersecurity processes, and reviewing security assessments and other security-related reports.

Our cybersecurity incident response and vulnerability management processes are designed to escalate certain cybersecurity incidents to members of management depending on the circumstances, including our General Counsel, and CEO. Our General Counsel and CEO work with the Company's Incident Response Team to help the Company triage, contain, mitigate and remediate cybersecurity incidents of which they are notified. In addition, the Company's incident response and vulnerability management processes include reporting to the Audit Committee for certain cybersecurity incidents.

The Board of Directors and Audit Committee receive regular reports from the Company's Cybersecurity Risk Management Team concerning the Company's significant cybersecurity threats and risk and the processes the Company has implemented to address them. The Board of Directors and Audit Committee also receive various reports, summaries and presentations related to cybersecurity threats, risk and mitigation.

Item 2. PROPERTIES

The following table summarizes the Company's principal leased facilities as of December 31, 2025.

	Approximate Square Footage	Primary Use	Lease Expiration	Remaining Lease Term (year)
Westlake Village, California.....	4,050	Corporate Headquarters	July 2027	1.6
San Diego, California.....	7,569	Manufacturing Facility Research and Development	October 2030	4.8
San Diego, California.....	6,755	Laboratory	October 2030	4.8
San Diego, California.....	3,928	Office Space	January 2028	2.0

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

Legal Proceedings are set forth in the Company's financial statement schedules in Part IV, Item 15 of this Annual Report on Form 10-K and are incorporated herein by reference. See Note 13 — Commitments and Contingencies of Notes to Financial Statements of Part IV, "Item 15. Exhibits and Financial Statement Schedules."

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock, par value $0.001 per share, is traded on The Nasdaq Capital Market under the symbol "GNLX." Trading of our common stock commenced on January 26, 2023, following the completion of our initial public offering (IPO).

Holders of Record

As of March 3, 2026, there were approximately 979 stockholders of record of our common stock. Certain shares are held in street name and accordingly, the number of beneficial owners of such shares is not known or included in the foregoing number.

Dividends

We have never paid dividends on our common stock and do not anticipate that we will do so in the foreseeable future.

Securities Authorized for Issuance under Equity Compensation Plans

See Item 12 of Part III of this Annual Report on Form 10-K for information about our equity compensation plans, which is incorporated by reference herein.

Recent Sales of Unregistered Securities

None.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

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 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 titled "Special Note Regarding Forward- Looking Statements."

OVERVIEW

Genelux is a late clinical-stage biopharmaceutical company focused on developing next-generation oncolytic viral immunotherapies for patients suffering from aggressive and/or difficult-to-treat tumor types. 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. Our lead 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.

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.

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 $32.1 million and $29.9 million, respectively, for the years ended December 31, 2025 and 2024. As of December 31, 2025, we had an accumulated deficit of $283.5 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.

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 require substantial additional funding to support our continuing operations and to pursue our growth strategy. Until we generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of public or private equity offerings, debt and/or other sources, such as milestone payments, royalties or other payments or funding from existing or potential collaboration agreements, strategic alliances, licensing arrangements and other 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. 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.

During the year ended December 31, 2025, we completed an underwritten offering of 3,000,000 shares of our common stock at an offering price of $3.50 per share. The gross proceeds received from the offering were $10.5 million, before deducting underwriting discounts and commissions and estimated offering expenses payable by us. As a result of the proceeds received through public offerings, and the conversion of preferred stock and convertible notes payable upon the closing of the IPO, we have stockholders' equity of $11.5 million at December 31, 2025. In January 2026, we completed an underwritten offering of 6,666,667 shares of our common stock at an offering price of $3.00 per share. The net proceeds received from the offering were $18.5 million after deducting underwriting discounts and commissions and offering expenses payable by us. We expect our cash, cash equivalents, restricted cash and marketable securities, totaling $14.6 million at December 31, 2025, and subsequent net proceeds of $18.5 million that were received in January 2026, representing a pro forma balance of $33.1 million, to last into the first quarter of 2027.

Business Highlights

Data from Lung Cancer Clinical Trials

On January 5, 2026, we announced interim results from two ongoing trials evaluating systemic (intravenous) administration of Olvi-Vec in patients with progressive small cell lung cancer (SCLC) and progressive non-small cell lung cancer (NSCLC), respectively, after failure of prior platinum-based regimens.

Platinum-relapsed or platinum-refractory advanced SCLC (Ph1b/2 SCLC trial)

The open-label Phase 1b/2 SCLC trial (NCT07136285) is evaluating a single intravenous cycle with multiple doses of Olvi-Vec administered in combination with platinum and etoposide chemotherapy in SCLC patients with platinum-relapsed or platinum-refractory disease after failing previous treatment with platinum and etoposide chemotherapy. The trial is being conducted by the Company's licensing partner, Newsoara, in China.

As of the data review cutoff date of December 23, 2025, systemic administration of Olvi-Vec in the initial dose escalation cohorts achieved the following preliminary results:

- 9 evaluable patients

  Overall response rate (ORR) of 33% (3/9 patients), including three partial responses (PRs)

  - Two of the three PRs occurred in Cohort 4, the highest dose cohort tested as of the data review cutoff date, with tumor shrinkage of approximately 55% and 85% from baseline, representing an ORR of 67% (2/3) in Cohort 4 and potentially suggesting a dose-response trend
  - Disease control rate (DCR) of 67% (6/9 patients)
  - Tumor shrinkage of 24–85% among the six DCR patients, all of whom experienced a reduction in all target lesions from baseline
  - Olvi-Vec generally well tolerated
- Exploratory durability signals: Two PR patients across different cohorts have been evaluated in long-term follow-up:
  - A patient with 1 prior line, at last scan, achieved a PR with an ongoing progression-free survival (PFS) of 12.1 months
  - A patient with 4 prior lines had a PFS of 7.7 months, which exceeds the PFS in the immediately preceding line in the same patient (1.9 months) by 5.8 months

Advanced or metastatic recurrent NSCLC (Phase 2 VIRO-25 Clinical trial)

The open-label Phase 2 VIRO-25 trial (NCT06463665) is evaluating a single intravenous cycle with multiple doses of Olvi-Vec in combination with platinum chemotherapy and an immune checkpoint inhibitor (ICI) in patients with advanced or metastatic recurrent NSCLC who failed standard frontline treatment of platinum chemotherapy and an ICI. The trial is being conducted in the United States.

As of the data review cutoff date of December 31, 2025, systemic administration of Olvi-Vec in the initial dose escalation cohorts achieved the following preliminary results:

- 5 evaluable patients
- DCR of 60% (3/5 patients)
- Tumor size changes among the three DCR patients were 8.9%, -18.9%, and -22.7%, respectively, as compared to baseline
- Olvi-Vec generally well tolerated

Underwritten Public Offering

In March 2025, we completed an underwritten offering of 3,000,000 shares of our common stock at $3.50 per share. The net proceeds received from the offering were $9.6 million, after deducting underwriting discounts, and commissions, and offering expenses payable by the Company.

In January 2026, we completed an underwritten offering of 6,666,667 shares of our common stock at an offering price of $3.00 per share. The net proceeds received from the offering were $18.5 million after deducting underwriting discounts, and commissions, and offering expenses payable by us.

US-Based Phase 2 Trial in NSCLC

In October 2024, the Company announced that the first patient had been dosed in a Phase 2, open-label, randomized, and controlled clinical trial designed to evaluate the efficacy and safety of intravenously delivered Olvi-Vec oncolytic VACV for patients with recurrent non-small cell lung cancer (NSCLC) in the United States. Pursuant to the Company's license agreement (as amended, the Newsoara License Agreement) with its partner in China, Newsoara HYK Biopharmaceuticals Co., Ltd. (Newsoara), Newsoara is generally obligated to fund the Phase 2 NSCLC trial in its entirety in the United States and China (VIRO-25 Trial). In November 2023, the Company agreed with Newsoara that the Company would directly engage a contract research organization (CRO) on mutually agreeable terms to conduct certain startup activities for the VIRO-25 Trial in the U.S. only, with Newsoara reimbursing the Company for the costs and expenses of such agreed-upon startup activities. Pursuant to a letter of understanding (the LOU), in September 2025, the Company agreed with Newsoara that the CRO would conduct additional study activities beyond startup for the VIRO-25 Trial in the United States and Newsoara would reimburse the Company for costs and expenses related to such additional activities; however, Newsoara is permitted to defer reimbursement of the foregoing costs and expenses until the earlier of: (i) completion of its next round of financing or (ii) December 31, 2026.

Officer Transition

In February 2025, the Company announced the appointment of Matt Pulisic as Chief Financial Officer. In July 2025, the Company announced the appointment of Eric Groen as General Counsel, Corporate Secretary, Chief Compliance Officer and Head of Business Development. In January 2026, the Company announced the appointment of Jason Litten as Chief Medical Officer.

2025 Financial Performance Summary

Net Sales

During the year ended December 31, 2025 and 2024, we recognized revenue of $0.01 million relating to our license agreement with ELIAS Animal Health, LLC, respectively.

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 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 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 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 and conduct 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, 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 and recruiting fees and fees paid to consultants engaged to supplement our personnel as well as insurance, travel, 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 are expected to result primarily from higher personnel-related costs associated with hiring additional personnel and increased fees paid to outside service providers, among other expenses. We also anticipate incurring additional expenses associated with operating as a public company, including audit, legal, regulatory and tax-related costs to comply with the rules and regulations of the U.S. Securities and Exchange Commission (the SEC), and listing standards applicable to companies listed on a national securities exchange, increased 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 additional costs related to establishing sales, marketing and distribution capabilities.

Results of Operations

Year Ended December 31, 2025 Compared to Year Ended December 31, 2024

The following table summarizes our results of operations for the periods indicated (in thousands):

	Year Ended December 31,	
	2025	2024
Revenue	$ 8	$ 8
Operating Expenses:		
Research and development	19,851	18,998
General and administrative	13,371	12,706
Total operating expenses	33,222	31,704
Loss from operations	(33,214)	(31,696)
Other income:		
Interest income	711	700
Bond accretion income	358	757
Gain on extinguishment of accounts payable	—	370
Total other income	1,069	1,827
Net loss	$ (32,145)	$ (29,869)

Research and Development (R&D) Expenses

R&D expenses are related to our R&D efforts and related candidate costs, which are comprised primarily of costs related to the manufacturing of clinical supplies, efficacy studies, and clinical trial expenses. Internal costs primarily relate to development operations at our research facilities in California, including facility costs and laboratory-related expenses.

