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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 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: 001-33958

SELLAS Life Sciences Group, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**20-8099512**
(State of incorporation)	*(I.R.S. Employer Identification No.)*

7 Times Square, Suite 2503, New York, NY 10036
(Address of principal executive officers)
(646) 200-5278
(Registrant's telephone number, including area code)

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

Title of Each Class	**Trading Symbol(s)**	**Name of Each Exchange on Which Registered**
Common Stock, $0.0001 Par Value per share	SLS	The Nasdaq Stock Market LLC

Securities registered pursuant to Section 12(g) of the Exchange 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 Exchange 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 Exchange Act). ☐ Yes ☒ No

The aggregate market value of the registrant's common stock, $0.0001 per value per share, held by non-affiliates of the registrant on June 30, 2025, the last business day of the registrant's most recently completed second fiscal quarter, was $219,132,515 (based on the closing sales price of the registrant's common stock on that date). Shares of the registrant's common stock held by each officer and director and each person who owns 5% or more of the outstanding common stock of the registrant have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes. As of March 18, 2026, SELLAS Life Sciences Group, Inc. had outstanding 179,582,574 shares of common stock, $0.0001 par value per share, exclusive of treasury shares.

DOCUMENTS INCORPORATED BY REFERENCE

Certain information required in Part III of this Annual Report on Form 10-K is incorporated from the registrant's Proxy Statement for its 2026 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission pursuant to Regulation 14A not later than 120 days after the end of the fiscal year covered by this Form 10-K, provided that if such Proxy Statement is not filed within such period, such information will be included in an amendment to this Form 10-K to be filed within such 120-day period.

SPECIAL NOTE REGARDING FORWARD LOOKING STATEMENTS

This Annual Report on Form 10-K includes forward-looking statements that reflect our current views with respect to our development programs, business strategy, business plan, financial performance and other future events. These statements include forward-looking statements both with respect to us, specifically, and our industry, in general. Such forward-looking statements include the words "expect," "intend," "plan," "believe," "project," "estimate," "may," "should," "anticipate," "will" and similar statements of a future or forward-looking nature identify forward-looking statements and include, without limitation, statements regarding:

- our future financial and business performance;
- strategic plans for our business and product candidates;
- our ability to develop or commercialize products;
- the expected results and timing of clinical trials and nonclinical studies;
- our ability to comply with the terms of our license agreements;
- developments and projections relating to our competitors and industry;
- our expectations regarding our ability to obtain, develop and maintain intellectual property protection and not infringe on the rights of others;
- our ability to retain and attract highly-skilled executive officers and employees;
- our future capital requirements and the timing of those requirements and sources and uses of cash;
- our ability to obtain funding for our operations; and
- changes in applicable laws or regulations.

These statements are subject to known and unknown risks, uncertainties and assumptions that could cause actual results to differ materially from those projected or otherwise implied by the forward-looking statements, including the following:

- risks associated with preclinical or clinical development and trials;
- changes in the assumptions underlying our expectations regarding our future business or business model;
- our ability to develop, manufacture and commercialize product candidates;
- general economic, financial, legal, political and business conditions and changes in domestic and foreign markets;
- changes in applicable laws, regulatory actions, judicial decisions, accounting standards, and tariffs or trade restrictions;
- the impact of natural disasters, including climate change, and the impact of health epidemics, on our business;
- the size and growth potential of the markets for our products, and our ability to serve those markets;
- market acceptance of our planned products;
- our ability to raise capital;

- the possibility that we may be adversely affected by other economic, business, and/or competitive factors; and
- other risks and uncertainties set forth in this report in the section entitled “Risk Factors.”

Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Forward-looking statements are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Given these risks and uncertainties, you should not place undue reliance on these forward-looking statements. We undertake no obligation to publicly update or review any forward-looking statement, whether as a result of new information, future developments or otherwise, except as required by law.

SELLAS LIFE SCIENCES GROUP, INC.
FORM 10-K - Annual Report
For the Year Ended December 31, 2025

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Unless the context otherwise indicates, references in these notes to the “Company,” “we,” “us” or “our” refer to SELLAS Life Sciences Group, Inc. and its wholly owned subsidiaries. The names “SELLAS Life Sciences Group, Inc.,” “SELLAS,” the SELLAS logo, and other trademarks or service marks of SELLAS Life Sciences Group, Inc. appearing in this Annual Report on Form 10-K are the property of SELLAS Life Sciences Group, Inc. Other trademarks, service marks or trade names appearing in this prospectus are the property of their respective owners. We do not intend the use or display of other companies’ trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of or by either, of these other companies.

SUMMARY OF PRINCIPAL RISK FACTORS

This summary briefly lists the principal risks and uncertainties facing our business, which are only a select portion of those risks. A more complete discussion of those risks and uncertainties is set forth in Part I, Item 1A of this Annual Report on Form 10-K, entitled “Risk Factors.” Additional risks not presently known to us or that we currently deem immaterial may also affect us. If any of these risks occur, our business, financial condition or results of operations could be materially and adversely affected. Our business is subject to the following principal risks and uncertainties:

- We have incurred substantial losses since our inception and anticipate that we will continue to incur substantial and increasing losses for the foreseeable future as we continue development and, subject to positive data and regulatory approval, the commercialization of our product candidates.
- We currently have no source of product revenues. We may never generate such revenues or achieve profitability.
- We will need additional financing to fund our operations and complete the development and, subject to positive data and regulatory approval, the commercialization of our product candidates. If we are unable to raise capital when needed, or our licensing partners are unable to make milestone or other payments in accordance with relevant agreements, we could be forced to delay, reduce or eliminate our development programs or commercialization efforts.
- Our lead product candidate galinpepimut-S, or GPS, represents a new therapeutic approach that presents significant challenges.
- Our business, in particular our clinical development programs, has been and may continue to be adversely affected by global health crises.
- Clinical drug development involves a lengthy and expensive process with an uncertain outcome. Our existing product candidates in clinical trials, and any other product candidates that may advance into clinical trials, may not have favorable results in later clinical trials or receive regulatory approval.
- Our current and future product candidates, the methods used to deliver them, or their dosage levels may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following any regulatory approval.
- Our current and future product candidates could fail to receive regulatory approval from the U.S. Food and Drug Administration, or FDA.
- Failure to obtain regulatory approval in international jurisdictions would prevent our product candidates from being marketed abroad.
- We have limited to no manufacturing, sales, marketing or distribution capability and must rely upon third parties for such.
- If any of the clinical manufacturing facilities of our contract manufacturing organizations, or CMOs, are damaged or destroyed or production at such facilities is otherwise interrupted, our business and prospects would be negatively affected.
- We rely on third parties to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, or if we lose any of our contract research organizations, or CROs, or other key third-party vendors, we may not be able to obtain regulatory approval for or commercialize our current or future product candidates on a timely basis, if at all.
- We have in-licensed a significant portion of our intellectual property from Memorial Sloan Kettering Cancer Center, or MSK, and GenFleet Therapeutics (Shanghai), Inc, or GenFleet. If we breach either or both of our

license agreements with MSK and GenFleet, respectively, we could lose the ability to continue the development and potential commercialization of GPS or SLS009 (tambiciclib), our second product candidate which we in-licensed from GenFleet.

- We may not be able to obtain and enforce patent rights or other intellectual property rights that cover our product candidates and that are of sufficient breadth to prevent third parties from competing against us.
- Our pending and future patent applications, and any collaboration or commercialization partner's pending and future patent applications, may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products.
- Our product candidates may face biosimilar competition sooner than expected after the expiration of our composition of matter patent protection for such products.
- Our commercial success depends upon attaining significant market acceptance of our current and future product candidates, if approved, among physicians, patients, health care payors and cancer treatment centers.
- Even if we are able to commercialize our current or future product candidates, the products may not receive coverage and adequate reimbursement from third-party payors in the United States and in other countries in which we seek to commercialize our products, which could harm our business.
- We have been involved in multiple legal and governmental proceedings, including securities class action litigation, relating to our predecessor in the past, and may in the future be involved in any such proceedings, that could divert management's attention and adversely affect our financial condition and our business.
- If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reports, which would harm our business, the trading price of our common stock and our ability to raise additional capital in the future.
- We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.
- Significant disruptions of information technology systems, computer system failures or cybersecurity incidents could adversely affect our business.
- We will need to secure additional capital which may cause dilution to you and our existing stockholders, provide subsequent investors with rights and preference that are senior to yours, restrict our operations or require us to relinquish rights to our product candidates on unfavorable terms to us.
- Our failure to meet the continued listing requirements of The Nasdaq Capital Market could result in a delisting of our common stock.

PART I

ITEM 1. BUSINESS

Overview

We are a late-stage clinical biopharmaceutical company focused on the development of novel therapeutics for a broad range of cancer indications. Our product candidates currently include galinpepimut-S, or GPS, a peptide immunotherapy directed against the Wilms tumor 1, or WT1, antigen, and SLS009 (tambiciclib), a highly selective small molecule cyclin-dependent kinase 9, or CDK9, inhibitor.

Galinpepimut-S: Highly Novel and Engineered Immunotherapy Targeting the WT1 Antigen

Our lead product candidate, GPS, is a cancer immunotherapeutic agent licensed from Memorial Sloan Kettering Cancer Center, or MSK, that targets the WT1 protein, which is present in 20 or more cancer types. Based on its mechanism of action as a directly immunizing agent, GPS has potential as a monotherapy or in combination with other immunotherapeutic agents to address a broad spectrum of hematologic, or blood, cancers, and solid tumor indications.

We have an ongoing open label randomized Phase 3 clinical trial, the REGAL study, for GPS monotherapy in patients with acute myeloid leukemia, or AML, in the maintenance setting after achievement of second complete remission, or CR2, following successful completion of second-line antileukemic therapy. Patients are randomized to receive either GPS or best available treatment, or BAT. We expect this study will be used as the basis for submission of a Biologics License Application, or BLA, subject to a statistically significant and clinically meaningful trial outcome and agreement with the U.S. Food and Drug Administration, or the FDA. The primary endpoint of the REGAL study is overall survival, or OS. We planned to enroll approximately 125 to 140 patients at approximately 95 clinical sites in North America, Europe and Asia with a planned interim safety, efficacy and futility analysis after 60 events (deaths). In March 2024, we announced the completion of enrollment. In December 2024, we announced that the pre-specified threshold of 60 events (deaths) per the protocol had been reached, triggering the interim analysis to be conducted by the Independent Data Monitoring Committee, or IDMC. In January 2025, we announced that the IDMC had completed pre-specified interim analysis of the REGAL study and had recommended that the study continue without modifications. The next and final analysis will be conducted once 80 events (deaths) are reached. In December 2025, we announced that our contract research organization informed us that the pooled number of events was 72 as of December 26, 2025. We remain blinded to all efficacy and survival data outcomes and, as no outcomes analyses were performed and no statistical penalty has been incurred, this one-time update on the aggregate number of events does not impact future statistical analyses. Because the final analysis is event driven, it is difficult to predict with any certainty and it may occur at a different time than currently expected. We will announce the 80th event when it occurs.

In December 2020, we entered into an exclusive license agreement, or the 3D Medicines Agreement, with 3D Medicines Inc., or 3D Medicines, a China-based biopharmaceutical company developing next-generation immuno-oncology drugs, for the development and commercialization of GPS, as well as the Company’s next generation heptavalent immunotherapeutic GPS+, which is at preclinical stage, across all therapeutic and diagnostic uses in mainland China, Hong Kong, Macau and Taiwan, which we refer to as Greater China. We have retained sole rights to GPS and GPS+ outside of Greater China. In November 2022, we announced that we had agreed with 3D Medicines for 3D Medicines to participate in the REGAL study through the inclusion of approximately 20 patients from mainland China. In December 2022, we entered into a Side Letter Agreement with 3D Medicines, or Side Letter, which together with the 3D Medicines Agreement, details the terms and conditions of 3D Medicines' participation in the REGAL study. Although the REGAL study has completed enrollment as announced in March 2024, in accordance with the predetermined statistical analysis plan, 3D Medicines may still enroll patients in mainland China. The timing of such participation and patient enrollment by 3D Medicines, if at all, cannot be predicted with certainty. As of December 31, 2025, we have received an aggregate of $10.5 million in upfront and milestone payments under our license agreement with 3D Medicines, or the 3D Medicines Agreement, and a total of $191.5 million in potential future development, regulatory and sales milestones, not including future royalties, remains under the license agreement, which milestones are variable in nature and not under our control. In December 2023, we announced that we had commenced a binding arbitration proceeding against 3D Medicines to

resolve a dispute regarding, among other things, the trigger and payment of relevant milestone payments due to us under the 3D Medicines Agreement. See *Item 3. Legal Proceedings*.

GPS was granted Orphan Drug Designations, or ODD, from the FDA, as well as orphan medicines designations from the European Medicines Agency, or EMA, in AML, malignant pleural mesothelioma, or MPM, and multiple myeloma, or MM, as well as Fast Track designations for AML, MPM, and MM from the FDA. In October 2024, the FDA granted Rare Pediatric Disease, or RPD, designation to GPS for the treatment of pediatric AML.

SLS009: Highly Selective Next Generation CDK9 Inhibitor

On March 31, 2022, we entered into an exclusive license agreement, or the GenFleet Agreement, with GenFleet Therapeutics (Shanghai), Inc., or GenFleet, a clinical-stage biotechnology company developing cutting-edge therapeutics in oncology and immunology, that grants rights to us for the development and commercialization of SLS009, a highly selective small molecule CDK9 inhibitor, across all therapeutic and diagnostic uses worldwide, except for Greater China.

CDK9 activity has been shown to correlate negatively with OS in a number of cancer types, including hematologic cancers, such as AML and lymphomas, as well as solid cancers, such as osteosarcoma, pediatric soft tissue sarcomas, melanoma, endometrial, lung, prostate, breast and ovarian. As demonstrated in preclinical and clinical data, to date, SLS009's high selectivity has the potential to reduce toxicity as compared to older CDK9 inhibitors and other next-generation CDK9 inhibitors currently in clinical development and to potentially be more efficacious.

We completed a Phase 1 dose-escalating clinical trial in the United States and China for SLS009 in mid-2023 and reported positive safety and efficacy data for both patient cohorts, that is relapsed and/or refractory AML and refractory lymphoma. We also established in the trial a recommended Phase 2 dose, or RP2D, of 60 mg once weekly or 30 mg twice weekly for AML and 100 mg once weekly for lymphomas.

In the second quarter of 2023, we commenced an open label, single arm, multi-center Phase 2a clinical trial with SLS009 in combination with venetoclax and azacitidine, or aza/ven, in patients with AML who failed or did not respond to treatment with venetoclax-based therapies. The trial evaluated safety, tolerability, and efficacy at two dose levels of SLS009, 45 mg once weekly, and 60 mg once weekly or 30 mg twice a week, in combination with aza/ven. In December 2024, we announced positive data from the first 3 cohorts in the Phase 2a trial.

In July 2025, we announced that the Phase 2 trial of SLS009 in r/r AML met all primary endpoints and received FDA guidance to advance into a first-line therapy study. The overall response rate, or ORR, in 54 evaluable patients was 33% across all cohorts and dose levels, 40% for the 30 mg BIW dose level, and 44% in the 30 mg BIW dose among patients with myelodysplasia-related molecular mutations, or AML MR, all exceeding the pre-specified ORR threshold of 20%. The highest efficacy was observed among patients with ASXL1 mutations, with an ORR of 50% (9/18) at 30 mg BIW dose levels, and AML MR with Myelomonocytic/Myelomonoblastic markers, or M4/M5 per FAB classification, patients with an ORR of 50% (6/12). The median overall survival, or mOS, reached 8.9 months in patients with AML MR and 8.8 months in patients r/r to venetoclax-based regimens at a 30 mg BIW dose level, surpassing the historical benchmark of ~2.4 months. SLS009 was well-tolerated with no new safety signals observed. No dose-limiting toxicities were observed across all dose levels.

Following a productive end of Phase 2 meeting, the FDA recommended that we proceed into a clinical trial to include newly diagnosed, first-line AML patients eligible for aza/ven therapy, where the FDA noted clinical benefit might be greatest. The randomized 80-patient Phase 2 clinical trial is currently ongoing and began enrollment in the first quarter of 2026. The clinical trial will include two groups: predictive biomarker cohort (newly diagnosed patients unlikely to benefit from standard aza/ven therapy based on molecular profiling) and early venetoclax resistance cohort (patients who initiate treatment with aza/ven, but demonstrate confirmed lack of any response after two treatment cycles).

In January 2026, we announced that we entered into an agreement with IMPACT-AML, a European collaborative initiative dedicated to advancing innovative treatments for patients with AML. Under the agreement, the IMPACT-AML network will conduct a clinical study evaluating SLS009, enabling access to multiple European clinical sites and patients. IMPACT-AML is a pan-European project and builds an inclusive clinical network (STREAM platform)

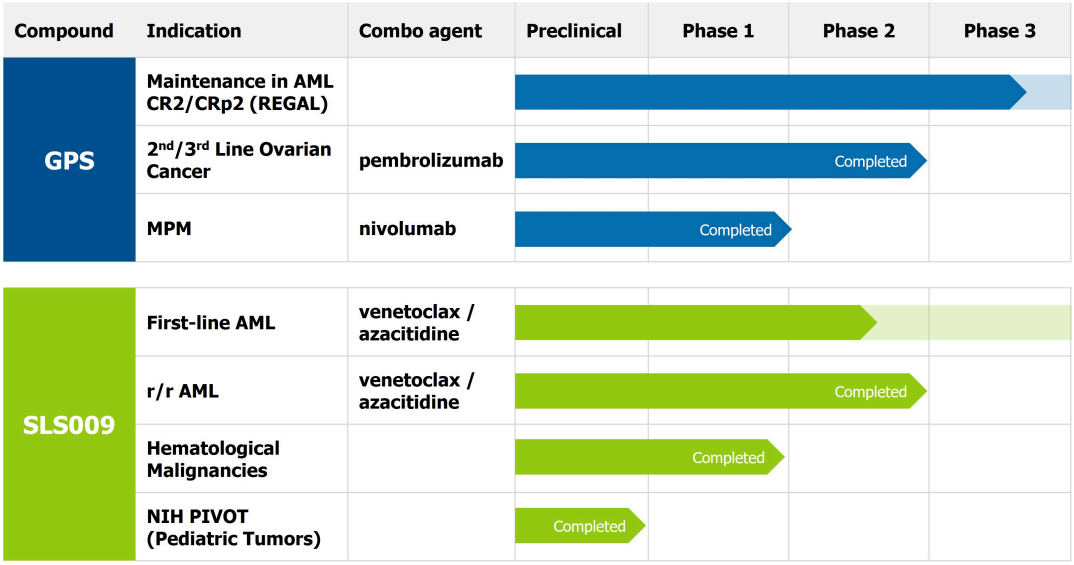
that connects patients, clinicians, and researchers to test novel AML therapies and improve patient outcomes. It is part of the prestigious EU Mission Cancer program and a top-tier scientific cluster. The IMPACT-AML project is led by a consortium of major research and clinical institutions in Europe, including IRST (IRCCS Istituto Romagnolo per lo Studio dei Tumori “Dino Amadori”), the University of Bologna, IIS LA FE (Health Research Institute Hospital La Fe), several European AML collaborative groups, and supranational organizations under the umbrella of the European Leukemia Net (ELN), as well as various university hospitals across Europe. By leveraging IMPACT-AML’s existing infrastructure and expertise, we expect to expand European patient access to SLS009 in a highly cost-efficient manner while supporting broader participation across the clinical program.

In November 2024, we announced data from preclinical studies identifying ASXL1 mutation as key predictor of SLS009 in response to solid cancers.

In May 2025, we announced data for pediatric acute lymphoblastic leukemia, or ALL, patients derived xenografts, or PDX. The experiment conducted and funded by the National Institute of Health, or NIH, through the NCI Pediatric Prelinical in Vivo Testing, or PIVOT, program, included 27 patient-derived ALL tumors from pediatric patients. Tumors were xenografted in mice in two groups, vehicle control arm and SLS009 arm. Mice were treated with a fractionated dose once per week for six consecutive weeks. Treatment was well tolerated. For all models, median survival was approximately tripled in the SLS009 arm, compared to vehicle control arm. SLS009 demonstrated delayed progression in 25/27 (93%) models and more than two times longer time to progression in 15/27 (56%) of ALL models. In addition, there were complete responses, or CR, in two models and in one of the two models CR was maintained after the treatment had been completed until the end of the study (four months). Among seven KMT2A rearranged models, time to progression was extended in all seven models, and in six out of seven (86%) time to progression was more than doubled.

For SLS009, the FDA granted Orphan Drug Product designations in AML and peripheral T-cell lymphoma, or PTCL, and Fast Track designations for r/r AML and r/r PTCL. The FDA granted RPD designation to SLS009 for the treatment of pediatric acute lymphoblastic leukemia, or ALL, in June 2024 and the FDA granted RPD designation to SLS009 for the treatment of pediatric AML in July 2024. Also, the European Medicines Agency granted Orphan Drug Designation for SLS009 in AML and in PTCL in June 2024 and July 2024, respectively.

The chart below summarizes the current status of our clinical development pipeline:



Our Strategy

Our overall goal is to develop multiple oncology product candidates in order to achieve marketing authorization in the United States and the rest of the world. We are particularly focused on developing better treatments for AML, the lead indication for both GPS and SLS009, which will allow us to leverage our clinical development expertise in hematology/oncology and to build a single streamlined commercial infrastructure sufficient for both of our current product candidates.

Products/Pipeline

Galinpepimut-S (GPS): Innovative WT1 Targeting Immunotherapy

Overview

GPS is a WT1-targeting peptide-based cancer immunotherapeutic being developed as a monotherapy and in combination with other therapeutic agents to treat different types of cancers that result from uninhibited tumor cell growth. GPS targets malignancies and tumors characterized by an overexpression of the WT1 protein. The WT1 protein is one of the most widely expressed cancer proteins in multiple malignancies. A previous pilot project regarding the prioritization of cancer antigens (substances that evoke an immune response) conducted by the National Cancer Institute, or NCI, a division of the National Institutes of Health, or NIH, ranked the WT1 protein as a top priority for immunotherapy.

WT1 is a protein that resides in the cell's nucleus and participates in the process of cancer formation and progression. As such, WT1 is classified as an "oncogene." WT1 plays a key role in the development of the kidneys in fetal life, but then almost disappears from normal organs and tissues. In approximately 20 cancer types, WT1 becomes detectable again in at least 50% of tumor pathology specimens in the cells of these cancers. WT1 appears in large amounts (*i.e.*, becomes "overexpressed") in numerous hematological malignancies, including AML, MM and chronic myeloid leukemia, as well as in many solid malignancies such as MPM, gastrointestinal cancers (such as colorectal cancer), glioblastoma multiforme, triple negative breast cancer, or TNBC, ovarian cancer and small cell lung cancer, or SCLC.

Mechanism of Action in Immune System

GPS is a multi-peptide product that has been modified to enhance the degree and duration of the immune response against the WT1 protein. Two of the four peptides in the peptide mixture comprising GPS are deliberately mutated in a single amino acid residue. These mutated peptides are recognized by the immune system as non-self entities and are therefore less likely to induce immune tolerance. These mutated peptides are designed using artificial intelligence, or AI, by researchers at MSK, to elicit strong T-cell response against both mutated peptides and naturally occurring peptides in cancer cells. This concept is called the heteroclitic principle.

We believe that GPS has a mechanism of action that involves direct activation of the patient's immune system specifically against the WT1 protein. Although the immune system is designed to identify foreign or abnormal proteins expressed on tumor cells, this process is often defective in cancer patients. Typically, patients harboring WT1-positive malignancies have very few or no T-cells specifically reactive or responsive to, and therefore activated by, WT1. T-cells are involved in both sensing and killing abnormal cells, in addition to coordinating the activation of other cells in an immune response. T-cells can be classified into two major subsets, CD4 cells and CD8 cells. CD8 cells, often called cytotoxic T-cells, are characterized by the expression of the CD8 protein on their cell surface. Once activated, cytotoxic T-cells recognize, bind and kill cancer cells marked by abnormal proteins. CD4 cells, known as helper T-cells, are critical to providing the signals necessary for sustained CD8 cell responses and are also capable of exerting direct anti-tumor activity. GPS is designed to elicit both CD4 and CD8 cell immune responses. We believe that the activation of CD8 cells by GPS could lead to direct cancer cell killing, or cytotoxicity, and the eventual establishment of immunologic memory against a WT1-expressing cancer. This occurs by two mechanisms: (i) conversion of some of the activated CD8 cells to memory CD8 cells, and (ii) activation of CD4 cells and the eventual creation of CD4 terminal effector memory cells.

GPS' proposed mechanism of action is based on the induction and stimulation of T-lymphocytes, both cytotoxic CD8 cells – which are attacking the tumor directly – and CD4 cells, which are very important for immunologic memory, maintenance, and helper function of the cellular immune response. Two of the peptides within the GPS mixture are native, meaning that they contain the exact same amino acid (AA) sequences as the fragments of the wild type (unmutated) WT1 protein they originated from. The remaining two peptides are by design modified by a single point AA mutation. In that sense, the heteroclitic WT1 peptide carries a mutation and is presented to the native CD8+ cell through the host's antigen-presenting cells - macrophages, dendritic cells or B cells. The CD8+ cell is reprogrammed and activated, thus becoming a cytotoxic T-cell specifically against the target antigen, and now may recognize not only the mutated version of the WT1 peptide (against which the host was immunized, and which does not get expressed naturally), but also the corresponding native WT1 fragment. The native fragment could get expressed and presented on the membrane of cancer cells in an MHC Class I context. Similar events occur in CD4+ cells after cross-presentation of the WT1 heteroclitic fragment and eventual activation of the CD4+ cells into effector and memory cells. The heteroclitic technology mitigates against the emergence of tolerance, as the mutated peptides are classified as 'non-self' antigens.

GPS is given under the skin, or subcutaneously, after mixing with Montanide™ an adjuvant, which creates a reservoir of GPS in a water in oil emulsion. Additionally, prior to the administration of GPS, patients receive another immune adjuvant, granulocyte-macrophage colony-stimulating factor, or GM-CSF, to non-specifically stimulate and activate antigen-presenting cells, or APCs, in the vicinity of the subcutaneously injected GPS.

As mentioned earlier, after subcutaneous injection, the WT1 peptides are ingested by APCs at the local injection sites. Antigen presenting cells migrate to lymph nodes where the ingested peptide fragments are then presented on the surface of APCs to CD8 and CD4 T-cells though major histocompatibility complex class II, (MHCII), where they can bind to T-cell receptor, (TCR). This process activates the CD4 and CD8 cells and sensitizes them to the key 25 epitopes of WT1, thus initiating the process of short- and long-term T-cell-mediated immunity against WT1.