The following table provides details of R&D expenses (in thousands):

	Year Ended December 31,		
	2025	2024	Change
Employee compensation and related expenses	$ 4,038	$ 3,766	$ 272
Stock compensation, including the cost of stock options and restricted stock grants	2,909	3,090	(181)
Manufacturing and laboratory materials and other expenses	1,236	556	680
Outsourced manufacturing services	1,474	1,602	(128)
Clinical and regulatory expenses	9,049	8,204	845
Facility-related expenses, including depreciation	703	1,320	(617)
Consulting expenses and contract labor	425	414	11
Other expenses	17	46	(29)
Total research and development expenses	$ 19,851	$ 18,998	$ 853

R&D expenses increased by $0.9 million for the year ended December 31, 2025 over the same period in 2024. The increase was primarily driven by $0.8 million in clinical and regulatory expenses relating to the increased clinical trial costs associated with our Phase 3 On Prime/GOG-3076 registration trial in 2025.

General and Administrative Expenses

The following table provides detail of general and administrative expenses (in thousands):

	Year Ended December 31,		
	2025	2024	Change
Employee compensation and related expenses	$ 3,826	$ 2,705	$ 1,121
Stock compensation, including the cost of stock options and restricted stock grants	4,666	5,024	(358)
Professional services	2,527	2,278	249
Facility-related expenses	292	457	(165)
Insurance expenses	870	966	(96)
Consulting and contract labor expenses	421	831	(410)
Other expenses	769	445	324
Total general and administrative expenses	$ 13,371	$ 12,706	$ 665

General and administrative expenses increased by $0.7 million for the year ended December 31, 2025 over the same period in 2024 primarily as a result of an increase of $1.1 million in employee compensation driven by the combination of annual salary increases and changes to headcount required to support our operations; partially offset by a decrease of $0.4 million in consulting services.

Other Income

Other income was $1.1 million and $1.8 million for the year ended December 31, 2025 and 2024, respectively. There was a decrease of $0.7 million in 2025 due to lower bond accretion income of $0.4 million and gain on extinguishment of accounts payable in 2024 of $0.4 million.

Liquidity and Capital Resources

We have experienced recurring losses from operations since inception and incurred a net loss of $32.1 million and used cash in operations of $25.3 million during the year ended December 31, 2025. 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. The financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

As of December 31, 2025, we had cash, cash equivalents, restricted cash and marketable securities of $14.6 million and subsequent net proceeds of $18.5 million that were received in January 2026, representing a pro forma balance of $33.1 million. However we do not have any committed external source of funds or other support for our development efforts, except for the Newsoara License Agreement. 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, debt and/or other capital sources such as milestone payments, royalties or other payments or funding from existing or potential collaborations, strategic alliances, licensing arrangements and other arrangements. Based on our research and development plans, we expect that our existing cash balance may not enable us to fund our planned operating expenses and capital expenditure requirements for the next 12 months from the date of filing of this Annual Report. In addition, because the design and outcome of our anticipated and any future clinical trials are 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 the development of Olvi-Vec or any other product candidate.

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, or cause substantial dilution for our stockholders, in case of equity financing, or grant unfavorable terms in future licensing agreements.

Cash Flows

The following table presents a summary of cash flows (in thousands):

	Year Ended December 31,	
Cash Flow from:	**2025**	**2024**
Operating activities	$ (25,268)	$ (21,228)
Investing activities	12,141	(8,131)
Financing activities	9,895	28,506
Net decrease in cash, cash equivalents and restricted cash	$ (3,232)	$ (853)
Cash, cash equivalents and restricted cash at end of period	$ 5,333	$ 8,565

During the year ended December 31, 2025, cash flow used in operating activities was $25.3 million, which consisted of a net loss of $32.1 million and, non-cash expense of stock-related compensation of $7.6 million, partially offset by a decrease in accrued expenses of $1.2 million. Cash provided by investing activities was $12.1 million, which was primarily attributable to net maturities of marketable securities of $13.2 million. Cash provided by financing activities of $9.9 million was related to cash received from sale of common stock. See “Stockholders’ Equity” in Note 8 to our audited condensed financial statements in Part I. Item 1 “Financial Statements” in this Annual Report for additional information.

During the year ended December 31, 2024, cash flow used in operating activities was $21.2 million, which consisted of a net loss of $29.9 million, non-cash expense of stock-related compensation of $8.1 million and accrued expenses of $2.2 million, and partially offset by a decrease in accrued payroll of $1.1 million. Cash used in investing activities was $8.1 million, which was primarily attributable to net purchase of marketable securities of $7.8 million. Cash provided by financing activities of $28.5 million was related to proceeds from the sale of common stock of $27.7 million and proceeds from the exercise of stock warrants of $0.7 million.

Equity Financings

Common Stock Issued for Cash Upon Closing of Public Offering in January 2026

In January 2026, we completed an underwritten offering of 6,666,667 shares of our common stock at an offering price of $3.00 per share. The net proceeds received from the offering were $18.5 million after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

Common Stock Issued for Cash Upon Closing of Public Offering in March 2025

In March 2025, we completed an underwritten offering of 3,000,000 shares of our common stock, at an offering price of $3.50- per share. The gross proceeds received from the offering were $10.5 million and we raised $9.6 million in net proceeds after deducting underwriting discounts and commissions and offering expenses payable by the Company.

Common Stock Issued for Cash Upon Closing of Public Offering in May 2024

In May 2024, we completed an underwritten offering of our common stock, in which we issued and sold 7,500,000 shares of our common stock at a price of $4.00 per share, which included 625,000 shares of common stock at $4.00 per share pursuant to the underwriters' partial exercise of their option to purchase additional shares of common stock. The total gross proceeds received from the offering were $30.0 million and we raised $27.7 million in net proceeds after deducting underwriting discounts and commissions and offering expenses payable by us.

Included in the offering were accompanying warrants to purchase 7,500,000 shares of common stock with an exercise price of $5.25 per share. The warrants expire five years from the date of grant

At-the-Market Offering

In February 2024, we entered into a Sales Agreement with Guggenheim Securities, LLC (Guggenheim) (the 2024 Sales Agreement) implementing an "at-the-market" offering program (the ATM). In the ATM, we had the ability to offer and sell, from time to time and at our option, up to an aggregate of $100.0 million of shares of our common stock through Guggenheim, acting as sales agent. Guggenheim was entitled to a fixed commission rate of up to 3.0% of the gross sales proceeds of shares sold under the ATM. During the year ended December 31, 2024, we sold an aggregate of 5,460 shares of common stock under the ATM for net proceeds of $0.02 million after deducting compensation. No shares were offered under the ATM during the year ended December 31, 2025. In March 2026, we terminated the 2024 Sales Agreement.

Funding Requirements

We expect our expenses to increase in connection with ongoing operations, particularly as research and development activities continue, including the initiation and conduct of preclinical studies and clinical trials, and efforts to obtain marketing approval for current and future product candidates. In addition, if marketing approval is obtained for any current or future product candidates, significant commercialization expenses are expected, including costs related to product sales, marketing, manufacturing, and distribution, which may be partially offset through collaboration agreements with third parties. Additional costs associated with operating as a public company are also expected. Accordingly, substantial additional funding will be required to support continuing operations. If capital cannot be raised when needed or on acceptable terms, research and development programs or future commercialization efforts may be delayed, reduced, or eliminated.

We believe that our existing cash, cash equivalents, restricted cash and marketable securities may not enable us to fund our operating expenses and capital expenditure requirements for the next 12 months from the date of filing of this Annual Report. 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;
- the costs of operating as a public company; and
- the impact of geopolitical and macroeconomic events, including future bank failures, new or increased tariffs, funding shortages at governmental and regulatory agencies on which we rely, geopolitical tensions between the U.S. and China, the Russia/Ukraine conflict, conflicts in the Middle East and global pandemics on U.S. and global economic conditions including changes in monetary and fiscal policy, U.S. political development and other sources of instability that may impact our ability to access capital on acceptable terms, if at all.

We anticipate needing to obtain further funding to achieve our business objectives beyond such date.

Until such time, if ever, as substantial product revenues are generated, cash requirements are expected to be financed through public or private equity offerings, debt and/or other sources, including as milestone payments, royalties or other payments or funding from existing or potential collaboration agreements, strategic alliances, licensing arrangements and other arrangements. To the extent additional capital is raised through the issuance of equity or convertible debt securities, existing stockholders' ownership interests may be diluted, and such securities may include liquidation or other preferences that could adversely affect the rights of common stockholders. Debt financing, if available, may involve restrictive covenants that limit the ability to take certain actions, including incurring additional indebtedness, making capital expenditures, business development activities or declaring dividends, which could adversely affect business operations.

If funding is obtained through collaborations, strategic alliances, or licensing arrangements with third parties, valuable rights to technologies, future revenue streams, research programs, or product candidates may be relinquished, or licenses may be granted on terms that are not favorable. The ability to raise additional funds may also be adversely affected by global economic conditions and volatility in U.S. and international credit and financial markets resulting from geopolitical and macroeconomic events, including changes in interest rates and inflation, current or future bank failures, tariffs, global pandemics, geopolitical tensions between the United States and China, the Russia/Ukraine conflict, and conflicts in the Middle East. If additional funding cannot be obtained when needed, product development or future commercialization efforts may be delayed, limited, reduced, or terminated, or rights to develop and commercialize product candidates may need to be granted to third parties that would otherwise be retained.

Critical Accounting Estimates

Management makes certain judgments and uses certain estimates and assumptions when applying U.S. generally accepted accounting principles (GAAP) in the preparation of our financial statements. On an ongoing basis, we evaluate our estimates, judgments and assumptions. We base our estimates on historical experience and on various other assumptions that we believe are reasonable, the results of which form the basis for making judgments about the carrying values of assets, liabilities and equity and the amount of revenue and expense. Actual results may vary from what we anticipate and different assumptions or estimates about the future could change its reported results. We believe the following accounting policies are the most critical to us, in that they require our most difficult, subjective or complex judgments in the preparation of our financial statements. For further information, see Note 1, Organization and Significant Accounting Policies of the Notes to the Company's Financial Statements in Part IV, "Item 15. Exhibits and financial statement Schedules."

Revenue Recognition

Revenues are recognized when control of our services are transferred to our customers, in an amount that reflects the consideration management expects to be entitled to in exchange for those services. We determine revenue recognition through the following steps: (1) identification of the contract, or contracts, with a customer; (2) identification of the performance obligations in the contract; (3) determination of the transaction price; (4) allocation of the transaction price to the performance obligations in the contract; and (5) recognition of revenue when, or as, we satisfy a performance obligation. We have not made any material changes in the accounting methodology that management uses to recognize revenue during the year ended December 31, 2025.