Key Features

The following table summarizes the key features of GPS:

Key features of an Optimal Cancer Active Immunizer Therapeutic	**GPS Properties and Clinical Strategy**
Selecting the right target antigen and epitopes within that antigen	Four peptides and 25 epitopes selected optimally with the objective of ensuring: - optimal MHC complex presentation; - specificity across different HLA types; - activation of both CD4 and CD8 T-cells; and - enhancing immune response and overcoming tolerance (the heteroclitic principle).
Optimal T-cell engagement leading to cancer cell destruction	Immune response data from the final analysis of the Phase 1 clinical study of GPS in MM in 12 evaluable patients that were presented at the 44th Annual Meeting of the European Society for Blood and Marrow Transplantation, or EBMT, in 2018 (Dr. Kohne et al.) showed 75% frequency of either CD8+ or CD4+ responses to an all-pool mixture of WT1-derived antigens after completion of the 12 vaccinations per the study protocol. This evidence of multi-epitope, broad cross-reactivity along the full-length of the WT1 protein is suggestive of epitope spreading, as it emerged across epitopes against which the patients were not specifically immunized. These data corroborate the results of an earlier analysis in mid-2017 and strongly suggest stimulation of T-cells towards intracellular antigen fragments from GPS-induced destruction of tumor cells, which effect is a hallmark of an effective vaccine, e.g., that it is targeting the right epitopes chosen by design.
Overcoming the barriers of an adverse/immunosuppressive tumor micro-environment, or TME	The GPS monotherapy clinical studies are in the setting of complete remission, or CR, and minimal residual disease, or MRD, whereby no bulky or measurable tumor deposits exist. This is typically seen after successful frontline therapy in select cancer types for which such debulking standard therapies exist (e.g., AML or MPM). In these settings, the tumor micro-environment, or TME, is substantially absent. We are also pursuing combination therapy with checkpoint inhibitors in tumor settings whereby measurable disease exists, as contemporaneous checkpoint inhibition would abrogate the immunosuppressive effects of the TME.
Overcoming or mitigating immune tolerance	Heteroclitic peptides are those in which mutations have been deliberately introduced in the amino acid sequence. The use of heteroclitic peptide in an active immunizer, such as GPS, increases immunogenicity without changes in the antigenicity profile, as well as strengthens MHC binding of the peptide to produce cytotoxic CD8 cells that continue to recognize the corresponding native peptide sequence. This is believed to be a key factor differentiating GPS from essentially all previously developed peptide vaccines, and applies a highly innovative technology platform, peptide heteroclicity, in a clinical late-stage cancer immunotherapeutic candidate product.
Addressing the broadest possible candidate patient population	GPS has activity across multiple HLA types that could allow treatment of a vast majority of global patient populations harboring WT1-positive malignancies.

Potential Key Differentiators

GPS' potential key differentiators as compared to other active immunization or vaccine-type approaches, as well as compared to immunotherapy approaches more generally, are as follows:

- heteroclitic peptides may offer increased immune response and less potential for tolerance;
- multivalent oligopeptide mixture potentially drives differentiated immunotherapeutic efficacy, targeting 25 key epitopes of WT1;
- potentially applicable to 20 or more cancer types worldwide and the vast majority of HLA types;
- CR or MRD status (after initial tumor debulking with preceding standard therapy) is the preferred setting for GPS monotherapy;
- not directly competitive with current clinical standard of care therapies, but rather believed to complement them in the maintenance setting;
- potential for combination approaches with other cancer immunotherapies, due to tolerable adverse event profile;
- anticipated cost-effective manufacturing; allogeneic, "off-the-shelf," vialed subcutaneously administered drug that is not patient-specific; and
- positive Phase 2 clinical data on effectiveness (based on OS in AML and PFS in MM) with good tolerability and a favorable safety profile.

Development Program for GPS

GPS has the potential as a monotherapy or in combination with other immunotherapeutic agents to address a broad spectrum of hematologic, or blood, cancers and solid tumor indications. We are currently exploring the potential role for GPS in both monotherapy and in combination therapy with checkpoint inhibitors such as PD-1 inhibitors as set forth in the table below:

Program	***Status***
GPS Monotherapy	
• Registrational Phase 3 REGAL open-label randomized clinical trial in AML patients who have achieved hematologic complete remission, with or without thrombocytopenia (CR2/CRp2), after second-line antileukemic therapy and who are deemed ineligible for, or unable to undergo, allogeneic stem-cell transplantation	*Ongoing*
• Phase 1 clinical trial of 3D189 (GPS) in China (our licensee, 3D Medicines is the sponsor)	*Completed; final data report pending*
• Phase 1 clinical trial in patients with hematologic and thoracic malignancies with no demonstrable residual/recurrent disease after debulking therapy	*Completed; final data reported*
• Phase 2 clinical trial in patients with AML with first complete remission (CR1) patients	*Completed; final data reported*
• Phase 2 clinical trial in patients with high-risk MDS or AML patients with ≥2 lines of prior therapy (CR2)	*Completed; final data reported*
• Phase 2 clinical trial in MM patients	*Completed; final data reported*
• Phase 2 randomized, double-blind, placebo-controlled clinical trial in MPM patients	*Completed; final data reported*
GPS Combination Therapy	
• Phase 1/2 clinical trial of GPS in combination with the anti-PD-1 therapy pembrolizumab (Keytruda) in ovarian cancer (second or third line) in collaboration with a Merck & Co., Inc., Kenilworth, N.J., U.S. subsidiary (known as MSD outside the United States and Canada), or Merck	*Completed; final data reported*
• Phase 1 open-label investigator-sponsored clinical trial of GPS, in combination with Bristol-Myers Squibb's anti-PD-1 therapy, nivolumab (Opdivo), in patients with MPM who harbor relapsed or refractory disease after having received frontline standard of care multimodality therapy	*Completed; final data reported*
• Phase 1/pilot open-label, non-randomized clinical trial of GPS in combination with nivolumab in patients with WT1-expressing, or WT1+, recurrent ovarian, fallopian tube or primary peritoneal cancer who were in second or greater clinical remission (after their successful first or subsequent "salvage" therapy)	*Completed; final data reported*

Current AML Treatment Therapies

AML is an aggressive and potentially lethal blood cancer characterized by the rapid growth of abnormal white blood cells that build up in the bone marrow and interfere with the production of normal blood cells. Its symptoms include fatigue, shortness of breath, bruising and bleeding, and increased risk of infection. The cause of AML is unknown, and the disease is typically fatal within weeks or months if untreated. AML most commonly affects adults, and its incidence increases with age.

A June 2021 report from DelveInsight estimates a global market size for AML of $5.09 billion by the end of 2030, with a compound annual growth rate, or CAGR, of 21.85% from 2018 to 2030. The total number of newly diagnosed patients with AML per year in the United States is approximately 20,050 (2022 epidemiological data: American Cancer Society). According to PharmaIntelligence (Informa, April 2022) as AML patients progress through their individual journeys and experience disease progression, the number of patients that ultimately receive a second-line treatment of any kind in the U.S. is roughly 36% (about 7,500 patients) of the stated incident population. The corresponding numbers of second-line treated patients in the key markets of the European Union (Germany, France, Italy and Spain) is approximately 6,520 and of Japan is approximately 3,482. According to CD DiNardo (N Engl J Med 2018; 378:2386-2398) and D Verma (Leuk Lymphoma 2010 May;51(5):778-82), about 50% of patients in second-line achieve complete remission, or CR2 (our Phase 3 REGAL patient population). These figures would substantiate a total of approximately 8,750 clinically appropriate patients for GPS in the referenced key markets.

Until recently, the overall treatment landscape for AML had remained static for decades, as numerous targeted and antiproliferative agents were unsuccessful in providing meaningful long-term clinical benefits, including increments in survival. In recent years, additional drugs have been approved and current standard treatments include chemotherapy (including the fixed molar ratio combination chemotherapy Vyxeos), hypomethylating agents, or HMAs, drugs that target mutations of the isocitrate dehydrogenase type-1 and -2 and the FMS-like tyrosine-protein kinase, FLT3, in patients whose disease harbors these genetic aberrations, the B-cell lymphoma 2 inhibitor venetoclax (in combination with chemotherapy or HMAs), the CD33-targeting antibody-drug conjugate gemtuzumab ozogamicin, and the sonic hedgehog signaling inhibitor glasdegib. Select patients could also undergo an allogeneic hematopoietic, or blood-forming, stem cell transplant, referred to as allo-HSCT. One of the fundamental goals of therapy for AML, both in the upfront and salvage settings, is for the patient to achieve a state of complete remission. Complete remission is defined per consensus criteria by the European Leukemia Net, or ELN, whereby the hematologic and clinical features of the disease are no longer detected. In the first line setting, AML patients who achieve a status of first complete remission, or CR1, have two options for a meaningful long-term benefit: allo-HSCT and maintenance therapy with the oral form of the HMA azacitidine, which the FDA approved for use in the second half of 2020. In the second line setting, i.e., in AML patients who have relapsed and are receiving salvage antileukemic therapy, we are not aware of any therapies, other than allo-HSCT, that have shown through rigorous blinded, randomized, controlled clinical trials to offer a meaningful long-term benefit (either relapse-free or OS) when used as maintenance after patients achieve a status of CR2. Once the disease relapses after second-line therapy, patients have limited options which currently include off-label administration of HMAs, venetoclax in combination with either HMAs or low-dose cytarabine or investigational agents in the context of a Phase 1/2 clinical trial.

AML as lead indication for GPS Program

We chose AML, for which we have been granted Fast Track and ODD by the FDA, as our lead indication for GPS for the reasons outlined below:

- AML presents a clinical setting in which complete remission status (specifically CR1 and/or CR2) can be achieved with standard antileukemic therapy;
- the high degree of unmet medical need in recurrent/relapsed AML and the absence of an effective maintenance therapy over the decades after salvage re-induction until and immediately after achievement of CR2 status, especially considering that most patients in this clinical scenario are older than 60 years of age;

- the almost universal expression of WT1 in leukemic blasts, which are AML's replicating malignant cells, as well as leukemic stem cells, or LSCs, cells that are or become extremely resistant to standard chemotherapy or targeted agent approaches and which can be realistically eradicated only with immunotherapy methods (including allo-HSCT). LSCs have been shown to be susceptible to targeting by cytotoxic T-cells (CD8 and CD4 cells) stimulated against leukemia-associated antigens and we believe this will be the case for GPS;

- the fact that WT1 has been associated with the actual development of leukemia;

- the positive correlation between the level of expression of WT1 and the prognosis in AML;

- the fact that the level of expression of WT1 can be followed over time in patients during and after therapy, including immunotherapy, as a method of monitoring for MRD;
- early evidence from mouse models that vaccination with peptides against select WT1 antigenic epitopes leads to detection of immune response;

- early evidence that human immunocytes sensitized ex-vivo to peptides contained in GPS were able to recognize naturally presented WT1 peptides on the surface of several leukemia cell lines;

- early anecdotal (at the time) clinical data showing antileukemic activity of WT1 monovalent vaccines in the CR1 maintenance setting in the Japanese population (albeit restricted to HLA-A*2401 type), as well as a dendritic cell vaccine in the Netherlands (independent of HLA haplotype) in the same setting;

- a predictive assumption of very low to negligible degree of clinical toxicity with a WT1-targeted immunotherapy such as GPS, due to the fact that WT1 in normal, non-cancerous, tissues is both expressed at extremely low levels and limited in number of organs and tissues, but also due to the fact that WT1 fragments, or peptide epitopes, in normal cells are presented to host APCs in a different manner than are WT1 fragments produced in cancer cells; of note, WT1 expression in normal tissues of adults is limited to the podocyte layer of the glomerulus (kidney), Sertoli cells (testis), granulosa cells (ovary), decidual cells (uterus), mesothelial cells (peritoneum, pleura), mammary duct and lobule (breast), and blood-forming (hematopoietic) progenitor cells (CD34+ cells in the bone marrow);

- the advent of modern immunotherapeutics in cancer and the promise of an innovative, off-the-shelf potentially effective, low adverse event burden immunotherapy to prevent or delay relapse in patients once they achieve complete remission status in AML, a disease that has historically been associated with dearth of deep and sustained responses to checkpoint inhibitors; and

- evidence from our completed Phase 1 and Phase 2 clinical trials that administration of GPS can lead to extended relapse free survival and OS especially in patients who demonstrated clear WT1 specific CD4 and/or CD8 immune response to GPS administration.

Furthermore, we believe that there is a significant unmet medical need for a clinically safe and effective therapy as maintenance after AML patients achieve CR1 and/or CR2 status following successful first-line or second-line (salvage) therapies, as a significant percentage of these patients are ineligible for, or unable to undergo, allo-HSCT. No third-line therapies have shown demonstrable clinical impact to date in AML patients after their second relapse and eventually AML patients in second relapse generally succumb to AML or complications associated therewith.

Our Clinical Data in AML CR1 and CR2 Patients

In an initial pilot clinical trial in AML, a total of nine adult patients of all ages with de novo AML were treated with upfront standard chemotherapy and were able to achieve CR1. Administration of GPS resulted in a median OS that was at least 35 months from the time of GPS administration. In this study, specifically for patients who were 60 years and older (n=5), median OS was at least 33 months from the time of GPS administration or approximately 43 months from the time of initial AML diagnosis. The mean time of follow-up was 30 months from the time of diagnosis

at the time of this analysis for all patients. Of the eight patients tested for immunologic response, seven, or 87.5%, demonstrated a WT1-specific immune response.

In a subsequent Phase 2 clinical trial in AML, a total of 22 adult patients of all ages with de novo AML were treated with upfront standard chemotherapy and were able to achieve CR1. Most patients also received one to four cycles of “consolidation” chemotherapy per standard AML treatment guidelines. GPS was then administered within three months from the completion of the consolidation chemotherapy regimen in up to 12 total doses: six initial doses (priming immunization) followed by six additional “booster” immunizations over a total period of up to 15 months to qualifying patients (i.e., patients who were clinically stable and did not show disease recurrence after the first six injections). This Phase 2 clinical trial met its primary endpoint of an actual OS rate of at least 34%, measured three years into the clinical trial (i.e., percentage of patients alive after three years of follow-up). An actual OS rate of 47.4% was demonstrated at three years post-GPS treatment, exceeding historical published data of OS of 20% to 25% by 2.4- to 1.9-fold (or 240% to 190%), respectively.

GPS administration was also shown to improve OS in comparison to historical data in patients in CR1. Administration of GPS resulted in a median OS that was poised to exceed 67.6 months from the time of initial AML diagnosis in patients of all ages, which represents a substantial improvement compared to best standard therapy. Only five of the 22 patients underwent allo-HSCT and an ad hoc statistical analysis failed to show a significant effect of the transplant upon OS (either in median survival times or survival rates at specific landmark time-points). In this study, the patients’ median age was 64 years old. Importantly, a preplanned subgroup analysis for the cohort of 13 patients within the clinical trial who were 60 years of age or older demonstrated a median OS of 35.3 months from time of initial diagnosis. Comparable historical populations have a median OS ranging from 9.5 to 16.8 months from initial diagnosis, which represents a 2.25 to 3.75-fold improvement in OS associated with GPS therapy in the CR1 maintenance setting as contrasted to these historical cohorts of broadly comparable patients.

The most frequent toxicities were mild to moderate local skin reactions and inflammation, as well as fatigue, which were self-limited and responded to local supportive measures and analgesics. None of the patients developed significant serious or high grade systemic adverse reactions (including anaphylaxis) attributable to GPS. GPS elicited WT1-specific immune responses in 88% of patients, including CD4 and CD8 T-cell responses. Further, the heteroclitic principle was confirmed, in that immune responses were seen against the native version of the two mutated WT1 peptides within the GPS mixture. The results showed a trend in improved clinical outcomes in patients who mounted an immune response with GPS compared to those patients who did not.

An additional Phase 2 clinical trial of GPS was performed at the H. Lee Moffitt Cancer Center & Research Institute, or Moffitt. This Phase 2 trial included 10 AML patients who had received first-line therapy for their disease, who then experienced relapse and were subsequently treated with second-line chemotherapy and achieved a CR2. This group of patients had a more advanced disease in comparison to those treated in the Phase 2 clinical trial in CR1 patients discussed above and typically demonstrated a historical OS of less than ~8 months, even with post-CR2 allo-HSCT. In the Moffitt trial, the efficacy of GPS (measured as median OS, from the time of achievement of CR2 until death from any cause) was compared with that of “watchful waiting” in a cohort of 15 contemporaneously treated (but not matched by randomization) broadly comparable patients treated by the same clinical team at Moffitt. Initial data, at a median follow-up of 19.3 months, showed that GPS administration resulted in a median OS of 16.3 months (495 days) compared to 5.4 months (165 days) from the time of achievement of CR2. This was a statistically significant difference (p=0.0175). Two of 14 AML patients demonstrated relapse-free survival of more than one year. Both of these patients were in CR2 at time of GPS administration, with duration of their second remission exceeding duration of their CR1, strongly suggesting a potential benefit based on immune response mechanisms.

Final data, at a median follow-up of 30.8 months, showed a median OS of 21.0 months in patients receiving GPS therapy compared to 5.4 months in the AML CR2 patients treated with best standard care resulting in a statistically significant difference (p-value < 0.02). GPS was well-tolerated in this clinical trial.

Phase 3 REGAL Clinical Trial

Building on the Phase 2 study in AML CR2 patients, which showed a median OS of 21.0 months, at a median follow-up of 30.8 months, in patients receiving GPS compared to 5.4 months in contemporaneously treated patients

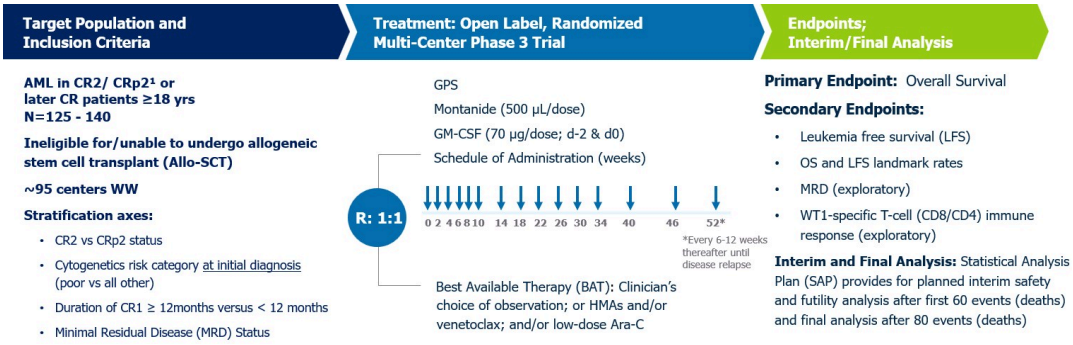
with best standard therapy, we currently have an ongoing Phase 3 pivotal registration-enabling study for GPS in AML patients in CR2, including those in complete remission with incomplete platelet recovery. This study, which we refer to as the REGAL study, is a 1:1 randomized, open-label study comparing GPS in the maintenance setting to investigators' choice of best available treatment, or BAT, in adult AML patients (age >18 years) who have achieved their second or later hematologic (morphological) complete remission, with or without thrombocytopenia, after second-line antileukemic therapy and who are deemed ineligible for, or unable to undergo, allo-HSCT. The primary endpoint is OS and secondary endpoints include leukemia-free survival, or LFS, landmark OS and LFS rates, and achievement of MRD negativity. Exploratory endpoints include antigen-specific T-cell immune response dynamics over time. We expect this study will be used as the basis for a BLA submission, subject to a statistically significant and clinically meaningful trial outcome and agreement with the FDA.

The REGAL study was expected to enroll approximately 125 to 140 patients (not including potentially 20-25 patients from mainland China) at approximately 95 clinical sites in North America, Europe and Asia. In March 2024, we announced the completion of enrollment.

The protocol specifies that the study will have a planned interim safety, efficacy and futility analysis after 60 events (deaths). In addition, the charter for the Independent Data Monitoring Committee, or IDMC, for the REGAL study provides that the IDMC may conduct risk-benefit assessments at earlier points in the clinical trial. The IDMC has met several times to perform these prespecified risk-benefit assessments of unblinded data from the study and have recommended in each instance that the trial continue without modifications. In December 2024, we announced that the pre-specified threshold of 60 events (deaths) per the protocol had been reached, triggering the interim analysis to be conducted by the Independent Data Monitoring Committee, or IDMC. In January 2025, we announced that following this interim analysis, the IDMC recommended that the trial continue without modifications. The interim futility, efficacy, and safety analysis is designed to assess whether the therapy is safe, demonstrates potential efficacy, and merits continuation. The IDMC's review of the interim data supports the continuation of the study according to its original protocol. Based on this positive evaluation, the trial is to advance toward completion. The next and final analysis will be conducted once 80 events (deaths) are reached, further determining the potential of GPS in addressing the needs of AML patients. In December 2025, we announced that our contract research organization informed us that the pooled number of events was 72 as of December 26, 2025. Because the final analysis is event driven, it is difficult to predict with any certainty and it may occur at a different time than currently expected. We will announce the 80th event when it occurs.

We have agreed with our partner in China, 3D Medicines, for 3D Medicines to participate in the REGAL study through the inclusion of approximately 20-25 patients from mainland China. Although the REGAL study has completed enrollment as announced in March 2024, in accordance with the predetermined statistical analysis plan, 3D Medicines may still enroll patients in mainland China. The timing of such participation and patient enrollment by 3D Medicines, if at all, cannot be predicted with certainty. In December 2023, we announced that we had commenced a binding arbitration proceeding administered by the Hong Kong International Arbitration Centre, which proceeding will be governed by New York law as per the terms of the 3D Medicines Agreement. We commenced the proceeding after having exhausted the dispute resolution provisions in the 3D Medicines Agreement to resolve a dispute regarding, among other things, the trigger and payment of relevant milestone payments due to us under the 3D Medicines Agreement as well as 3D Medicines' failure to use commercially reasonable best efforts to develop GPS in accordance with the terms of the agreement. See *Item 3. Legal Proceedings*.

The key features and schema of this study are shown in the following graphic:



Phase 1 clinical trial of 3D189 in China

In January 2022, 3D Medicines submitted an Investigational New Drug, or IND, application to initiate the first clinical trial in China for 3D189, also known as GPS. The IND for the Phase 1 clinical trial, which is investigating safety, was accepted by China's National Medical Products Administration, or NMPA, and the trial commenced in mid-2022. 3D Medicines is responsible for all expenses related to executing the trial in China. In the second quarter of 2022, we received a $1.0 million milestone payment which was triggered by the NMPA's approval of the IND. The study has been completed and the final data report is pending.

Expanded Access Program

At the request of several investigators, in 2022 we instituted an Expanded Access Program for GPS that allows qualified physicians to treat patients who do not meet currently required study entry criteria for the ongoing REGAL trial with GPS. This access is provided on a case-by-case basis to patients in the United States. Patients treated under the Expanded Access Program are not considered participants in the REGAL study. Currently, our Expanded Access Program is available for GPS only.

GPS Combination Therapy with Checkpoint Inhibitors

Phase 1/2 Clinical Trial of GPS in Combination with Pembrolizumab

Given the potential immunobiologic and pharmacodynamic synergy between GPS and an immune check-point inhibitor (e.g., PD-1 inhibitor), we entered into a Clinical Trial Collaboration and Supply Agreement with Merck (known as MSD outside the United States and Canada), to assess the efficacy and safety of GPS in combination with Merck's anti-PD-1 therapy pembrolizumab with exploratory long-term follow-up for OS and safety. In December 2018, we, in collaboration with Merck, initiated a Phase 1/2 open-label, non-comparative, multicenter, multi-arm clinical trial of GPS in combination with pembrolizumab in patients with WT1-positive advanced cancers, including both hematologic malignancies and solid tumors. We, together with Merck, determined to focus on 2nd or 3rd line WT1+ relapsed or refractory ovarian metastatic cancer as the primary indication for the study.

Ovarian cancer represents an intriguing opportunity to study both the clinical and immunologic effects of GPS in this solid tumor. Additionally, therapeutic targeting of WT1 through immune pathways has largely not been pursued by others to date for this indication and ovarian cancer remains "incurable" once it advances and becomes disseminated, even in the face of significant advances in the field. Ovarian cancer was chosen as a target indication for the following reasons:

- ovarian cancer presents a clinical setting whereby MRD status can be achieved with standard upfront therapy both immediately after first line therapy, but also after effective debulking of the "first relapse." The

latter subgroup of patients (after successful second line treatment/first salvage, lacking demonstrable macroscopic residual disease) would be optimal candidates for GPS therapy, as no standard maintenance therapy exists for such patients and the subsequent relapse patterns and metrics are known and predictable;

- the high levels of expression of WT1 in ovarian cancer cells. In fact, WT1 expression is so frequent that pathologists routinely use immunohistochemical stains for WT1 (with a standardized convention for describing expression and determining as “positive” or “negative”) to help distinguish epithelial ovarian cancers from other tumors;

- preliminary evidence, in a previous study of GPS with nivolumab in ovarian cancer, that WT1 expression may be linked to prognosis in ovarian cancer and that it may play an anti-apoptotic role in ovarian cancer cell lines;

- the high degree of unmet medical need in ovarian cancer patients after first (or subsequent) successful “salvage” debulking therapy and the absence of effective therapies for such patients; and

- a predictive assumption of very low to negligible degree of clinical toxicity with a WT1-targeted immunotherapy such as GPS due to the fact that WT1 in normal, non-cancerous tissues is both expressed at extremely low levels and limited in number of organs and tissues, but also due to the fact that WT1 fragments, or peptide epitopes, in normal cells are presented to host APCs in a different manner than are WT1 fragments produced in cancer cells.

Epithelial cancer of the ovary, or ovarian cancer, is a relatively common gynecologic cancer that develops insidiously, and hence is associated with vague or no symptoms that would urge patients to seek medical attention. Not surprisingly, most women with ovarian cancer present with advanced (at least locally or regionally, and often systemically spread) disease. Ovarian cancer is managed with initial surgical resection followed by platinum-based chemotherapy. During the past decade, incremental advances in chemotherapy, and the introduction of targeted therapies (such as poly-ADP-ribose polymerase inhibitors and several others) and specially formulated compounds (such as liposomal anthracyclines) have resulted in improved survival and in more effective treatment of relapsed disease. In addition, a better understanding of genetic risk factors, along with aggressive screening, has permitted a tailored approach to preventive strategies, such as bilateral salpingo-oophorectomy in selected women along in specific patient populations genetically predisposed to this cancer (such as those harboring genetic alterations of the BRCA gene family). Although a complete clinical remission following initial chemotherapy can be anticipated for many patients, a review of “second-look” laparotomy, when it was often performed as a matter of routine care, indicates that less than 50% of patients are actually free of disease. Furthermore, nearly half of patients with a negative “second-look” procedure relapse and require additional treatment. Many patients will achieve a CR2 clinical response with additional chemotherapy. However, almost all patients will relapse after a short remission interval of nine to 11 months, with median OS of nine to 12 months. Effective strategies, such as introduction of novel immunotherapies, to prolong remission or to prevent relapse are required, as subsequent remissions are of progressively shorter duration until chemotherapy resistance broadly develops, leading to eventual disease-related demise.

The purpose of the study was to determine if the administration of GPS in combination with pembrolizumab has the potential to demonstrate clinical activity in the presence of macroscopic disease, where monotherapy with either agent would have a more limited effect. This study was the first clinical trial of GPS in a patient population harboring overt bulky disease. The negative influence of TME factors on the immune response is predicted to be mitigated by PD1 inhibition (by pembrolizumab), thus allowing the patient's own immune cells to invade and destroy cancerous growth deposits specifically sensitized against WT1 (by concomitantly-administered GPS). The endpoints of the study were safety, immunobiological response, overall response rate (as measured by “response evaluation criteria in solid tumors”, or RECIST), progression free survival and OS and other analyses of interest. GPS has been designed as maintenance therapy in order to provide an OS benefit after patients reach MRD status or complete remission. The final topline data from this study demonstrated that the combination of GPS and pembrolizumab could halt or slow down the progression in highly active disease refractory to other therapies.

On February 1, 2022, we announced the completion of enrollment in the study.

On November 10, 2022, we reported the following confirmatory topline data from 17 evaluable patients in the study.