Judgment and Uncertainties: Our revenue recognition accounting methodology involves significant judgments and estimates, which often include multiple performance obligations, variable consideration in the form of milestone payments, and royalties on future product sales. In applying this methodology, we are required to exercise judgment and make estimates to, among other things: (1) determine whether multiple obligations are distinct and should be accounted for as separate performance obligations; (2) estimate the standalone selling price of each performance obligation; (3) allocate the transaction price among performance obligations based on relative standalone selling prices; and (4) determine whether revenue should be recognized at a point in time or over time for each performance obligation. These judgments and estimates may change as additional information becomes available or as underlying assumptions are revised. Changes in these judgments or estimates could result in a material increase or decrease in the amount of revenue or deferred revenue recognized in a particular reporting period.

Research and Development Accrual

We record accrued expenses for research and development activities based on estimates of services provided to date by third-party vendors, including CROs, preclinical research organizations, clinical sites, research institutions, and other service providers. Research and development expenses are recognized as incurred and are based on a combination of factors, including contractual terms, the progress of preclinical and clinical activities, patient enrollment and dosing, preclinical study progress, and information provided by our vendors. We have not made any material changes in the accounting methodology that management uses to recognize expenses during the year ended December 31, 2025.

Judgment and Uncertainties: The process of estimating accrued research and development expenses involves significant judgment and is subject to inherent uncertainties. In particular, management is required to estimate the extent of services performed under its research and development agreements, including preclinical studies and clinical trials, when invoices have not yet been received. These estimates are based on, among other things: (1) patient enrollment, dosing, and follow-up activities; (2) the timing and completion of preclinical and clinical milestones; (3) vendor-reported progress and data, which may be incomplete or subject to delay; and (4) assumptions regarding the rate at which services are rendered over the course of preclinical and clinical programs. Actual costs incurred may differ materially from our estimates due to changes in preclinical or clinical development plans, patient enrollment rates, protocol amendments, site activation or closure, manufacturing requirements, study outcomes, or other factors outside of our control. Changes in these estimates could result in material adjustments to research and development expenses and accrued liabilities in future periods.

Stock-Based Compensation

We recognize stock-based compensation expense for equity awards, including stock options, restricted stock units (RSUs), and shares issued under the Employee Stock Purchase Plan (ESPP), based on the estimated grant-date fair value of the awards. Compensation expense is recognized on a straight-line basis over the requisite service period, generally the vesting period. We account for forfeitures as they occur. The grant-date fair value of stock option awards is estimated using the Black-Scholes option pricing model, which requires the use of subjective assumptions, including expected term, expected volatility, risk-free interest rate, and expected dividend yield. Expected volatility and expected term are primarily based on our historical data and other relevant information, while the risk-free interest rate is based on U.S. Treasury yields in effect at the time of grant with a maturity commensurate with the expected term of the award. Management does not assume any expected dividend yield, as we have not declared or paid dividends on our common stock. Management has not made any material changes in the accounting methodology we use to recognize expenses during the year ended December 31, 2025.

Judgment and Uncertainties: The valuation of stock-based awards and the resulting compensation expense involve significant judgment and estimation. Changes in assumptions used to estimate the fair value of stock options, particularly expected volatility and expected term, could result in materially different stock-based compensation expense. In addition, differences between actual forfeitures and our estimates, as well as changes in the timing or amount of equity awards granted, could impact the amount and timing of stock-based compensation expense recognized in future periods. Changes in these assumptions or estimates, or differences between actual outcomes and our assumptions, could result in a material increase or decrease in the amount of stock-based compensation expense recognized in a particular period, which could materially affect our operating expenses and results of operations.

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.

We have not entered into, nor do we currently have, any off-balance sheet arrangements (as defined under SEC rules).

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 1 to the 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 RISK

We are subject to market risk exposures primarily due to our investing activities. The primary market risk exposure is change in interest rates. Adverse changes to rates may occur due to changes in the liquidity of a market or to changes in market perceptions of creditworthiness and risk tolerance.

We primarily invest our excess cash in securities of reputable financial institutions, corporations, and U.S. government agencies with strong credit ratings. Due to the relatively short-term nature of the investments that we hold, we do not believe that the results of operations or cash flows would be affected to any significant degree by a sudden change in market interest rates relative to its investment portfolio.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

See the financial statements filed as part of this Annual Report as listed under Part IV, Item 15 below.

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

None.

Item 9A. CONTROLS AND PROCEDURES

None.

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures designed to ensure that information required to be disclosed in our reports filed under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to its management, including our Chief Executive Officer and Chief Financial Officer (our principal executive officer and principal financial officer, respectively), as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management necessarily was required to apply its judgment in evaluating the cost benefit relationship of possible controls and procedures.

As required by Rule 13a-15(b) of the Exchange Act, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of the end of the period covered by this Annual Report on Form 10-K. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at a the reasonable assurance level as of December 31, 2025.

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 2025 that materially affected, or are reasonably likely to materially affect, its internal control over financial reporting.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act. Our internal control over financial reporting is a process designed by, or under the supervision of, our principal executive officer and principal financial officer, and effected by our board of directors, management and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of its financial statements for external purposes in accordance with GAAP. Management conducted an assessment of the effectiveness of our internal control over financial reporting based its assessment on the criteria set forth in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, management concluded that our internal control over financial reporting was effective as of December 31, 2025.

Item 9B. OTHER INFORMATION

Notice of 2026 Annual Meeting Date and Related Deadlines

As of the date of this Annual Report, we intend to hold our 2026 annual meeting of stockholders (the "2026 Annual Meeting") on or about June 16, 2026. This date is more than 30 days before the one-year anniversary of our 2025 annual meeting of stockholders (the "2025 Annual Meeting"), which was held on August 27, 2025.

Our bylaws provide that for stockholder nominations to our board of directors or other proposals to be considered at an annual meeting of stockholders, the stockholder must give timely notice thereof in writing to the Corporate Secretary at Genelux Corporation, 2625 Townsgate Road, Suite 230, Westlake Village, CA 91361.

Because the date of the 2026 Annual Meeting is more than 30 days before the one-year anniversary of the date of our 2025 Annual Meeting, for the stockholder notice to be timely, it must be delivered to the Corporate Secretary at our principal executive offices not earlier than 5:00 p.m. Pacific Time on the 120th day prior to the date of the 2026 Annual Meeting, February 16, 2026, and not later than 5:00 p.m. Pacific Time on the later of (1) the 90th day prior to the 2026 Annual Meeting, March 18, 2026, or (2) the close of business on the tenth day following the day on which public announcement of the date of such meeting is first made by us, March 29, 2026. A stockholder's notice to the Corporate Secretary must set forth as to each matter the stockholder proposes to bring before the 2026 Annual Meeting the information required by applicable law and our bylaws.

In addition, stockholder proposals submitted pursuant to Rule 14a-8 under the Exchange Act and intended to be presented at our 2026 Annual Meeting must be received by us a reasonable time before we mail our proxy materials for the 2026 Annual Meeting. We have determined that March 16, 2026, which is the date disclosed in our definitive proxy statement on Schedule 14A for our 2025 Annual Meeting, remains a reasonable time before we expect to mail our proxy materials for the 2026 Annual Meeting, and that any stockholder proposals must be received on or before the close of business on that date in order to be considered for inclusion in our proxy materials for the 2026 Annual Meeting. A stockholder's notice to the Corporate Secretary must set forth as to each matter the stockholder proposes to bring before the 2026 Annual Meeting, the information required by applicable law and our bylaws.

In addition, stockholders who intend to solicit proxies in support of director nominees other than our nominees must provide in their notice any additional information required by Rule 14a-19(b) under the Exchange Act.

Trading Arrangements

During the three months ended December 31, 2025, no director or officer adopted, terminated, or modified any Rule 10b5-1 trading arrangement or any non-Rule 10b5-1 trading arrangement (as such terms are defined pursuant to Item 408(a) of Regulation S-K of the Exchange Act).

Item 9C. Disclosure Regarding Jurisdictions That Prevent Inspections

Not Applicable.

PART III

We will file a definitive Proxy Statement for our 2026 Annual Meeting of Stockholders (the 2026 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 2026 Proxy Statement that specifically address the items set forth herein are incorporated by reference.

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

We have adopted a written code of business conduct and ethics (the 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). A copy of the Code of Conduct can be obtained free of charge in the "Corporate Governance" section of our website, www.genelux.com. 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 will be set forth in sections headed "Election of Directors," "Delinquent Section 16(a) Reports" and "Executive Officers" contained in our 2026 Proxy Statement, all of which is incorporated herein by reference.

Item 11. EXECUTIVE COMPENSATION

The information required under this Item will be set forth in the section headed "Executive and Director Compensation" contained in our 2026 Proxy Statement and is incorporated herein by reference.

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

The information required by this Item will be set forth in the sections headed "Security Ownership of Certain Beneficial Owners and Management" and "Executive and Director Compensation" contained in our 2026 Proxy Statement and is incorporated herein by reference.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

The information required by this Item will be set forth in the sections headed "Transactions with Related Persons and Indemnification" and "Information Regarding the Board of Directors and Corporate Governance" contained in our 2026 Proxy Statement and is incorporated herein by reference.

Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this Item will be set forth in the section headed "Ratification of Selection of Independent Registered Public Accounting Firm" contained in our 2026 Proxy Statement and is incorporated herein by reference.

PART IV

Item 15. EXHIBITS AND FINANCIAL STATEMENTS 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.

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	Form of Representative's Warrant (incorporated by reference to Exhibit 4.7 the Amendment No. 2 of Form S-1 (File No. 333-265828), filed with the SEC on September 19, 2022).
4.3	Form of Underwriter Warrant dated March 26, 2025 (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K (File No. 001-41599), filed with the SEC on March 25, 2025).
4.4	Form of Warrant (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K (File No. 001-41599), filed with the SEC on May 24, 2024).
4.5	Description of Registrant's Capital Stock (incorporated by reference to Exhibit 4.16 to the Registrant's Annual Report on Form-K (File No. 001-41599), filed with the SEC on March 28, 2025.
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).