- Median OS was 18.4 months compared to 13.8 months with pembrolizumab alone in a checkpoint inhibitor single agent study in a similar patient population treated with checkpoint inhibitor alone.
- Median progression-free survival, or PFS, was 12 weeks compared to 8 weeks in a checkpoint inhibitor single agent study in a similar patient population treated with checkpoint inhibitor alone.
- The overall response rate of the trial was 6.3 percent with a DCR of 50.1 percent at a median follow-up of 14.4 months. In a checkpoint inhibitor single agent study in a similar platinum-resistant ovarian cancer patient population treated with a checkpoint inhibitor alone, the observed DCR was 37.2 percent, consistent with a DCR rate increase of approximately 45 percent in the GPS combination with pembrolizumab over that seen for checkpoint inhibitors alone.
- Survival and disease control benefits were observed in patients harboring tumors with any level of detectable PD-L1 expression, i.e., those with Combined Positive Score, or CPS, of 1 or higher. The DCR is 63.6% in patients with a CPS of 1 or higher. Patients with a CPS score of less than 1 showed a median OS of 3.2 months vs. patients with a CPS greater than or equal to 1 who had a median OS of 18.4 months and, as it relates to time to progression, patients with a CPS score of less than 1 had a median PFS of 1.9 months and patients with a CPS score of greater than or equal than 1 showed a median PFS of 3.8 months.
- In 16 evaluable patients in whom serial peripheral blood samples were available, a correlation was observed between PFS and OS and WT1-specific immune response after GPS vaccination across more than 1 channel with intracellular cytokine flow-cytometry assays in peripheral blood lymphocytes assaying reactivity against the four pooled WT1 antigens comprising GPS. The data were consistent with those seen in previous studies of GPS.
- The safety profile of GPS in combination with pembrolizumab was similar to pembrolizumab alone, with only the addition of low-grade rapidly resolving local reactions at the GPS injection site, consistent with observations from other GPS clinical studies.

In November 2023, additional immunobiological and clinical data from the study for 16 safety and efficacy evaluable patients who had follow-up cross-sectional imaging (CT/MRI) were presented at the International Gynecologic Cancer Society 2023 Annual Global Meeting:

- WT1-specific T-cell (CD8 and CD4) immune response data showed a positive trend over time post-baseline with highest consistency and potential biomarkers for consistency being IFNγ and MIP1β.
- GPS in combination with pembrolizumab was strongly immunogenic, as evidenced by the positive T-cell responses seen post-vaccination.
    - 42.8% of patients (6/14) achieved CD8 T-cell immune response.
    - 85.7% of patients (12/14) achieved CD4 T-cell immune response.
- A correlation between WT1 specific T-cell immune responses (CD8 or CD4) and PFS was observed in a subset of analyzed patients with 41% longer PFS in patients with recorded immune response vs without (p=0.025).

GPS Combination Therapy with Nivolumab for MPM

A single-center, open-label, single-arm, non-randomized investigator-sponsored Phase 1 trial of concomitant administration of GPS in combination with Bristol-Myers Squibb's anti-PD-1 therapy, nivolumab (Opdivo) was initiated in February 2020 at MSK in patients with MPM who have previously received treatment with pemetrexed-based chemotherapy and have measurable disease on imaging, either due to residual disease after prior treatment or recurrent disease. We provided GPS and Bristol-Myers Squibb provided nivolumab for this study.

The principal investigator for the study was Dr. Marjorie G. Zauderer, MD, Co-Director, Mesothelioma Program and Associate Attending Physician in the Thoracic Oncology Service, Department of Medicine at MSK. The purpose of the trial was to determine if the administration of GPS in combination with nivolumab has the potential to demonstrate antitumor immune responses and meaningful clinical activity in the presence of macroscopic disease in MPM patients. The study also investigated the tolerability of the combination, evaluated the immunogenicity of the two agents administered together, by CD4+ and CD8+ T-lymphocytes (both peripherally and at the tumor site), and gauged the degree of clinical benefit by assessment of the overall response rate with the combination in comparison with that reported with nivolumab alone in historical comparable patient populations.

With approximately 3,300 cases in the United States each year, accompanied by a rising incidence in developing countries, MPM is notoriously difficult to treat and can lead to poor clinical outcomes with respect to both OS and progression-free survival, especially for those patients with the sarcomatoid variant who show a median OS of approximately 4.0 to 5.0 months. In relapsed and refractory patients who progressed after the first line standard of care pemetrexed, a similar patient population to that in the GPS nivolumab combination trial, the common treatment regimen is vinorelbine and OS in those patients is reported to be between 4.5 and 6.2 months. In patients treated with other chemotherapy regimens, such as carboplatin and irinotecan, median OS is reported to be approximately 7.0 months.

In a randomized, controlled, blinded Phase 2 clinical trial in MPM patients completed in 2017, GPS monotherapy given as maintenance after first line tumor-debulking multimodality treatment demonstrated meaningful clinical activity with median survival of 22.8 months vs. 18.3 months in the control group (n=41) and with associated sustained immune responses (both CD4+ and CD8+) against the WT1 antigen while adverse events were mainly comprised of low grade reactions at the site of the injection. See *GPS Monotherapy: Completed Clinical Trials in Other Indications.*

Study enrollment (target total n=10) was completed at the end of 2022. In June 2023, we reported positive topline safety and efficacy data from the study:

- Nine of the 10 patients enrolled received at least three doses of GPS, with the third GPS dose given in combination with nivolumab.
- All enrolled patients had either received and progressed with or were refractory to frontline pemetrexed-based chemotherapy.
- Median OS in patients who received the combination therapy (9/10 patients) was 70.3 weeks (17.6 months) and 54.1 weeks (13.5 months) for all 10 patients (nine patients with combination therapy and one GPS only patient). Median OS for patients who entered the study as Stage IV patients was 62.3 weeks (15.6 months). OS was calculated as the time from cessation of the most recent previous therapy until confirmed death or most recent data update for patients who still alive.
- Median PFS for all patients was 11.9 weeks.
- DCR was 30% with three patients achieving stable disease per RECIST criteria with the tumor volume decrease of up to 17%.
- As expected in this high-risk advanced cancer population, all patients experienced adverse events, unrelated and related. Seven out of 10 patients (70%) had treatment related toxicities and six (60%) had nivolumab related toxicities. Grade 3, or G3, and higher toxicities were observed in three patients (30%). None of the G3 and higher toxicities were related to GPS. GPS related toxicities were observed in three patients (30%), all were Grade 1, or G1, and included G1 skin induration at the site of injection/injection site reaction and/or fatigue in two patients and G1 dizziness and non-cardiac chest pain, each in one patient.
- Of the 10 evaluable patients, eight were male and two were female, with a median age of 69 years. Sixty percent entered the study as Stage III or IV patients. Initial tumor stages were I (one patient), II (three patients), III (two patients) and IV (four patients).

- All patients had MPM epithelioid and/or sarcomatoid variant, a tumor which universally expresses WT1.

In December 2023, we reported positive follow-up immune response and survival data:

- The median OS among patients who did not have an immune response to GPS was 9.0 months; the median OS for patients who had an immune response to GPS was 27.8 months, which was more than three times longer (208.3% increase) than for those patients without an immune response. Among the nine evaluable patients, four patients had a CD4+ immune response (44.4%) and three patients had a CD8+ immune response (33.3%) to GPS. Three patients had both CD4+ and CD8+ immune responses (33.3%).

- Among patients who had a full immune response (both CD4+ and CD8+) to GPS, two patients achieved an objective response (66.7%), while among the patients who did not have an immune response to GPS one patient achieved an objective response (14.3%).

GPS Monotherapy: Completed Clinical Trials in Other Indications

MPM

MPM is an asbestos-related cancer that forms on the protective tissues that cover many of the internal organs. The most common area affected is the lining of the lungs and abdomen, though it can also form around the lining of the heart. Most cases are traced to job-related exposures to asbestos and it can take approximately 40 years between exposure and cancer formation. Symptoms may include shortness of breath, a swollen abdomen, chest wall pain, cough, feeling tired, and weight loss. MPM is generally resistant to radiation and chemotherapy, and long-term survival is rare, even in cases where aggressive upfront debulking multimodality therapy (i.e., extirpative surgery, chemotherapy and in some cases radiotherapy, often described as “trimodality therapy” when used to treat MPM) are used.

A randomized, double-blind, placebo-controlled Phase 2 clinical trial in MPM patients enrolled a total of 41 patients at MSK and MDACC. Data from this Phase 2 clinical trial was presented in 2016. Based on an initial analysis of 40 patients who were eligible at the time with a median follow-up of 16.3 months, a median OS of 24.8 months was seen for GPS-treated MPM patients, compared to a median OS of 16.6 months for patients in the control arm. For patients with a basic reproductive ratio tumor resection and subsequent treatment with GPS, a significant survival benefit was observed compared to those who received a placebo, with a median OS of 39.3 months compared to 24.8 months (HR: 0.415) in favor of GPS. In a subsequent analysis for the entire cohort (n=41) in August 2016, with a median follow-up of 17.2 months, a median OS of 22.8 months was observed for GPS-treated MPM patients, compared to a median OS of 18.3 months for patients in the control arm. In the datasets from both of these analyses, GPS was shown to induce WT1-specific CD8 and CD4 T-cell activation. There were no clinically significant severe adverse events in this study.

Multiple Myeloma (MM)

MM is a cancer formed by malignant plasma cells, and its cause is unknown. The overgrowth of plasma cells in the bone marrow crowds out normal blood-forming cells, causing low blood counts and anemia (a shortage of red blood cells). MM can also cause a shortage of platelets (cells responsible for normal blood clotting) and lead to increased bleeding and bruising, along with problems fighting infections due to low white cell counts and/or lower levels of infection-fighting antibodies. MM causes a host of organ problems and symptoms, including fatigue, bone pain, fractures, circulatory problems (in small vessels of the brain, eye retina, heart, bowel, etc.) and kidney failure. Treatment for MM includes chemotherapy, glucocorticoids, drugs that modulate the immune system (immunomodulatory drugs, or IMiDs), proteasome inhibitors, histone deacetylase inhibitors, targeted monoclonal antibodies, radiation and autologous stem cell transplants, or ASCTs. The prognosis in MM is highly variable and depends on numerous risk factors, some related to the biology of the disease, others to the host (*e.g.*, age and functional status). Consequently, median survival can vary from up to at least 15 years in non-high-risk patients who achieve complete remission, as defined by the International Myeloma Working Group, or IMWG, criteria, to approximately three years (from time of initial treatment) in patients with MM who achieve less than partial response, or PR, after ASCT. There are patients with MM who fare even more poorly than described above. For example, those in the immediately aforementioned group who also have high-risk cytogenetics at baseline may

survive on average less than three years. Similarly, patients who are ineligible for ASCT and are managed only with chemotherapy and long-term IMiD maintenance (with up to nine cycles of lenalidomide) who also achieve less than complete remission and remain MRD-positive demonstrate a three-year OS rate of only about 55%; these landmark three-year OS rates decrease by approximately 40 to 50% in patients who also have high-risk cytogenetics at baseline. Despite significant therapeutic advances in the management of MM, the prognosis of patients with high-risk cytogenetics at the time of diagnosis remains quite poor, even when they successfully complete an ASCT, particularly if such patients continue to have evidence of MRD.

We have reported comprehensive final data from a Phase 2 study for GPS in 19 patients with MM. All non-progression events were confirmed and remained ongoing as of the time of the latest presentation (median follow-up at 20 months for survivors). The data indicate promising clinical activity among MM patients with high-risk cytogenetics at initial diagnosis who also remain MRD(+) after successful frontline therapy (induction regimen followed by ASCT). This subgroup of MM patients, when serially assessed per IMWG criteria, typically relapse/progress within 12 to 14 months after ASCT, even when they receive maintenance therapy with IMiDs such as thalidomide or proteasome inhibitors such as bortezomib - 18 of the 19 patients received lenalidomide maintenance starting after the first three GPS administrations following ASCT; the remaining single patient received bortezomib under the same schedule. All patients had evidence of at least MRD (MRD+) after ASCT, while 15 of the 19 also had high-risk cytogenetics at diagnosis. Combined, these characteristics typically result in low PFS rates that do not exceed 12 to 14 months following ASCT, even while on maintenance therapy with IMiDs or proteasome inhibitors, which are the current standards of care. At June 2017, median PFS with GPS was 23.6 months, while median OS had not been reached. Our results compare favorably with an unmatched cohort of broadly comparable MM patients with high-risk cytogenetics published by the Spanish PETHEMA group from the PETHEMA Network No. 2005-001110-41 trial. Our GPS therapy demonstrated a 1.87-fold increase in median PFS, as well as a 1.34-fold increase in the PFS rate at 18 months compared to the aforementioned historical cohort, which included MM patients with high-risk cytogenetics and MRD(+) post-ASCT and on continuous intensive maintenance with thalidomide +/- bortezomib. The safety profile was devoid of grade 3/4/5 treatment-related adverse events. Immune response data showed that up to 91% of patients had successfully developed T-cell (CD8 or CD4) reactivity to any of the four peptides within the GPS mixture, while up to 64% of patients demonstrated immune response positivity (CD4/CD8) against more than one WT1 peptide (multivalent responses). Moreover, multifunctional cross-epitope T-cell reactivity was observed in 75% of patients to antigenic epitopes against which hosts were not specifically immunized, in a pattern akin to epitope spreading. Further, a distinctive link was shown between the evolution of immune responses and changes in clinical response status (achievement of CR/very good partial response clinical status per IMWG criteria) over time following treatment with GPS, with each patient being used as his or her own control for each longitudinal comparison. This association has not been previously described for a peptide vaccine in MM. We believe that these results offer mechanistic underpinnings for immune activation against WT1 in patients with aggressive, high-risk MM, and support the potential antimyeloma activity of GPS.