Exhibit Number	Description
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 2023 Inducement Plan (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-41599), filed with the SEC on November 14, 2023).
10.9+	Forms of Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement for Executive Officers under the Genelux Corporation 2023 Inducement Plan (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-41599), filed with the SEC on November 14, 2023).
10.10+	Forms of Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement for Non-Executives under the Genelux Corporation 2023 Inducement Plan (incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-41599), filed with the SEC on November 14, 2023).
10.11+	Forms of Stock Option Grant Notice, Option Agreement and Notice of Exercise for Executive Officers under the Genelux Corporation 2023 Inducement Plan (incorporated by reference to Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-41599), filed with the SEC on November 14, 2023).
10.12+	Forms of Stock Option Grant Notice, Option Agreement and Notice of Exercise for Non-Executives under the Genelux Corporation 2023 Inducement Plan (incorporated by reference to Exhibit 10.6 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-41599), filed with the SEC on November 14, 2023).
10.13+*	Genelux Corporation Non-Employee Director Compensation Policy.
10.14+*	Form of Indemnification Agreement by and between the Registrant and its directors and executive officers.
10.15+	Executive Employment Offer Letter, by and between the Registrant and Matt Pulisic, dated January 16, 2025 (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-41599), filed with the SEC on May 6, 2025).
10.16+	Executive Employment Offer Letter, by and between the Registrant and Thomas Zindrick, J.D., dated May 30, 2023 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-41599), filed with the SEC on June 2, 2023).
10.17+	Executive Employment Offer Letter, by and between the Registrant and Ralph Smalling, MS, dated June 1, 2023 (incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-41599), filed with the SEC on August 14, 2023).
10.18+	Executive Employment Offer Letter, by and between the Registrant and Eric Groen, dated July 1 2025 (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-41599), filed with the SEC on November 5, 2025).
10.19	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).
10.20	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).
10.21¥#	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).
10.22	Letter of Understanding dated September 30, 2025 by and between the Registrant and Newsoara BioPharma Co., Ltd. (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-41599), filed with the SEC on November 5, 2025.
19	Registrant's Insider Trading Policy (incorporated by reference to Exhibit 19 to the Annual Report on Form 10-K (File No. 001-41599), filed with the SEC on March 28, 2025).
23.1*	Consent of Weinberg & Company, P.A., independent registered public accounting firm.
24.1*	Power of Attorney (included on the signature page hereto).

Exhibit Number	Description
31.1*	Certification of Principal Executive 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.
31.2*	Certification of 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.
97	Incentive Compensation Recoupment Policy (incorporated by reference to Exhibit 97 to the Registrant's Annual Report on Form 10-K (File No. 001-41599) filed with the SEC on March 29, 2024.
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* 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 19, 2026

GENELUX CORPORATION

By: */s/ Thomas Zindrick*
Name: Thomas Zindrick, J.D.
Title: President and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Thomas Zindrick, J.D. and Matthew Pulisic, 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 U.S. 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 19, 2026
/s/ Matthew Pulisic Matthew Pulisic	Chief Financial Officer (Principal Accounting Officer)	March 19, 2026
/s/ Mary Mirabelli Mary Mirabelli	Director	March 19, 2026
/s/ James L. Tyree James L. Tyree	Director	March 19, 2026
/s/ John Thomas John Thomas, Ph.D.	Director	March 19, 2026
/s/ John Smither John Smither	Director	March 19, 2026

Index to the Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
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, 2025 and 2024, the related statements of operations, comprehensive loss, stockholders' equity, and cash flows for the years then ended and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024, 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 has had recurring losses from operations since inception and has incurred a net loss and used cash in operations during the year ended December 31, 2025. 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 audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement, 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 19, 2026

Genelux Corporation
Balance Sheets
(in thousands, except for share amounts)

	December 31, 2025	December 31, 2024
ASSETS		
Current assets:		
Cash, cash equivalents and restricted cash	$ 5,333	$ 8,565
Marketable securities	9,262	22,330
Prepaid expenses and other current assets	535	653
Total current assets	15,130	31,548
Property and equipment, net	2,170	1,316
Right of use assets	1,583	1,760
Other assets	144	92
Total Assets	$ 19,027	$ 34,716
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ 4,358	$ 5,570
Accrued payroll and payroll taxes	1,440	1,004
Lease liabilities, current portion	427	329
Total current liabilities	6,225	6,903
Lease liabilities, net of current portion	1,258	1,539
Total liabilities	7,483	8,442
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Common stock, par value $0.001, 200,000,000 shares authorized; 38,139,144 and 34,728,140 shares issued and outstanding	38	35
Treasury stock, 433,333 shares, at cost	(433)	(433)
Additional paid-in capital	295,468	278,001
Accumulated other comprehensive income	9	64
Accumulated deficit	(283,538)	(251,393)
Total stockholders' equity	11,544	26,274
Total Liabilities and Stockholders' Equity	$ 19,027	$ 34,716

The accompanying notes are an integral part of these financial statements.

Genelux Corporation
Statements of Operations and Comprehensive Loss
(in thousands, except for share amounts and per share data)

	Year Ended December 31,	
	2025	**2024**
Revenue	$ 8	$ 8
Operating expenses:		
Research and development	19,851	18,998
General and administrative	13,371	12,706
Total operating expenses	33,222	31,704
Operating loss	(33,214)	(31,696)
Other income:		
Interest income	711	700
Bond accretion income	358	757
Gain on extinguishment of accounts payable	-	370
Total other income	1,069	1,827
Net loss	**$ (32,145)**	**$ (29,869)**
Net loss per common share - basic and diluted	$ (0.86)	$ (0.95)
Weighted-average shares outstanding – basic and diluted	37,176,527	31,450,727
Other comprehensive loss:		
Unrealized (loss) gain on available-for-sale securities	(55)	50
Comprehensive loss	**$ (32,200)**	**$ (29,819)**

The accompanying notes are an integral part of these financial statements.

Genelux Corporation
Statements of Stockholders' Equity
For the years ended December 31, 2025 and 2024
(in thousands, except share amounts)

	Common Stock		Treasury Stock		Additional Paid-in	Accumulated Other Comprehensive Income	Accumulated	
	Shares	Amount	Shares	Amount	Capital	(Loss)	Deficit	Total
Balance, December 31, 2023	**26,788,986**	**$ 27**	**(433,333)**	**$ (433)**	**$ 241,389**	**$ 14**	**$ (221,524)**	**$ 19,473**
Stock compensation	-	-	-	-	5,738	-	-	5,738
Unrealized gain on available-for-sale securities	-	-	-	-	-	50	-	50
Fair value of vested restricted stock units	303,389	-	-	-	2,044	-	-	2,044
Cost of stock option modifications and repricing	-	-	-	-	332	-	-	332
Issuance of common shares for cash and warrants	7,505,460	8	-	-	27,685	-	-	27,693
Common stock issued under equity award plans	53,818	-	-	-	125	-	-	125
Issuance of common shares upon exercise of stock warrants	76,487	-	-	-	688	-	-	688
Net loss during the year ended December 31, 2024	-	-	-	-	-	-	(29,869)	(29,869)
Balance, December 31, 2024	**34,728,140**	**$ 35**	**(433,333)**	**$ (433)**	**$ 278,001**	**$ 64**	**$ (251,393)**	**$ 26,274**

	Common Stock		Treasury Stock		Additional Paid-in	Accumulated Other Comprehensive Income	Accumulated	
	Shares	Amount	Shares	Amount	Capital	(Loss)	Deficit	Total
Balance, December 31, 2024	**34,728,140**	**$ 35**	**(433,333)**	**$ (433)**	**$ 278,001**	**$ 64**	**$ (251,393)**	**$ 26,274**
Stock compensation	312,792	-	-	-	5,792	-	-	5,792
Unrealized gain on available-for-sale securities	-	-	-	-	-	(55)	-	(55)
Fair value of vested restricted stock units	-	-	-	-	898	-	-	898
Cost of stock option modifications and repricing	-	-	-	-	806	-	-	806
Issuance of common stock for cash	3,000,000	3	-	-	9,550	-	-	9,553
Common stock issued under equity award plans	50,463	-	-	-	183	-	-	183
Common shares issued upon exercise of stock warrants	42,749	-	-	-	224	-	-	224
Issuance of common shares upon exercise of stock option	5,000	-	-	-	14	-	-	14
Net loss during the year ended December 31, 2025	-	-	-	-	-	-	(32,145)	(32,145)
Balance, December 31, 2025	**38,139,144**	**$ 38**	**(433,333)**	**$ (433)**	**$ 295,468**	**$ 9**	**$ (283,538)**	**$ 11,544**

The accompanying notes are an integral part of these financial statements.

Genelux Corporation
Statements of Cash Flows
(in thousands)

	Year Ended December 31,	
	2025	**2024**
Cash Flows from operating activities		
Net loss	$ (32,145)	$ (29,869)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	244	235
Accretion of discount on marketable securities	(226)	(757)
Right-of-use asset	330	668
Stock compensation	5,871	5,738
Fair value of restricted stock units	898	2,044
Cost of stock option modifications and repricing	806	332
Gain on extinguishment of accounts payable	-	(370)
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	66	359
Accounts payable and accrued expenses	(1,213)	2,156
Accrued payroll and payroll taxes	438	(1,113)
Lease liability	(337)	(651)
Net cash used in operating activities	(25,268)	(21,228)
Cash Flows from investing activities		
Purchases of property and equipment	(1,098)	(381)
Purchase of marketable securities	(18,261)	(29,000)
Proceeds from sales and maturities of marketable securities	31,500	21,250
Net cash provided by (used in) investing activities	12,141	(8,131)
Cash Flows from financing activities		
Proceeds from common stock issued	9,553	27,693
Proceeds from common stock issued in connection with the Company's equity award programs	104	125
Proceeds from the exercise of stock options	14	-
Proceeds from the exercise of stock warrants	224	688
Net cash provided by financing activities	9,895	28,506
Net decrease in cash, cash equivalents and restricted cash	(3,232)	(853)
Cash, cash equivalents and restricted cash		
BEGINNING OF PERIOD	8,565	9,418
END OF PERIOD	$ 5,333	$ 8,565
Supplemental non-cash financing disclosures:		
Unrealized (loss) gain on marketable securities	$ (55)	$ 50
Initial recognition of right-of-use asset obtained in exchange for operating lease liabilities	$ 153	-

The accompanying notes are an integral part of these financial statements.

Genelux Corporation
Notes to Financial Statements
For the years ended December 31, 2025 and 2024
(in thousands, except for share amounts)

NOTE 1 – ORGANIZATION AND SIGNIFICANT ACCOUNTING POLICIES

Genelux Corporation (Genelux or the Company), a Delaware Corporation, incorporated on September 4, 2001, is a late clinical-stage biopharmaceutical 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 developing a pipeline of next-generation oncolytic immunotherapies for patients suffering from aggressive and/or difficult-to-treat tumor types.

Basis of Presentation

The financial statements have been prepared in conformity with U.S. generally accepted accounting principles (GAAP). Certain prior period amounts, which are not material, have been reclassified to conform with the current period presentation.