GPS Combination Therapy: Completed Clinical Trial in Ovarian Cancer

GPS was studied in combination with nivolumab in an open-label, non-randomized Phase 1/pilot clinical trial, which was independently sponsored by MSK. The aim of the study was to evaluate the safety and efficacy of this combination in patients with WT1+ recurrent ovarian, fallopian tube or primary peritoneal cancer who were in second or greater clinical remission (after their successful first or subsequent “salvage” therapy). Eligible patients were devoid of macroscopic residual or recurrent disease, i.e., were free of locally or distantly metastatic deposits detectable by imaging modalities (CT, MRI and/or PET scan). This Phase 1/pilot clinical trial enrolled 11 patients with recurrent ovarian cancer who were in second or greater clinical remission at MSK, of whom 10 were evaluable. Patients enrolled in the clinical trial received the combination therapy during a 14-week treatment period. Individuals who had not progressed by the end of this period also received a maintenance course of GPS. In this study, treatment was continued until disease progression or toxicity. Information on the primary endpoint of this clinical trial, which was the safety of repeated GPS administrations, for a total of six doses, in combination with seven infusions of nivolumab was presented at the American Society of Clinical Oncology, or ASCO, 2018 annual meeting (O’Cearbhaill RE, et al). The secondary endpoint of the study was immune response, and the exploratory endpoints included landmark one-year PFS rate compared to historical controls and correlative analyses between clinical and immune responses. Exploratory efficacy interim data from this pilot trial showed that GPS, when combined with a PD-1 inhibitor, in this case nivolumab, demonstrated PFS of 64% at one year in an intent to treat the group of 11 evaluable patients with WT1+ ovarian cancer in second or greater remission. Among patients who received at least

three doses of GPS in combination with nivolumab, PFS at one year was 70% (7/10). The historical rates with best standard treatment do not exceed 50% in this disease setting. The most common adverse events were Grade 1 or 2, including fatigue and injection site reactions. Dose limiting toxicity was observed in one patient, following the second dose of the combination. No additional adverse event burden was observed for the combination as compared to nivolumab monotherapy. The combination induced a high frequency of T- and B-cell immune responses.

Follow-up data now show that three of the 11 patients enrolled in the study have continued to show no signs of disease progression. The mean PFS for these three patients is 35.4 months from the initiation of salvage chemotherapy, or mean PFS of 30.1 months from the first administration of GPS plus nivolumab. Based on this follow-up information, the estimated two-year PFS rate for this study is now 27.3% for the intent-to-treat, or ITT, patients (n=11) and approximately 30% for patients who received greater than two doses of GPS and nivolumab (n=10), as compared to a historical 3% to 10% PFS rate for patients receiving only salvage chemotherapy. No new serious adverse events were noted during the longer follow-up period.

SLS009 (Tambiciclib): Highly Selective Next Generation CDK9 Inhibitor

Overview

SLS009, or tambiciclib, is a next generation highly selective CDK9 inhibitor which we in-licensed from GenFleet in March 2022. We have worldwide development and commercialization rights, except for Greater China. See *Strategic Collaborations and License Agreements - Exclusive License Agreement with GenFleet Therapeutics (Shanghai), Inc.* CDK9 activity has been shown to correlate negatively with OS in several cancer types, including hematologic cancers, such as AML and lymphomas, as well as solid cancers, such as osteosarcoma, pediatric soft tissue sarcomas, melanoma, endometrial, lung, prostate, breast and ovarian cancer.

Mechanism of Action

CDK9 is a major cancer target. CDK9, together with cyclin T1, forms positive transcription elongation factor b, or P-TEFb, which plays an important role in allowing long RNA strands to be quickly transcribed. P-TEFb is crucial for the synthesis of some of the key proteins necessary for survival of cancer cells, including short-lived proteins such as MCL-1, which is a key anti-apoptotic (preventing programmed cell death) protein, and oncogenes such as c-MYC. These proteins must be constantly replenished for cancer cells to survive. Inhibition of CDK9 can decrease the levels of MCL-1 and c-MYC which can result in apoptosis and cell cycle arrest. Cyclin-dependent kinases, or CDKs, play a role not only in cancer cells but also healthy cells. Drug candidates that broadly target CDKs, i.e., those with lower specificity, can have issues with toxicity because healthy cells as well as cancer cells are targeted. The first generation of CDK9 inhibitors worked across many CDK targets in addition to CDK9. These first-generation drug candidates showed some clinical activity but had significant toxicity due to low specificity. Next generation CDK9 inhibitors, including SLS009, have potential for higher specificity for CDK9 and lack of binding to other CDKs, potentially resulting in less toxicity and more consistent clinical activity.

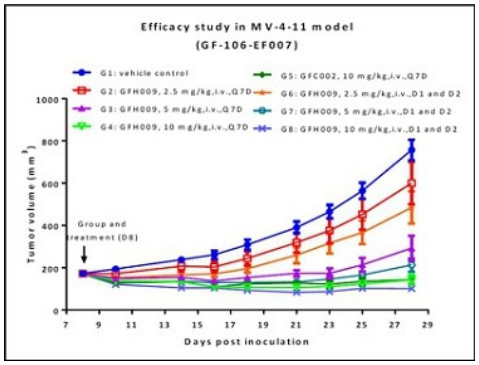
Key Attributes

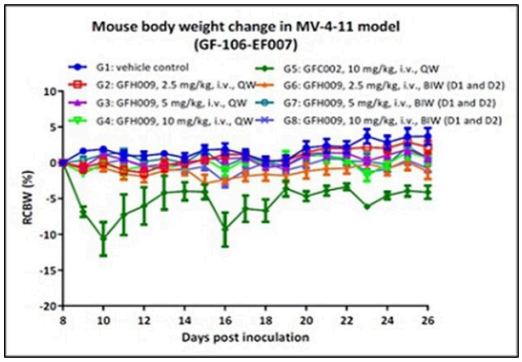
Higher selectivity: In preclinical studies, SLS009 has demonstrated higher selectivity for CDK9 than other members of the human kinome when compared to other non-oral CDK9 inhibitors in clinical development in the United States for hematological cancers, including AZD-4573 being developed by AstraZeneca and enitociclib (VIP152) being developed by Vincerx Pharma. The human kinome is a set of all 538 kinases, which are enzymes that play essential functions by catalyzing protein phosphorylation. SLS009 has been shown to block activity of fewer kinases, other than CDK9, than these competing development candidates which, as demonstrated in clinical trials, has resulted in a better safety profile with fewer treatment related adverse events.

Higher anti-cancer activity: The preclinical data below is a comparison of SLS009 and an exact molecular copy of enitociclib (VIP152) (shown in the graphs as GFC002). The top table shows the maximal inhibitory concentration, which is the amount of drug that is needed to inhibit survival of cancer cells, across different cell lines of cancer in vitro. Across multiple cancer cell line histologies, a smaller concentration of SLS009 is needed to achieve the same inhibitory effect as compared to the exact molecular copy of enitociclib (VIP152). In a mouse AML xenograft model,

the lowest tumor growth and the highest AML cell killing was achieved by SLS009. In this mouse model, there was significantly more toxicity, including weight loss, observed with enitociclib (VIP152) treated mice.

Cell lines	SLS009 IC50 (72h)	VIP152 IC50 (72h)
AML	4.8 ~33 nM	15.9 ~136 nM
Lymphoma	10.6~77.9 nM	16.6 ~138 nM
MM	33.6 ~151 nM	51.4 ~397 nM
ALL	13.4~35.7 nM	42.3 ~68.6 nM
CLL	25 nM	40.7 nM



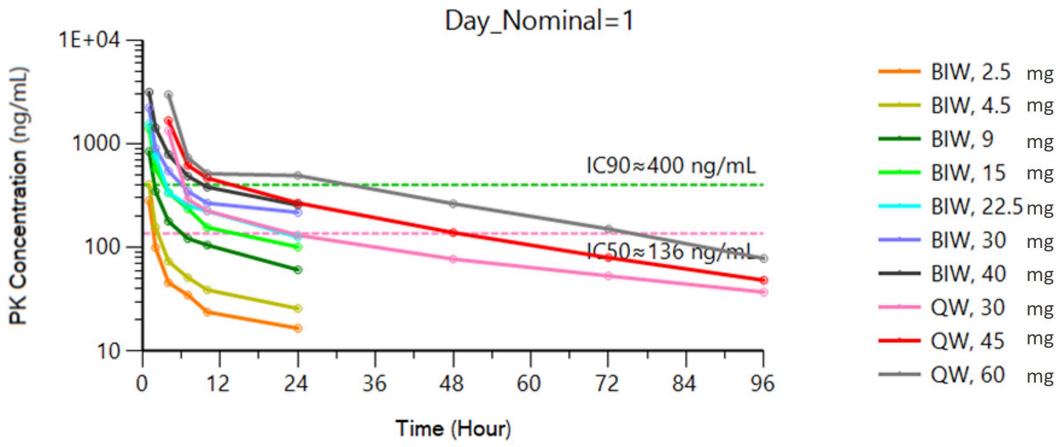


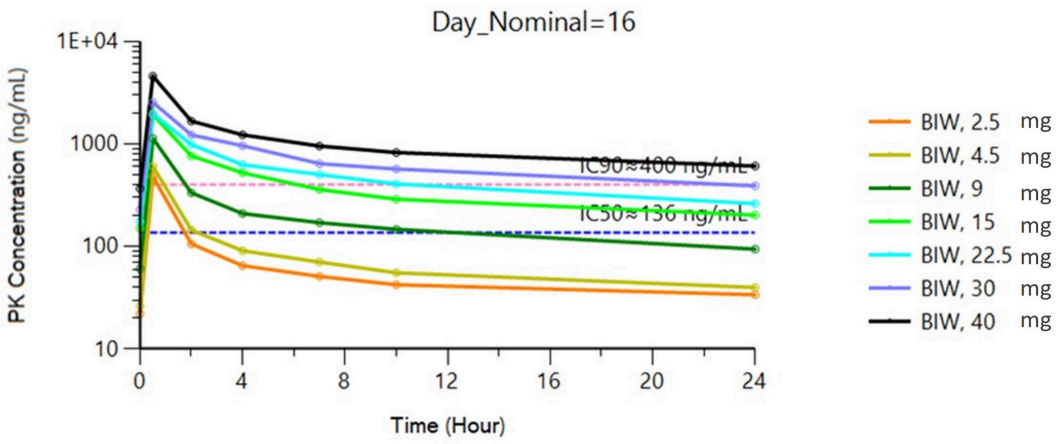
Pharmacokinetic, or PK, Data: PK data observed from the completed Phase 1 trial are shown below. PK data show the relationship between the dosing regimen and the body's exposure to a drug as indicated by the concentration time curve. An important component of the mechanism of CDK9 inhibition in cancer is to achieve very high concentration immediately which then shuts down the cancer cell and leads to apoptosis, while quickly ramping down so that there is not apoptosis of neutrophils. PK analyses were made for both twice a week dosing regimen (BIW cohorts) and once a week dosing regimen (QW cohorts).

BIW cohorts: The PK analysis result showed that after intravenous infusion of 2.5 mg (N=1), 4.5 mg (N=5), 9 mg (N=8), 15 mg (N=11), 22.5 mg (N=7), 30 mg (N=8), and 40 mg (N=3) of SLS009 twice a week (BIW, administered on the first and second days of each week for one hour), the plasma concentration reached peak at the end of the infusion. The exposure parameters (C_{max} and AUC) of SLS009 increased in an approximately proportional manner in the dose range 2.5 mg to 40 mg. The PK profiles in single and repeated administration were comparable.

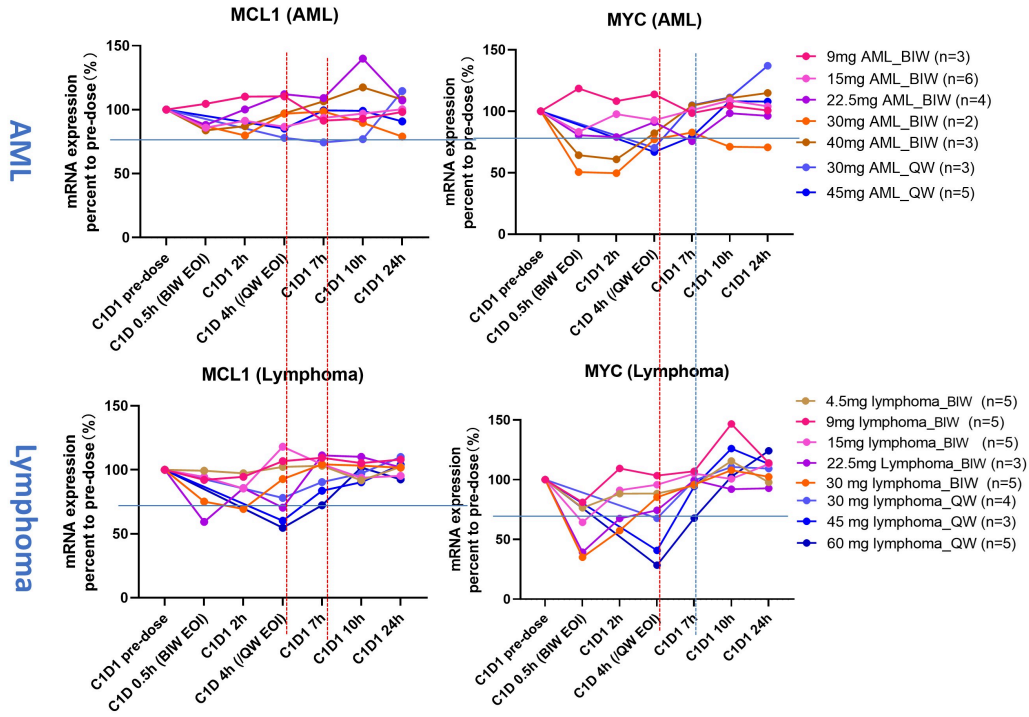
QW cohorts: After intravenous infusion of 30 mg (N=7), 45 mg (N=8), and 60 mg (N=9) of SLS009 once a week (QW, administered on the first day of each week for four hours), the plasma concentration-time profiles were comparable to those of BIW administration, indicating a similar characterization of distribution and metabolism. The plasma concentration reached peak at the end of the infusion. The exposure parameters (C_{max} and AUC) of SLS009 increased in an approximately proportional manner with the dose range 30 mg~60 mg. After QW administration, there was no obvious accumulation of SLS009.