Liquidity and Capital Resources

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 has experienced recurring losses from operations since inception and incurred a net loss of $32.1 million and used cash in operations of $25.3 million during the year ended December 31, 2025. 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.

As of December 31, 2025, the Company had cash, cash equivalents, restricted cash and marketable securities of $14.6 million, and subsequent net proceeds of $18.5 million that were received on January 8, 2026 (see Note 13), representing a pro forma balance of $33.1 million. However the Company does not have any committed external source of funds or other support for its development efforts, except for payment and reimbursement obligations of the Company's collaboration partner, Newsoara HYK Biopharmaceuticals Co., Ltd., under a License Agreement entered into in September 2021 (as amended, the Newsoara License Agreement). Until the Company can generate sufficient product revenue to finance its cash requirements, which it may never do, the Company expects to finance its future cash needs through a combination of public or private equity offerings, debt and/or other capital sources such as milestone payments, royalties or other payments or funding from existing or potential collaborations, strategic alliances, licensing arrangements, and other arrangements. Based on its research and development plans, the Company expects that its existing cash balance may not enable it to fund its planned operating expenses and capital expenditure requirements for the next 12 months from the date of filing of this Annual Report. In addition, because the design and outcome of its anticipated and any future clinical trials is highly uncertain, the Company cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of Olvi-Vec or any future product candidates. The Company's existing cash balance may not be sufficient to complete the development of Olvi-Vec or any other product candidate.

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 its operations, in the case of debt, or cause substantial dilution for its stockholders, in case of equity financing, or grant unfavorable terms in future licensing agreements.

SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Use of Estimates

The preparation of the financial statements in conformity with U.S. GAAP 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. On an ongoing basis, the Company evaluates its estimates, judgments, and assumptions. The Company bases its estimates on historical experience and various other assumptions that it believes are reasonable, the results of which form the basis for making judgments about the carrying values of assets, liabilities and equity, and the amount of revenue and expense. Actual results could differ from these estimates.

Cash, Cash Equivalents and Restricted Cash

All highly liquid marketable securities are classified as cash equivalents. These marketable securities mainly include money market with maturities of three months or less when purchased. The carrying value of these cash equivalents approximate fair value.

As of December 31, 2025 and 2024, cash equivalents were comprised of money market funds that totaled $3.0 million and $7.6 million, respectively.

There was $2.0 million restricted cash at December 31, 2025, that is primarily held as a refundable security deposit for an equipment lease (see Note 6). At December 31, 2024, there was no restricted cash.

Marketable Securities

The Company classified all of its investments in securities as marketable securities and current assets as they represent the investment of funds available for current operations as of December 31, 2025 and 2024. The marketable securities may consist of investment-grade interest bearing instruments, primarily money market accounts, government-sponsored enterprise securities, and treasury bonds, which are accounted for at fair value. Changes in fair values are reported as unrealized gains or losses and are recorded in the Company's statement of operations and comprehensive loss. There were no realized gains or losses during the years ended December 31, 2025 and 2024. Non-credit related losses are reported as a component of accumulated other comprehensive loss and included in stockholders' equity.

The Company evaluates its marketable securities for impairment. If an unrealized loss is determined to be other-than-temporary, it is written off as a realized loss through the statements of operations and comprehensive loss. The Company's methodology of assessing other-than-temporary impairments is based on security-specific analysis as of the balance sheet date and considers various factors, including the length of time to maturity and the extent to which the fair value has been less than the cost, recoverability of future cash flows as compared to carrying value of the security, the financial condition and the near-term prospects of the issuer, and the Company's ability and intent to hold the security. If a decline in fair value of marketable securities is determined to be other than-temporary, the securities are written down to fair value as the new cost basis and the amount of the write down is accounted for as realized losses. The Company did not recognize any other-than-temporary impairments of its marketable securities for the years ended December 31, 2025, and 2024. In addition, no impairments have been recognized on the Company's marketable securities in available-for-sale securities during the years ended December 31, 2025 and 2024.

Concentration of Credit Risk

Financial instruments that potentially expose the Company to concentration of credit risk, consist primarily of cash, cash equivalents, restricted cash, and marketable securities. The Company has established guidelines relative to diversification and maturities that maintain safety and liquidity. The Company periodically reviews and modifies these guidelines to maximize trends in yields and interest rates without compromising safety and liquidity. These accounts are insured by the Federal Deposit Insurance Corporation (FDIC) for up to $250,000 per institution. The Company has not experienced any losses on deposits since inception.

Property and Equipment

Property and equipment are recorded at cost, net of accumulated depreciation. Depreciation expense is recorded on a straight-line basis over the estimated useful lives of the assets. Leasehold improvements are amortized over the lesser of the expected useful life or the remaining lease term. Construction in progress reflects amounts incurred for construction or improvements of property and equipment that have not been placed in service. Upon disposition, the cost and accumulated depreciation of assets retired or sold are removed from the respective asset category, and any gain or loss is recognized in the Company's statement of operations and comprehensive loss.

The estimated useful lives of property and equipment are as follows (in years):

	Estimated Useful Lives
Furniture and office equipment	5
Laboratory equipment	5
Computer equipment	3
Leasehold improvements	Shorter of asset life or remaining lease term

The Company periodically assesses long-lived assets or asset groups, including property and equipment, for recoverability when events or changes in circumstances indicate that their carrying amounts may not be recoverable. If the Company identifies an indicator of impairment, the Company assesses recoverability by comparing the carrying amount of the asset to the sum of the undiscounted cash flows expected to result from the use and the eventual disposal of the asset. An impairment loss is recognized when the carrying amount is not recoverable and is measured as the excess of carrying value over fair value. There were no impairment charges during the years ended December 31, 2025, and 2024.

Leases

The Company determines whether a contract is, or contains, a lease at inception. Leases with terms greater than one-year are recognized on the Company's balance sheets as right-of-use assets that represent the Company's right to use an underlying asset for the lease term, and lease liabilities that represent its obligation to make lease payments arising from the lease. Lease assets and liabilities are recognized at the lease commencement date based on the estimated present value of lease payments over the expected lease term. As of December 31, 2025 and 2024, the Company is not reasonably certain that it will exercise renewal options for any lease facilities. Therefore, these options are not included in the right-of-use assets and liabilities.

The interest rate implicit in lease contracts is typically not readily determinable. As such, the Company utilizes the appropriate incremental borrowing rate, which is the rate incurred to borrow on a collateralized basis an amount equal to the lease payments over a similar term and in a similar economic environment. The Company records expense to recognize lease payments on a straight-line basis over the expected lease term. Costs determined to be variable and not based on an index or rate are not included in the measurement of the lease liability and are expensed as incurred.

Research Contract Costs and Accruals

The Company has entered into various research and development-related contracts with companies inside of the United States. These agreements are generally cancellable, and related costs are recorded as research and development expenses as incurred. The Company records prepaid expenses and accruals for estimated ongoing research costs. When evaluating the adequacy of the prepaid expenses and accrued liabilities, the Company analyzes progress of the studies or clinical trials, including the phase or completion of events, invoices received, and contracted costs. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates. The Company's historical accrual estimates have not been materially different from the actual costs.

Revenue Recognition

Pursuant to Accounting Standards Codification (ASC) 606, Revenue from Contracts with Customers, the Company recognizes revenue when a customer obtains control of promised goods or services. The Company records the amount of revenue that reflects the consideration that it expects to receive in exchange for those goods or services. The Company applies the following five-step model in order to determine this amount: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation.

The Company only applies the five-step model to contracts when it is probable that it will collect the consideration to which it is entitled in exchange for the goods or services that it transfers to the customer. Once a contract is determined to be within the scope of ASC 606 at contract inception, the Company reviews the contract to determine which performance obligations it must deliver and which of these performance obligations are distinct. The Company recognizes as revenue the amount of the transaction price that is allocated to each performance obligation when that performance obligation is satisfied or as it is satisfied.

Research and Development Expenses

Costs and expenses that can be clearly identified as research and development are charged to expense as incurred. Research and development costs consist of costs incurred to discover, research, and develop drug candidates, including compensation-related expenses for research and development personnel, 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.

Stock-Based Compensation

Share-based compensation expenses for all stock-based awards, including stock options, restricted stock units (RSUs), and shares issued under the Employee Stock Purchase Plan (ESPP), are based on their estimated grant-date fair value. 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 fair value of stock option awards is estimated using the Black-Scholes option valuation model which requires the input of subjective assumptions to calculate the value of stock options. The Company uses historical data and other information to estimate the expected price volatility and the expected forfeiture rate for stock option awards. For restricted stock units, the value of the award is based on the Company's stock price at the grant date.

The Company was a private company through January 30, 2023 and, as a result, lacked sufficient company-specific historical and implied volatility data. Accordingly, the expected stock price volatility for the year ended December 31, 2024 is estimated based on the historical volatility of a group of publicly traded peer companies with characteristics similar to the Company. The expected stock price volatility for the year ended December 31, 2025 is determined using the blended volatility by examining the historical volatility for the industry peer companies and the volatility of the Company's stock from the effective date that the Company's shares were publicly traded. The Company determined the average expected life of stock options based on the anticipated time period between the measurement date and the exercise date by examining the option holder's past exercise patterns.

The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect on the grant date for maturities corresponding to the expected term of the awards. The Company does not assume any expected dividend yield, as it has never declared or paid dividends on its common stock.

The Company accounts for forfeitures as they occur. Compensation cost previously recognized for awards that are forfeited due to the failure to satisfy service or performance conditions is reversed in the period in which the forfeiture occurs.

Income Taxes

Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial reporting basis and the respective tax basis of the Company's assets and liabilities, and expected benefits of utilizing net operating loss, capital loss, and tax-credit carryforwards. The Company assesses the likelihood that its deferred tax assets will be realized and, to the extent management does not believe these assets are more likely than not to be realized, a valuation allowance is established. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates or laws is recognized in earnings in the period that includes the enactment date. As of December 31, 2025 and 2024, the Company's deferred tax assets, consisting primarily of capitalized R&D under IRC Section 174, net operating loss carryforwards and research and development tax credit carryforwards, have been fully offset by a valuation allowance.

The Company has generated significant Net Operating Loss (NOL) carryforwards and research and development tax credits (R&D credits) as a result of its incurrence of losses and its conduct of research activities since inception. As of December 31, 2025, the Company had federal and state NOL carryforwards of approximately $192.2 million and $190.5 million, respectively. The Company does not anticipate generating revenue from sales of products for the foreseeable future, if ever, and the Company may never achieve profitability. The Company's 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 $93.7 million, may be carried forward indefinitely, but the utilization of such U.S. federal NOLs is limited. As of December 31, 2025, the Company also had federal and state R&D credit carryforwards of $3.9 million and $3.0 million, respectively. The Company's 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.