Comparison of pharmacokinetics results in twice a week and once a week dosing regimens at different dose levels is shown below.





Pharmacodynamic, or PD, Data: The graphs below show certain correlative pharmacodynamic data from the completed Phase 1 study. At higher dose levels, a pattern of drug induced decreases in two biomarkers commonly used for assessing pharmacodynamics of CDK9 inhibitors, MCL1 and MYC, is seen. These data are important in that we believe they demonstrate that SLS009 is translating CDK9 inhibition into a meaningful suppression of cancer associated proteins. MCL1 is a key antiapoptotic protein. It is postulated that CDK9 inhibitors can indirectly inhibit MCL1. We believe that these PD data demonstrate that SLS009 does inhibit MCL1. MYC is a key driver in many cancers, both hematological and solid tumors. We believe that the data presented below demonstrate meaningful MYC suppression.



Efficacy in venetoclax resistant disease: Venetoclax, in combination with hypomethylating agents, is a key component of treatment for AML across all patient categories, especially older patients, who are the vast majority of AML patients. We believe that SLS009 has potential as a treatment option for AML patients who are refractory to or relapsed after treatment with venetoclax. We observed in the Phase 1 study that a r/r AML patient achieved a complete response and four additional r/r AML patients achieved greater than or equal to 50% decrease in bone marrow blasts which includes patients who had prior treatment with venetoclax. To our knowledge, as of March 1, 2026, SLS009 is the only CDK9 inhibitor for which a complete response as monotherapy in r/r AML has been reported. See *Phase 1 Clinical Trial.*

Phase 1 Clinical Trial

The Phase 1 dose-escalating clinical trial in the United States and China for SLS009 was completed in 2023. The study evaluated both twice-a-week and once-a-week dosing and the indications were r/r AML, chronic lymphocytic leukemia, or CLL, small lymphocytic leukemia, or SLL, and lymphoma. The primary goal of the trial was to establish the RP2D which was established at 60 mg for AML and 100mg for lymphomas.

Two dosing regimens were tested in incremental SLS009 dose levels from 2.5 mg to 100 mg, either twice a week, or BIW, dosing regimen or once a week, or QW, dosing regimen. A total of 34 patients were treated in the AML cohort and 52 patients in the r/r lymphoma cohort. Among the 52 r/r lymphoma patients, 15 were diagnosed with PTCL.

For the cohort of patients with AML and with lymphomas, all key study objectives regarding PK, PD, safety and clinical activity data were met:

Efficacy:

AML cohort:

- Anti-tumor activity and clinical responses across groups and dose levels were observed, indicating a broad therapeutic index. Meaningful cell killing activity was defined as ≥50% reduction in blasts in the bone marrow.
    - AML cohort: cell killing activity observed at the following dose levels:
        - 9 mg BIW: 50.0% bone marrow blast (BMB) reduction;
        - 15 mg BIW: 53.8% BMB reduction;
        - 30 mg QW: 57.1% BMB reduction;
        - 45 mg QW: 61.3% BMB reduction;
        - 60 mg QW: 77.3% BMB reduction.
    - Durable complete remission (CR) with no MRD in one patient with AML who had failed prior aza/ven therapy was achieved. The duration of the CR was eight months. Historically, best available therapy median OS for patients relapsed after aza/ven is estimated at 2.5 months.

Lymphomas cohort:

- Among 34 evaluable r/r lymphoma patients, five (14.7%) achieved a clinical response with a reduction in tumor burden of up to 62%.
- An additional seven patients (20.6%) achieved stable disease, or SD, resulting in an overall DCR of 35.3%.
- In the subgroup of PTCL patients, four out of 11 (36.4%) evaluable patients achieved a clinical response.

Safety:

AML cohort:

- No dose limiting toxicities and no higher grade non-hematologic toxicities of any kind were observed.
- Some hematologic toxicities were difficult to determine in patients with hematologic cancers but were short in duration and reversible.

Lymphomas cohort:

- There were no drug-related fatalities at any dose level, and the drug was well tolerated.
- In patients treated with BIW dosing regimen, no significant safety events appeared to be dose-dependent.
- In patients receiving the QW dosing regimen, ≥ G3 treatment-related adverse events, or TRAEs, occurred, primarily hematologic events, at higher dose levels.
- Non-hematologic toxicities were rare across all dose levels with five out of 52 patients (9.6%) experiencing higher grade toxicities, including hypokalemia (3/52 patients, 5.8%), upper respiratory tract infection (1/52 patients, 1.9%) and increase in bilirubin (1/52 patients, 1.9%).
- Maximum Tolerated Dose, or MTD, was not reached with only 1/5 patients at the highest dose level studied (100 mg) experiencing a dose-limiting toxicity, or DLT.
- No DLTs were observed at any other dose level, and there were no unexpected toxicities across the study.

PK Data:

AML cohort:

- Achieved desired 24 hours > IC90 peripheral blood concentrations after the first infusion, with IC90 concentrations resulting in up to 97% cancer cells killed.

Lymphomas cohort:

- Exposure parameters (maximum concentration, or $C_{max,}$ and area under curve, or AUC) increased in an approximately proportional manner with the dose range of 30 mg~60 mg QW. The exposure of 100 mg was the highest, and the mean plasma concentration remained above IC_{90} for the longest time period (nearly 50 hours).

PD Data:

AML cohort:

- Achieved desired levels of MCL1 and MYC suppression in peripheral blood with decrease in MCL1 or MYC observed in 97% (66/68) of analyzed patients. A trend of proportionally increased maximum inhibition of MCL1 and MYC observed among higher doses (22.5 mg to 60 mg) in both AML and lymphoma patients, which is more prominent in QW cohorts compared to BIW cohorts. QW regimen was able to induce longer sustained inhibition (at least 6 hours) of MCL1 and MYC than BIW treatment, allowing longer period for CDK9 inhibition to induce cancer cell apoptosis.

Lymphomas cohort:

- Desired levels of suppression in peripheral blood were achieved, leading to a decrease in MCL1 or MYC biomarkers in all (100%) studied patients. Biomarker suppression was dose-dependent in patients receiving QW dosing. The biomarkers studied included MYC and MCL1 with SLS009 administration resulted in biomarkers suppression across dose levels in both administration regimens (BIW and QW) and a dose-dependent decrease in QW groups. 100mg QW dose level resulted in the longest sustained inhibition of both MCL1 and MYC.

Phase 2 Development Program

Phase 2a clinical trial in AML patients

In the second quarter of 2023, we commenced an open label, single arm, multi-center Phase 2a clinical trial of SLS009 in combination with aza/ven in AML patients who failed or did not respond to treatment with venetoclax-based therapies. The trial was designed to evaluate safety, tolerability, and efficacy at two dose levels of SLS009, 45 mg QW, and 60 mg QW or 30 mg BIW, in combination with aza/ven. In addition to safety and tolerability of SLS009 in combination with aza/ven, the primary endpoints were overall response rate and duration of response. Additional endpoints included event free survival, OS, and PK assessments. The trial included several sites in the United States and was designed to enroll a minimum of 20 patients.

Patients with AML that fail venetoclax-based therapies have limited treatment options and a poor prognosis with a median OS of approximately 2.5 months. See *Current AML Treatment Therapies* for more information on the AML treatment landscape.

In July 2025, we announced that all primary endpoints were met in the Phase 2 clinical trial of SLS009 in r/r AML. 54 evaluable r/r AML patients who previously failed venetoclax-based therapies were enrolled and treated with SLS009, and venetoclax/azacitidine. Among the 54 treated patients, 47 had AML MR (87%) and 23 had ASXL1 mutations (43%). Among the AML MR patients, 17 had myelomonocytic/myelomonoblastic subtype of AML (M4 and M5), representing 31% of all patients.

Efficacy:

- The results exceeded the pre-specified ORR threshold of 20%, demonstrating robust clinical activity and supporting advancement into late-stage development.
- The ORR in all evaluable patients was 33% across all cohorts and dose levels and 40% for the 30mg BIW dose level.
- At the 30 mg BIW dose, among AML MR patients, the ORR was 44%.
- The highest efficacy was observed among patients with ASXL1 mutations, with an ORR of 50% (9/18) at 30 mg BIW dose levels and M4/M5 patients with 50% (6/12) ORR.
- The mOS surpassed the historical benchmark of best available therapy of 2.4 months for patients who received one prior line of therapy and 1.8 months for those who received more than one prior line of therapy.
- The mOS for patients treated with 30mg BIW, with a median of 1 prior line of therapy, was 8.8 months, while the mOS in AML MR patients reached 8.9 months vs. 2.4 months with best available therapy.
- The mOS for cohorts with a median of 2 prior lines of therapies was 4.1 months vs.1.8 months with best available therapy.

Safety: The addition of SLS009 to the venetoclax/azacitidine regimen was well tolerated and did not result in increased toxicities compared to ven/aza alone. No DLTs were observed across all dose levels.

In addition, following a productive end of Phase 2 meeting, the FDA recommended that we proceed into a trial to include newly diagnosed, first-line AML patients eligible for aza/ven therapy, where the FDA noted clinical benefit might be greatest. The randomized 80-patient trial is currently ongoing and began enrollment in the first quarter of 2026. The trial will include two groups: predictive biomarker cohort (newly diagnosed patients unlikely to benefit from standard aza/ven therapy based on molecular profiling) and early venetoclax resistance cohort (patients who initiate treatment with aza/ven, but demonstrate confirmed lack of any response after two treatment cycles).

Preclinical Studies

In August 2022, we announced results from preclinical in vitro studies for SLS009 in AML cell lines. The in vitro studies were conducted at an independent third-party contract research organization, and utilized the following cell lines based on their unique characteristics in combination with SLS009's mechanism of action: RH30, a pediatric soft tissue sarcoma cell line that is a model for studying high-risk pediatric rhabdomyosarcoma, NCI-H209, a small cell lung cancer cell line characterized by the loss of function of two major tumor suppressor genes, RB1 and TP53, and which also expresses MCL-1, a major target of CDK9 inhibition, SKOV-3, an ovarian cancer cell line containing the wild type BRCA1 gene and highly expresses CDK9, and OCI-AML-2, an AML cell line that develops resistance to venetoclax. The data showed that SLS009 demonstrated significant anti-tumor effects in all four selected cell lines. In three out of the four cell lines, SLS009 inhibited cancer cell growth by 90 to 100 percent.

In August 2022, we announced results from a new preclinical in vitro study for SLS009 in neuroendocrine prostate cancer, or NEPC. The data shows that SLS009 demonstrated significant anti-tumor effects in the selected cell line at nanomolar concentrations and, in certain samples, complete growth inhibition with no viable cancer cells. Additionally, in December 2022, we announced results from a preclinical in vivo study for SLS009 that demonstrated robust inhibition of tumor growth in a mouse xenograft model of SCLC. SLS009 was tested against NCI-H209 SCLC xenografts in athymic nude mice in four treatment groups of eight mice each (n=32) consisting of SLS009 alone, olaparib (a PARP inhibitor) alone, a combined regimen of SLS009 and olaparib, and a vehicle control. Treatments were initiated after tumor xenograft volumes exceeded 120 mm3 in each animal group and mice were subsequently sacrificed after mean tumor volume exceeded 1,500 mm3 in the control group. SLS009 treated mice exhibited a 40.4% decrease in mean tumor growth compared to the control group in this very aggressive cancer model which had a tenfold increase in average tumor volume over 20 days. Strongest effects were observed with SLS009 in combination with olaparib, with mean tumor growth decreased by 72.3%. Treatment with olaparib alone resulted in a 30.2% mean decrease in tumor growth. No significant toxicity or safety concerns were observed in any of the treatment groups.

In November 2024, we announced data from preclinical studies identifying ASXL1 mutation as key predictor of SLS009 in response to solid cancers. We performed experiments in patient derived cell lines (PDCs), exposing them to SLS009 at various concentrations and determining the inhibitory concentration (IC50) for each cell line. All cell lines were analyzed for presence of ASXL1 mutations and other genetic markers. High efficacy was prespecified as IC50 < 100 nM, significantly lower than the standard threshold definition for an effective compound

(IC50 < 1,000 nM). This threshold was chosen based on the observed long-lasting concentrations of SLS009 observed in patients, which were ~400 nM.

Negative controls consisted of untreated cell lines, while active negative control varying concentrations of revumenib (drug used in hematologic malignancies). Positive controls involved cell lines treated with staurosporine at different concentrations (staurosporine is a standard control compound for kinase inhibitors due to its high broad-spectrum potency in inhibiting most protein kinases at sub-micromolar concentrations).

The results were as follows:

- In CRC MSI-H, ASXL1 mutations were observed in 7/12 (58%) of PDCs, aligning with predicted frequency of ~55%
- In NSCLC, ASXL1 mutations occurred in 2/6 (33%) studied cell lines, higher than predicted 2.6%
- Overall, in 18 studied solid cancer cell lines, ASXL1 mutations were recorded in nine cell lines and no ASXL1 mutations were recorded in 9 cell lines which were designated as control
- In ASXL1 mutated cell lines, high SLS009 efficacy (IC50 <100 nM) was observed in 6/9 (67%) solid cancer cell lines and in non-ASXL1 mutated cancer high SLS009 efficacy was observed in 0/9 (0%) of studied solid cancer cell lines
    - In CRC MSI-H, high efficacy (IC50 <100 nM) was observed in 4/7 (57%) of ASXL1 mutated cell lines and in 0/5 (0%) of non-ASXL1 mutated cell lines
    - In NSCLC, high efficacy (IC50 <100 nM) was observed in 2/2 (100%) of ASXL1 mutated cell lines and in 0/4 (0%) of non-ASXL1 mutated cell lines
- No activity was observed in any of the studied cell lines with revumenib (negative control) at any concentration
- Staurosporine activity was confirmed, but interestingly and importantly, SLS009 outperformed positive control staurosporine in 5/9 cell lines

PIVOT Program

In December 2022, we announced that SLS009 will be evaluated in pediatric solid tumors and leukemia models through the NCI Pediatric Preclinical in Vivo Testing, or PIVOT, program. SLS009 testing through the program involves a three-phase research plan for PK, tolerability, and efficacy in pediatric tumors. In the first phase, PIVOT principal investigators will conduct PK experiments to confirm the appropriate dose and route administration for SLS009. In the second phase, tolerability of the dose and route of administration selected from the PK phase will be determined. In the last phase, monotherapy in vivo efficacy testing for SLS009 will be performed by PIVOT investigators. Studies will be supported through cooperative agreement grants from the NCI to the seven PIVOT research programs performing the testing and a centralized coordinating center.