On July 4, 2025, H.R. 1, commonly known as the One Big Beautiful Bill Act (the OBBB), was signed into law. This includes significant changes to the federal corporate tax provisions and extends certain otherwise expiring provisions of the 2017 Tax Cuts and Jobs Act. The key provisions include the creation of Section 174A allowing immediate expensing of domestic research and experimental expenditures, new limitations on interest expense deductibility, and reinstatement of 100% bonus depreciation. The Company immediately expensed domestic research and experimental expenditures starting tax year ended December 31, 2025. Due to valuation allowances, the OBBB has no impact on the Company's financial statements except changes in footnote disclosures.

Segment Information

The Company operates as a single segment because its chief operating decision maker (CODM) reviews operating results on an aggregate basis and manages its operations as a single operating segment.

Recent Accounting Pronouncements

In November 2024, FASB issued ASU 2024-03 Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40) Disaggregation of Income Statement Expenses. The guidance in ASU 2024-03 requires public business entities to disclose in the notes to the financial statements, among other things, specific information about certain costs and expenses including purchases of inventory, employee compensation, and depreciation and amortization expense for each caption on the income statement where such expenses are included. The update is effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. Early adoption is permitted, and the amendments may be applied prospectively to reporting periods after the effective date or retrospectively to all periods presented in the financial statements. The Company is currently evaluating the provisions of this guidance and assessing the potential impact its financial statement 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 2 – LICENSE AGREEMENTS

In September 2021, the Company entered into the Newsoara License Agreement with Newsoara BioPharma Co. Ltd. In October 2025, Newsoara BioPharma Co. Ltd. assigned all of its rights and obligations under the Newsoara License Agreement to an affiliate, Newsoara HYK Biopharmaceuticals Co., Ltd. The counterparty to the Newsoara License Agreement is referred to herein as "Newsoara." Pursuant to the Newsoara License Agreement, the Company granted Newsoara an exclusive license to research, develop, commercialize or exploit (i) any and all oncolytic viruses that are controlled by the Company, 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 the Company's 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 mainland China, Taiwan, Hong Kong and Macau (the "Newsoara Territory") in the field of 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 Agreement, Newsoara granted the Company an exclusive and royalty bearing license to develop, commercialize, and exploit outside the Newsoara Territory any derived products developed by Newsoara. Under the terms of the Newsoara License Agreement and to date, the Company has received from Newsoara an aggregate of $11.0 million ($5.0 million as an upfront payment and $6.0 million as a milestone payment) associated with the Newsoara License Agreement. Newsoara is obligated to pay the Company 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 Newsoara 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 the Company (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 10th 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 the Company, at its discretion, elects to develop and commercialize outside the territory any derived product developed by Newsoara, the Company is required to make certain milestone and royalty payments to Newsoara.

Pursuant to the Newsoara License Agreement, Newsoara is required to use commercially reasonable efforts to research, develop, manufacture, and commercialize the licensed products in the Newsoara Territory in the 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, which is the VIRO-25 clinical trial. Newsoara is generally obligated under the Newsoara License Agreement to fund the costs of the VIRO-25 clinical trial in the United States and China. In November 2023, the Company and Newsoara agreed that the Company would engage a clinical research organization (CRO) to conduct certain start-up activities for the trial in the United States only, with Newsoara to reimburse the Company for the costs and expenses. Pursuant to a letter of understanding (the LOU), in September 2025, the Company agreed with Newsoara that the CRO would conduct additional study activities beyond startup for the VIRO-25 clinical trial in the United States and Newsoara would reimburse the Company for costs and expenses related to such additional activities; however, Newsoara is permitted to defer reimbursement of the foregoing costs and expenses until the earlier of: (i) completion of its next round of financing, or (ii) December 31, 2026.

In November 2022, the Company entered into a Clinical Supply Agreement with Newsoara to manufacture and supply Olvi-Vec for Newsoara's clinical trials in the Newsoara Territory. The Company is responsible for supplying Olvi-Vec at its own costs of manufacturing, without markup.

NOTE 3 - FAIR VALUE MEASUREMENTS

The Company employs a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The fair value of a financial instrument is the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date using the exit price. Accordingly, when market observable data is not readily available, the Company's own assumptions are used to reflect those that market participants would be presumed to use in pricing the asset or liability at the measurement date.

Assets and liabilities recorded at fair value on the balance sheets are categorized based on the level of judgment associated with inputs used to measure their fair values and the level of market price observability, as follows:

Level 1 Unadjusted quoted prices are available in active markets for identical assets or liabilities as of the reporting date.

Level 2 Pricing inputs are other than quoted prices in active markets, which are based on the following:

- Quoted prices for similar assets or liabilities in active markets;
- Quoted prices for identical or similar assets or liabilities in non-active markets; or
- Either directly or indirectly observable inputs as of the reporting date.

Level 3 Pricing inputs are unobservable and significant to the overall fair value measurement, and the determination of fair value requires significant management judgment or estimation.

In certain cases, inputs used to measure fair value may fall into different levels of the fair value hierarchy. In such cases, the level in the fair value hierarchy within which the fair value measurement in its entirety falls has been determined based on the lowest level input that is significant to the fair value measurement in its entirety. Thus, a Level 3 fair value measurement may include inputs that are observable (Level 1 or Level 2) and unobservable (Level 3). The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment and consideration of factors specific to the asset or liability.

The Company uses prices and inputs that are current as of the measurement date, including during periods of market disruption. In periods of market disruption, the ability to observe prices and inputs may be reduced for many instruments. This condition could cause an instrument to be reclassified from Level 1 to Level 2, or from Level 2 to Level 3. The Company recognizes transfers between levels at either the actual date of the event or a change in circumstances that caused the transfer. There were no transfers during the years ended December 31, 2025 and 2024. At December 31, 2025 and 2024, the Company did not have any financial assets or financial liabilities based on Level 3 measurements.

The following table presents information about the Company's assets measured at fair value on a recurring basis, and indicates the fair value hierarchy of the valuation techniques utilized by the Company:

	December 31, 2025			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Cash equivalents:				
Money market funds	$ 2,953	$ —	$ —	$ 2,953
Marketable securities:				
US Government Agency bonds	—	7,983	—	7,983
US Treasury bonds	—	1,279	—	1,279
Total financial assets	$ 2,953	$ 9,262	$ —	$ 12,215

	December 31, 2024			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Cash equivalents:				
Money market funds	$ 7,578	$ —	$ —	$ 7,578
Marketable securities:				
US Government Agency bonds	—	8,927	—	8,927
US Treasury bonds	—	13,403	—	13,403
Total financial assets	$ 7,578	$ 22,330	$ —	$ 29,908

The underlying securities in the money market funds held by the Company are all government backed securities.

NOTE 4 – MARKETABLE SECURITIES

The Company's marketable securities consisted of the following:

	As of December 31, 2025 (in thousands)			
	Adjusted Basis	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
US Government agency bonds	$ 7,977	$ 6	$ —	$ 7,983
US Treasury bonds	1,279	—	—	1,279
	$ 9,256	$ 6	$ —	$ 9,262

	As of December 31, 2024 (in thousands)			
	Adjusted Basis	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
US Government agency bonds	$ 8,910	$ 17	$ —	$ 8,927
US Treasury bonds	13,358	45	—	13,403
	$ 22,268	$ 62	$ —	$ 22,330

As of December 31, 2025 and 2024, all marketable securities consisted of investments that mature within one year.

The Company has determined that the marketable securities that were in an unrealized loss position did not have any credit loss impairment as of December 31, 2025 and 2024.

NOTE 5 – BALANCE SHEET ACCOUNTS

Property and Equipment

The following table summarizes the Company's major classes of property and equipment:

	December 31,	
	2025	2024
	(in thousands)	
Furniture and office equipment	$ 148	$ 148
Laboratory equipment	2,918	2,869
Computer equipment	127	127
Leasehold improvements	557	557
Construction in progress	2,347	1,299
Total gross carrying amount	6,097	5,000
Less: Accumulated depreciation and amortization	(3,927)	(3,684)
Property and equipment, net	$ 2,170	$ 1,316

Depreciation expense for each of the years ended December 31, 2025 and 2024, was $0.2 million, respectively.

Construction in progress is related to developments of the Company's manufacturing and laboratory facilities in San Diego, California.

Accrued Expenses

Accrued expenses consist of the following:

	December 31,	
	2025	2024
	(in thousands)	
Accrued research and development expenses	$ 3,903	$ 5,379
Accrued personnel-related expenses	1,440	1,004
Other	455	191
Total accrued expenses	$ 5,798	$ 6,574

As of December 31, 2025, the Company's accrued research and development expenses were primarily attributable to ongoing clinical trial operations.

NOTE 6 – LEASES

Westlake Village, California: The Company leases 4,050 square feet of office space located at 2625 Townsgate Road for its corporate headquarters. The lease expires on July 14, 2027. The lease contains an option to renew for two additional five-year terms and first right of refusal for certain additional space at the same premises. The Company is not reasonably certain that it will exercise this option to renew and therefore it is not included in right-of-use assets and liabilities as of December 31, 2025.

San Diego, California: The Company leases 6,755 square feet of office and research and development laboratory space located at 6365 Marindustry Drive. The lease expires on October 31, 2030. The lease contains an option to renew for one five-year term. The Company is not reasonably certain that it will exercise this option to renew and therefore it is not included in right-of-use assets and liabilities as of December 31, 2025.

The Company leases 7,569 square feet of manufacturing space located at 6335 Marindustry Drive. The lease expires on October 31, 2030. The lease contains an option to renew for one five-year term. The Company is not reasonably certain that it will exercise this option to renew and therefore it is not included in right-of-use assets and liabilities as of December 31, 2025.

On December 9, 2025, the Company entered into a lease agreement, whereby the Company leases an office space located at 6215 Ferris Square, San Diego. The lease expires on December 31, 2027. The lease contains an option to renew for one additional year. The Company is not reasonably certain that it will exercise this option to renew and therefore it is not included in right-of-use assets and liabilities as of December 31, 2025.

Manufacturing equipment lease: On September 4, 2025, the Company entered into written agreements (Equipment Agreements), whereby the Company agreed to acquire certain equipment through a financing arrangement structured as a capital lease. Lease commencement will occur when the equipment is made available to the Company, which is the final onsite installation date and is expected to be approximately 14 months after the execution of the Equipment Agreements, or approximately November 2026. Upon commencement, the lease term will be 60 months (Initial Term), with future lease payments up to approximately $6.2 million. The Company has the right to terminate the lease without cause at the end of the Initial Term or any term thereafter upon 90 days prior written notice without incurring penalties or interest.

As of December 31, 2025, no right-of-use asset or liability has been recognized in the financial statements, as the Company does not have possession of the equipment. The Equipment Agreements also include a refundable security deposit, equal to $2.0 million as of December 31, 2025, which is classified as restricted cash on the Company's balance sheet.

Lease Assets and Liabilities	Classification	December 31, 2025	December 31, 2024
		(in thousands)	
Operating lease assets	Right-of-use assets	$ 1,583	$ 1,760
Current operating lease liabilities	Lease liabilities	427	329
Non-current operating lease liabilities	Lease liabilities, net of current portion	1,258	1,539

Lease Cost Classification	Year Ended December 31, 2025	Year Ended December 31, 2024
	(in thousands)	
Research and development	$ 106	$ 124
General and administrative expense	48	53

The following table presents maturities of operating lease liabilities on an undiscounted basis as of December 31, 2025:

Year	Amount
	(in thousands)
2026	$ 530
2027	489
2028	330
2029	312
2030	136
Total	$ 1,797
Less: imputed interest	112
Total operating lease liabilities (include current portion)	**$ 1,685**

Supplemental cash flow and other information related to leases was as follows:

	Year ended December 31, 2025	Year ended December 31, 2024
	(in thousands, except discount rate)	
Weighted-average remaining lease term (in years)	3.3	4.7
Weighted-average discount rate	6.9%	6.5%
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows for operating leases	$ 436	$ 392

Other Leases

In November 2019, the Company entered into a short-term lease agreement for one of its office facilities, which was subsequently extended until December 2022 and is currently on a month-to-month basis. Rent expense was de minimis during the years ended December 31, 2025 and 2024, respectively. In February 2026, the Company terminated the lease agreement effective March 31, 2026.

NOTE 7 – STOCKHOLDERS' EQUITY

The following table summarizes the Company's share of common stock and preferred stock:

		Shares		
	Par Value	Authorized	Issued	Outstanding
As of December 31, 2025				
Preferred Stock	0.001	10,000,000	-	-
Common Stock	0.001	200,000,000	38,139,144	38,139,144
As of December 31, 2024				
Preferred Stock	0.001	10,000,000	-	-
Common Stock	0.001	200,000,000	34,728,140	34,728,140

The Company's Amended and Restated Certificate of Incorporation authorizes the Company to issue up to 200,000,000 shares of its common stock. Holders of shares of common stock have full voting rights, one vote for each share held of record. Stockholders are entitled to receive dividends as may be declared by the Company's board of directors (the "Board") out of funds legally available therefore and share pro rata in any distributions to stockholders upon liquidation. Shares of common stock do not include conversion, pre-emptive or subscription rights. All outstanding shares of common stock are fully paid and non-assessable. As of December 31, 2025, and December 31, 2024, there were 38,139,144 and 34,728,140 shares of common stock issued and outstanding, respectively.

2025 Common Stock Issuance

In March 2025, the Company completed an underwritten offering of 3,000,000 shares of its common stock at an offering price of $3.50 per share. The Company received net proceeds of $9.6 million from the offering, after deducting discounts and commissions and offering expenses payable by the Company.

The Company also agreed to issue the underwriter a warrant to purchase 120,000 shares of the Company's common stock at an exercise price of $4.20 per share and which may be exercised until March 25, 2030, subject to certain terms and conditions (see Note 8).

2024 Common Stock Issuances

In May 2024, the Company completed an underwritten public offering of its common stock and accompanying warrants, in which the Company issued and sold 7,500,000 shares of its common stock and accompanying warrant to purchase 7,500,000 shares of the Company's common stock, including the partial exercise of the underwriters' option to purchase 625,000 shares of the Company's common stock and accompanying warrants to purchase 625,000 shares of the Company's common stock, at a combined offering price of $4.00 per share and accompanying warrant. The Company raised $27.7 million in net proceeds after deducting underwriting discounts and commissions and offering expenses payable by the Company.

Each warrant has an exercise price of $5.25 per share. The warrants expire five years from the date of grant.

During the three months ended December 31, 2024, the Company sold 5,460 shares of its common stock under an At-the-Market (ATM) offering for net proceeds of $15.

NOTE 8 – STOCK BASED COMPENSATION

In August 2009, the Board approved the adoption of the 2009 Equity Incentive Plan (the 2009 Plan). No shares are available for grant under the 2009 Plan.

In September 2018, the Board approved the adoption of the 2019 Equity Incentive Plan (the 2019 Plan). No shares are available for grant under the 2019 Plan.

In June 2022, the Board approved the adoption of the 2022 Equity Incentive Plan (the 2022 Plan). The 2022 Plan provides for the grant of incentive stock options (ISOs) to employees, including employees of any parent or subsidiary, and for the grant of non-qualified stock options (NSOs), stock appreciation rights, restricted stock awards, RSUs, performance awards and other forms of stock awards to employees, directors, and consultants, including employees and consultants of its affiliates. The 2022 Plan is a successor to the 2019 Plan. The aggregate number of shares of the Company's common stock initially reserved for issuance under the 2022 Plan is 2,800,000 shares. In addition, the number of shares of the Company's common stock reserved for issuance under the 2022 Plan automatically increases 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 its 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 Board. In January 2025, the number of shares available to be issued under the 2022 Plan automatically increased by 1,729,664 shares, as determined by the 2022 Plan. As of December 31, 2025, the total number of shares reserved for issuance was 2,227,576.

In September 2023, the Board approved the adoption of the Company's 2023 Inducement Plan (the Inducement Plan) to reserve 1,000,000 shares of the Company's common stock to be used exclusively for grants of awards to individuals that were not previously employees or directors of the Company as an inducement material to the individual's entry into employment with the Company. The Inducement Plan provides for the grant of NSOs, stock appreciation rights, restricted stock awards, RSUs, performance-based cash and stock awards, and other stock-based awards. The terms and conditions of the Inducement Plan are substantially similar to the Company's stockholder-approved 2022 Plan.

In June 2025, the Board approved an amendment of the Inducement Plan to increase the maximum aggregate number of shares of Common Stock issuable by 1,000,000. As of December 31, 2025, the total number of shares reserved for issuance was 1,133,700.

The following table presents a summary of awards outstanding:

	December 31, 2025				
	2009 Plan	2019 Plan	2022 Plan	Inducement Plan	Total
Stock options	1,555,037	1,637,562	2,653,080	866,300	6,711,979
RSUs	-	-	1,221,432	-	1,221,432
	1,555,037	1,637,562	3,874,512	866,300	7,933,411

The following table summarizes stock-based compensation expenses included in operating expenses:

	Year Ended December 31,	
	2025	2024
	(in thousands)	
General and administrative	$ 4,667	$ 5,024
Research and development	2,909	3,090
	$ 7,576	$ 8,114

	Year Ended December 31,	
	2025	2024
	(in thousands)	
Stock Options	$ 6,599	$ 6,072
RSUs	898	2,042
ESPP	79	-
	$ 7,576	$ 8,114

Restricted Stock Units

The following table summarizes the activity of the Company's RSUs:

	Number of RSUs	Weighted Average Grant Date Fair Value
Outstanding as of December 31, 2024	621,364	$ 3.06
Granted	960,472	3.55
Vested	(314,042)	4.99
Forfeited	(46,362)	2.29
Outstanding as of December 31, 2025	1,221,432	$ 4.41

As of December 31, 2025, $3.9 million of unamortized stock compensation expense remains.

Stock Options Awards

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) with respect to awards under the 2019 Plan or 2022 Plan, 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 the date of grant.

In September 2025, the Board approved a reduction in the exercise prices of certain stock options held by employees to purchase shares of the Company's common stock under the Company's 2022 Plan, 2019 Plan and 2009 Plan that had exercise prices greater than $5.00 per share. The exercise price for such options was reduced to $3.33 per share, which was the closing price of the common stock on September 1, 2025, the effective date of the reduction. The total cost of the repricing was $1.3 million, of which $0.8 million was recorded as expense during the year ended December 31, 2025. The remainder of the cost will be recorded over the future vesting periods of the options.

In September 2022, the Board approved a stock option repricing whereby the exercise price 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, was adjusted to $6.00 per share, the closing price of the Company's initial public offering. The total cost of the repricing was $2.73 million, of which $2.72 million was recorded as of December 31, 2024, and the remaining was recorded during the twelve months ended December 31, 2025.

The following table presents a summary of stock option activity for the year ended December 31, 2025:

	Number of Option Shares	Weighted Average Exercise Price (Per share)	Weighted Average Remaining Contractual Terms (in Years)	Aggregate Intrinsic Value
Balance, December 31, 2024	5,375,323	$ 8.82	5.66	94
Granted	1,805,728	3.06		
Cancelled	(154,894)	9.96		
Exercised	(5,000)	2.75		
Expired	(309,178)	8.76		
Balance, December 31, 2025	6,711,979	$ 3.92	$ 6.51	5,863
Vested and exercisable, December 31, 2025	4,184,735	$ 5.04	$ 4.06	-
Unvested, December 31, 2025	2,527,244			

As of December 31, 2025, unvested stock option expense of $11.7 million remained and will be amortized over the remaining vesting period, through December 2029.

The assumptions used for the options granted during the period are as follows:

	Year Ended December 31,	
	2025	2024
Exercise prices	$ 2.83 – 4.73	$ 1.96 – 7.44
Expected dividends	-	-
Expected volatility	109.0%	100.0%
Risk free interest rate	3.6 - 4.4%	3.9% -4.5%
Expected life of options	5.5 – 10.0	5.0 - 6.0

Stock Warrants

The table below summarizes the Company's warrants activities for the years ended December 31, 2025:

	Number of Warrant Shares	Exercise Price Range Per Share	Weighted Average Exercise Price
Balance, December 31, 2024	7,897,975	$ 3.00 - 9.00	$ 5.32
Granted	120,000	4.20	4.20
Cancelled	-	-	-
Exercised	(42,749)	5.25	5.25
Expired	(44,441)	5.40	5.40
Balance, December 31, 2025	7,930,785	$ 3.00 - 9.00	$ 4.92
Vested and exercisable, December 31, 2025	7,930,785	$ 3.00 – 9.00	$ 4.92

Stock warrants to purchase up to an aggregate total of 44,441 shares of its common stock with an exercise price of $5.40 per share issued to certain noteholders in prior years expired in December 2025.

During the year ended December 31, 2025, warrant holders exercised 42,749 warrants to acquire common stock at an exercise price of $5.25 per share for proceeds of $0.2 million. During the year ended December 31, 2024, the Company issued warrants to purchase 7,500,000 shares of its common stock with an exercise price of $5.25 per share to the underwriters of its second public offering. The warrants expire five years from the date of grant. During the year ended December 31, 2024, warrant holders exercised 76,487 warrants to acquire common stock at an exercise price of $9.00 per share for proceeds of $0.7 million.

There was $0.2 million and no aggregate intrinsic value for warrant shares outstanding at December 31, 2025.

Employee Stock Purchase Plan

The Company's 2022 Employee Stock Purchase Plan (ESPP) permits eligible employees to purchase Company shares on an after-tax basis in an amount between 1% and 15% of their earnings: (i) on May 16th of each year at a 15% discount of the fair market value of the Company's common stock on November 17th of the previous year or May 16th of the then-current year, whichever is lower, and (ii) on November 15th of each year at a 15% discount of the fair market value of the Company's common stock on May 17th or November 15th of the then-current year, whichever is lower. The ESPP includes an "evergreen" feature, which provides that an additional number of shares of common stock will automatically be added to the shares authorized for issuance under the ESPP on January 1st of each year, beginning on January 1, 2024 and ending on (and including) January 1, 2032. The number of shares added each calendar year will equal the lesser of 1% of the Company's common stock outstanding on December 31st of the preceding calendar year or 2,100,000 or a lesser number as determined by the Board.

During the twelve months ended December 31, 2025, 50,463 shares of common stock were purchased for an aggregate purchase price of $0.18 million under the ESPP, and as of December 31, 2025, 1,209,541 shares remain authorized and available for issuance.

NOTE 9 - INCOME TAXES

Significant components of the provision for income taxes for the years ended December 31, 2025 and 2024 are as follows:

	Year Ended December 31,	
	2025	2024
	(in thousands)	
Current		
Federal	$ —	$ (4,442)
State	1	(1,873)
Total	1	(6,315)
Deferred		
Federal	54,508	46,515
State	24,012	20,036
Total	78,520	66,551
Total income tax expense before change in valuation allowance	78,521	60,236
Change in valuation allowance	(78,521)	(60,236)
Total income tax expense	$ —	$ —

The following table presents a reconciliation of the tax expense based on the statutory rate to the Company's actual tax expense in the statements of operations and comprehensive loss. A notional 21% tax rate was applied as follows (in thousands):

	Year Ended December 31,			
	2025		2024	
U.S. Federal statutory income tax	$ (6,750)	21.0%	$ (6,272)	21.0%
State and local income taxes	(2,201)	6.9%	(2,120)	7.1%
Other temporary differences	(7,368)	22.9%	(5,171)	17.3%
Change in valuation allowance	16,319	(50.8)%	13,563	(45.4)%
Provision for income taxes	$ —	—	$ —	—

Significant components of the Company's deferred tax assets and liabilities as of December 31, 2025 and 2024 were as follows:

	December 31,	
	2025	2024
	(in thousands)	
Deferred tax assets		
Stock-based compensation	$ 13,198	$ 10,200
Accruals	371	1,482
Fixed assets	1,678	77
Net operating losses	56,891	48,821
Capitalized research and development expenses	4,530	4,282
Tax credits	6,925	1,116
Other	42	—
Total deferred tax assets	83,635	65,978
Deferred tax liabilities		
State taxes	(5,114)	(5,105)
Prepaid expenses	—	(154)
Total deferred tax liabilities	(5,114)	(5,259)
Net deferred tax assets before valuation allowance	78,521	60,719
Valuation allowance	(78,521)	(60,719)
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, 2025 and 2024.

At December 31, 2025 and 2024, the Company had federal income tax net operating loss carryforwards of approximately $192.2 million and $160.0 million, respectively. At December 31, 2025 and 2024, the Company had California income tax net operating loss carryforwards of approximately $190.5 million and $165.9 million, respectively. Of the total federal net operating loss, approximately $93.7 million has an indefinite carryforward period as of December 31, 2025. The remaining federal and California net operating loss carryforwards will expire through December 31, 2045, unless previously utilized. At December 31, 2025, the Company also has federal and California research and development tax credits of approximately $3.9 million and $3.0 million, respectively. The federal credits will expire through 2042 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 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, 2025 and 2024, 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 2010 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 10 - COMMITMENTS AND CONTINGENCIES

Legal Proceedings

From time to time, the Company may be subject to various claims and legal proceedings in the ordinary course of business. If the potential loss from any claim, asserted or unasserted, or legal proceeding is considered probable and the amount is reasonably estimable, the Company will accrue liability for the estimated loss. There were no contingent liabilities recorded as of December 31, 2025 and 2024.

NOTE 11 – SEGMENT INFORMATION

The Company operates and manages its business as one reportable and operating as a clinical stage biopharmaceutical company. The Company's current focus is on developing oncolytic immunotherapies for the treatment of cancer. The Company's Chief Operating Decision Maker (CODM) reviews financial information presented and decides how to allocate resources based on net income (loss). Net income (loss) is used for evaluating financial performance.

Significant segment expenses include research and development, salaries, insurance, and stock-based compensation. Operating expenses include all remaining costs necessary to operate our business, which primarily include external professional services and other administrative expenses. The following table presents the significant segment expenses and other segment items regularly reviewed by the Company's CODM:

	Year ended December 31,	
	2025	2024
	(in thousands)	
Revenue	$ 8	$ 8
Less:		
Research and development, excluding salaries	12,904	12,144
Salaries	4,038	3,764
Insurance	857	966
Stock-based compensation	7,576	8,114
Operating expenses	5,709	3,062
Other income	1,069	1,827
Net loss	$ (32,145)	$ (29,869)

NOTE 12 – NET LOSS PER SHARE

The following table presents the computation of basic and diluted net loss per share for the years ended December 31, 2025 and 2024.

	Year ended December 31,	
	2025	2024
	(in thousands, except share amounts)	
Numerator:		
Net loss	$ (32,145)	$ (29,869)
Denominator:		
Weighted-average basic shares outstanding	37,176,527	31,450,727
Effect of dilutive securities	-	-
Weighted-average dilutive shares outstanding	37,176,527	31,450,727
Basic and dilutive net loss per share	$ (0.86)	$ (0.95)

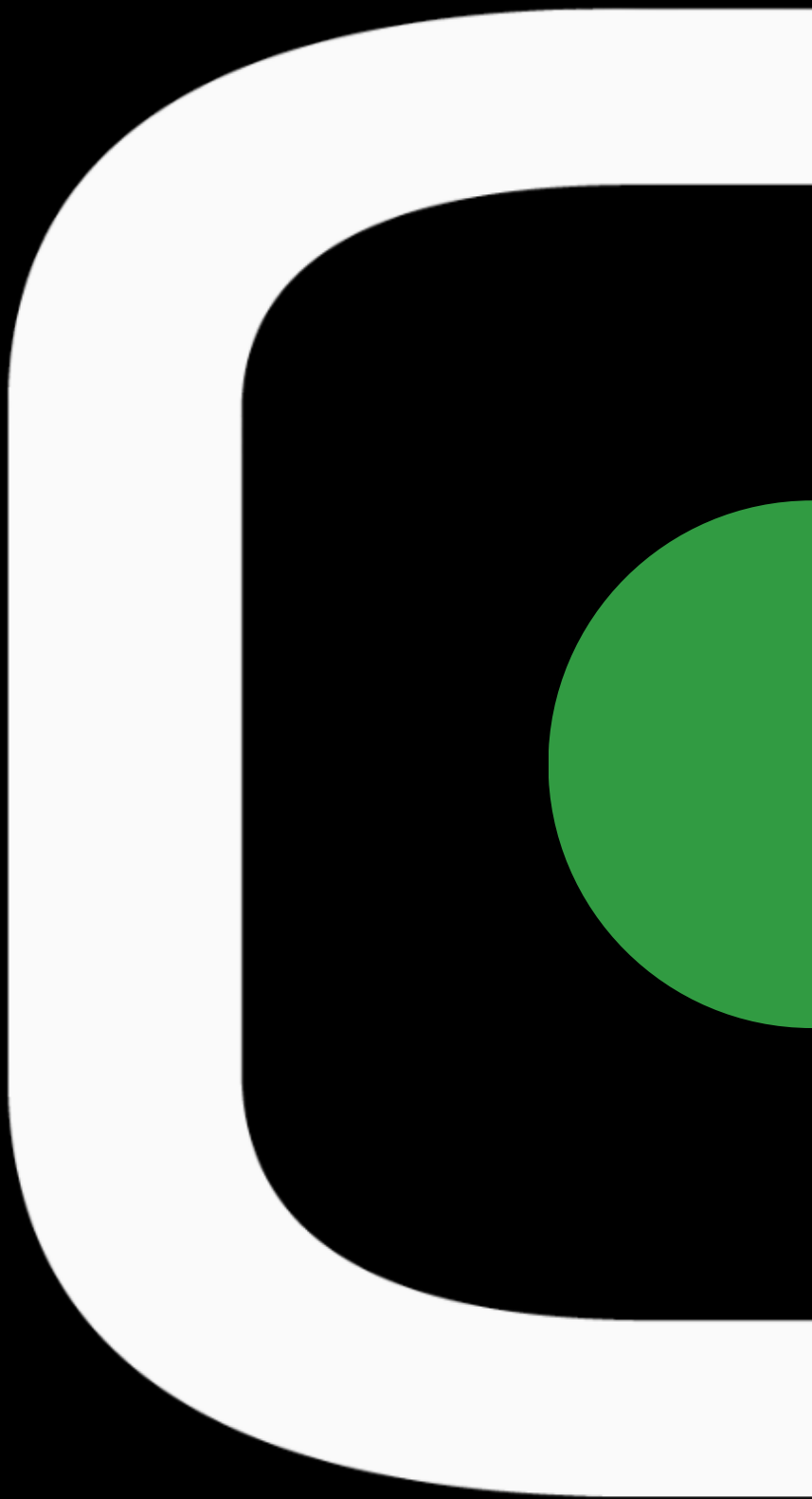
The following table sets forth the potentially dilutive securities that have been excluded from the calculation of diluted net loss per share.

	Year Ended December 31,	
	2025	2024
Stock options	6,711,979	5,375,323
Stock warrants	7,930,785	7,897,975
RSUs	1,221,432	621,364
	15,864,196	13,894,662

NOTE 13 - SUBSEQUENT EVENTS

On January 8, 2026, the Company completed an underwritten offering of 6,666,667 shares of its common stock at $3.00 per share. The net proceeds received from the offering were $18.5 million, after deducting underwriting discounts, commissions, and offering expenses payable by the Company.

Effective as of March 18, 2026, the Company terminated the 2024 Sales Agreement with Guggenheim.



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