The PIVOT program is a comprehensive program to systematically evaluate novel agents against genomically characterized pediatric solid tumor and leukemia models at eight participating research institutions. By supporting a more reliable agent prioritization process, the PIVOT program contributes to the goal of accelerating discovery of more effective treatments for children with cancer.

Each PIVOT principal investigator has expertise in preclinical testing of childhood cancer in vivo models. These models utilize patient derived xenografts, many of which are refractory to current standard of care treatments, from high-risk childhood cancers and have undergone comprehensive genomic characterization to demonstrate close resemblance to genetic alterations seen in the respective human cancers. Research strategies are based on a substantial body of data showing that preclinical testing in the appropriate pediatric cancer models, combined with expertise on relative drug exposures tolerated in mice and humans, provides powerful insights into likely clinical utility of investigational agents.

PIVOT Program participating institutions and relevant pediatric cancer models are as follows:

- Jackson Laboratory which serves as PIVOT Coordinating Center
- St. Jude Children’s Research Hospital for soft tissue sarcomas including rhabdomyosarcoma

- MD Anderson Cancer Center for osteosarcoma
- University of Texas Health Science Center San Antonio for Ewing sarcoma rhabdomyosarcoma, kidney, and liver cancers
- Memorial Sloan Kettering Cancer Center for pediatric sarcomas and other solid tumors
- Children's Hospital of Chicago for orthotopic CNS tumors
- Children's Cancer Inst Australia for acute lymphoblastic leukemia
- Children's Hospital of Philadelphia for neuroblastoma

The first and second phases of the program, pharmacokinetics and tolerability, respectively, have been successfully completed and dosing regimens have been developed.

In May 2025, we announced data from this PIVOT program, which included 27 patient-derived ALL tumors from pediatric patients. Tumors were xenografted in mice in two groups, vehicle control arm and SLS009 arm. Mice were treated with a fractionated dose once per week for six consecutive weeks. Treatment was well tolerated. For all models, median survival was approximately tripled in the SLS009 arm, compared to vehicle control arm. SLS009 demonstrated delayed progression in 25/27 (93%) models and more than two times longer time to progression in 15/27 (56%) of ALL models. In addition, there were complete responses, or CR, in two models and in one of the two models CR was maintained after the treatment had been completed until the end of the study (four months). Among seven KMT2A rearranged models, time to progression was extended in all seven models, and in six out of seven (86%) time to progression was more than doubled.

Strategic Collaborations and License Agreements

Exclusive License Agreement-Memorial Sloan Kettering Cancer Center

In September 2014, we entered into a license agreement with MSK under which we were granted an exclusive license to develop and commercialize MSK's WT1 peptide vaccine technology. The MSK original license agreement was first amended in October 2015, further amended in August 2016, amended and restated in May 2017 and again amended and restated in October 2017. In connection with the entry of the original license agreement and its amendments, MSK was issued or assigned an aggregate of 4,846 ordinary shares of the privately held Bermuda exempted company, Sellas Life Sciences Group Ltd., or Private SELLAS, common stock for the year ended December 31, 2017. These common stock shares were converted into our common stock shares upon the business combination with Private SELLAS on December 29, 2017.

Under the terms of the current amended and restated MSK license agreement, we agreed to pay minimum royalty payments in the amount of $0.1 million each year commencing in 2015 and research funding costs of $0.2 million in each year and for three years commencing in January 2016. We also agreed to pay MSK a mid-six digit amount over a one year period in exchange for MSK's agreement to further amend and restate the MSK license agreement in October 2017. In addition, to the extent certain development and commercial milestones are achieved, we also agreed to pay MSK up to $17.4 million in aggregate milestone payments for each licensed product, and for each additional patent licensed product, up to $2.8 million in additional milestone payments. We also agreed to pay MSK a tiered royalty in the mid-single digits in the event of commercial sales of any licensed products and agreed to raise $25.0 million in gross proceeds no later than December 31, 2018. We raised this amount from the proceeds received from the sale of our Series A Convertible Preferred stock in March 2018 and our underwritten public offering of shares of common stock, pre-funded warrants to purchase shares of common-stock, and warrants to purchase shares of common stock in July 2018. Under the terms of the agreement, we achieved a clinical development milestone at the end of the fourth quarter of 2018, triggering a $0.5 million payment in the first quarter of 2019.

Unless terminated earlier in accordance with its terms, the MSK license agreement as amended and restated, will continue on a country-by-country and licensed product-by-licensed product basis, until the later, of: (a) expiration of the last valid claim embracing such licensed product; (b) expiration of any market exclusivity period granted by law with respect to such licensed product; or (c) ten years from the first commercial sale in such country.

Merck & Co., Inc. Clinical Trial Collaboration and Supply Agreement

In September 2017, we entered into a clinical trial collaboration and supply agreement through a Merck subsidiary, whereby we agreed with the Merck subsidiary to collaborate on a clinical program to evaluate GPS as it is administered in combination with their PD-1 inhibitor pembrolizumab in a Phase 1/2 clinical trial enrolling patients in up to five cancer indications, including both hematologic malignancies and solid tumors.

The Phase 1/2 clinical trial was designed to explore the combination of GPS plus pembrolizumab in patients with WT1+ relapsed or refractory tumors in both solid tumor and hematological cancer indications and to assess the efficacy and safety of the combination, comparing overall response rates and immune response markers achieved with the combination compared to prespecified rates based on those seen with pembrolizumab alone in comparable patient populations. This trial was initiated in December 2018. In 2020, we, together with Merck determined to focus on ovarian cancer (second or third line). We reported updated clinical and initial immune response data from this study in June 2021. In February 2022 we reported that we had completed enrollment of 17 evaluable patients in this study. In November 2022, we reported topline clinical and initial immune response data from this study, which showed that treatment with the combination of GPS and pembrolizumab compared favorably to treatment with anti-PD-1 therapy alone in a similar patient population and presented final data from this study at the International Gynecologic Cancer Society 2023 Annual Global Meeting in November 2023.

Exclusive License Agreement with 3D Medicines Inc.

In December 2020, we, together with our wholly-owned subsidiary, SLSG Limited, LLC, entered into an Exclusive License Agreement (the “3D Medicines Agreement”) with 3D Medicines pursuant to which we granted 3D Medicines a sublicensable, royalty-bearing license, under certain intellectual property owned or controlled by us, to develop, manufacture and have manufactured, and commercialize GPS and heptavalent GPS, or GPS-Plus, product candidates, or the GPS Licensed Products, for all therapeutic and other diagnostic uses in Greater China, or the 3DMed Territory. The license is exclusive, except with respect to certain know-how that has been non-exclusively licensed to us and is sublicensed to 3D Medicines on a non-exclusive basis. We have retained development, manufacturing and commercialization rights with respect to the GPS Licensed Products in the rest of the world.

In partial consideration for the rights granted by us, 3D Medicines agreed to pay us (i) a one-time upfront cash payment of $7.5 million in order to reimburse us for certain expenses incurred with respect to the development of the GPS Licensed Products prior to execution of the 3D Medicines Agreement, and (ii) milestone payments totaling up to $194.5 million in the aggregate upon the achievement of certain technology transfer, development and regulatory milestones, as well as certain net sales thresholds of GPS Licensed Products in the 3DMed Territory in a given calendar year.

3D Medicines also agreed to pay tiered royalties based upon a percentage of annual net sales of GPS Licensed Products in the 3DMed Territory ranging from the high single digits to the low double digits. The royalties are payable on a GPS Licensed Product-by- GPS Licensed Product and region-by-region basis commencing on the first commercial sale of a GPS Licensed Product in a region and continuing until the latest of (i) the date that is 15 years from the receipt of marketing authorization for such GPS Licensed Product in such region and (ii) the date that is 10 years from the expiration of the last valid claim of a licensed patent covering or claiming such GPS Licensed Product in such region. The royalty rate is subject to reduction under certain circumstances, including when generic competition for a GPS Licensed Product exists in a particular region.

3D Medicines is responsible for all costs related to developing, obtaining regulatory approval of and commercializing the GPS Licensed Products in the 3DMed Territory. 3D Medicines is required to use commercially reasonable best efforts to develop and obtain regulatory approval for, and upon receipt of regulatory approval, commercialize the GPS Licensed Products in the 3DMed Territory. A joint development committee has been established between 3D Medicines and us to coordinate and review the development, manufacturing and commercialization plans with respect to the GPS Licensed Products in the 3DMed Territory. We and 3D Medicines also agreed to negotiate in

good faith the terms and conditions of a clinical supply agreement, a commercial supply agreement, and related quality agreements pursuant to which we will manufacture or have manufactured and supply 3D Medicines with all quantities of the GPS Licensed Product necessary for 3D Medicines to develop and commercialize the GPS Licensed Products in the 3DMed Territory until 3D Medicines has received all approvals required for 3D Medicines or its designated contract manufacturing organization to manufacture the GPS Licensed Products in the 3DMed Territory.

The 3D Medicines Agreement will expire on a GPS Licensed Product-by-GPS Licensed Product and region-by-region basis on the date of the expiration of all of 3D Medicines' payment obligations to us. Upon expiration of the 3D Medicines Agreement, the license granted to 3D Medicines will become fully paid-up, perpetual and irrevocable. Either party may terminate the 3D Medicines Agreement for the other party's material breach following a cure period or upon certain insolvency events. We may terminate the 3D Medicines Agreement if 3D Medicines or its affiliates or sublicensees challenge the validity or enforceability of the licensed patents. At any time following the two-year anniversary of the effective date, 3D Medicines has the right to terminate the 3D Medicines Agreement for convenience, subject to certain requirements. 3D Medicines may terminate the 3D Medicines Agreement upon prior notice to us if the grant of the license to 3D Medicines is prohibited or delayed for a period of time due to a change of U.S. export laws and regulations.

The 3D Medicines Agreement includes customary representations and warranties, covenants and indemnification obligations for a transaction of this nature.

Under the 3D Medicines Agreement, we achieved regulatory milestones relating to agreement upon and completion of a technology transfer plan in March 2021 and June 2021, respectively, for $1.0 million each and upon approval by the NMPA in March 2022 of an IND for a Phase 1 study, which triggered a $1.0 million milestone payment to us. A total of $191.5 million in potential future development, regulatory and sales milestones, not including future royalties, remains under the 3D Medicines Agreement.

We entered into a Side Letter Agreement with 3D Medicines, dated December 5, 2022, or Side Letter, arising from our agreement with 3D Medicines for 3D Medicines to participate in the REGAL study through the inclusion of approximately 20 patients from mainland China. The Side Letter, together with the 3D Medicines Agreement, details the terms and conditions of 3D Medicines' participation in the REGAL study.

In December 2023, we announced that we had commenced a binding arbitration proceeding against 3D Medicines regarding, among other things, the trigger and payment of relevant milestone payments due to us as well as 3D Medicines' failure to use commercially reasonable best efforts to develop GPS in accordance with the terms of the agreement. See *Item 3. Legal Proceedings*.

Exclusive License Agreement with GenFleet Therapeutics (Shanghai), Inc.

On March 31, 2022, or the GenFleet Agreement Effective Date, we entered into a License Agreement, or the GenFleet Agreement, with GenFleet pursuant to which GenFleet granted to us a sublicensable, royalty-bearing license, under certain of its intellectual property, to develop, manufacture and have manufactured, and commercialize a small molecule CDK9 inhibitor, or the CDK9 Licensed Product, for the treatment, diagnosis or prevention of disease in humans and animals in all territories other than Greater China, or the SLS009 Territory. The CDK9 inhibitor, known as SLS009, is currently in a Phase 1 clinical trial in the United States and China.

In consideration for these rights, we agreed to pay to GenFleet (i) an initial payment of $10.0 million as an upfront license fee and for a technology transfer, $4.5 million of which was paid within 30 days of the GenFleet Agreement Effective Date and $5.5 million of which is due upon the first day of the 15th calendar month following the GenFleet Agreement Effective Date, (ii) development and regulatory milestone payments for up to three indications totaling up to $48.0 million in the aggregate, and (iii) milestone payments totaling up to $92.0 million in the aggregate upon the achievement of certain net sales thresholds of CDK9 Licensed Products in the SLS009 Territory in a given calendar year.

We also agreed to pay GenFleet tiered royalties based upon a percentage of annual net sales of CDK9 Licensed Products in the SLS009 Territory ranging from the low to high single digits. The royalties are payable on a CDK9 Licensed Product-by-CDK9 Licensed Product and region-by-region basis commencing on the first commercial sale

of a CDK9 Licensed Product in a region and continuing until the later of (i) the date that is 10 years following the date of first commercial sale for such CDK9 Licensed Product in such region and (ii) the date of the expiration of the last valid claim of a licensed patent covering or claiming such CDK9 Licensed Product in such region. The royalty rate is subject to reduction under certain circumstances, including when generic competition for a CDK9 Licensed Product exists in a particular region.

We are responsible for all costs related to developing, obtaining regulatory approval of and commercializing the CDK9 Licensed Products in the SLS009 Territory and we are required to use commercially reasonable efforts to develop and obtain regulatory approval for, and upon receipt of regulatory approval, commercialize the CDK9 Licensed Products in the SLS009 Territory. We and GenFleet have established a joint steering committee to coordinate and review the development, manufacturing and commercialization plans with respect to the CDK9 Licensed Products in the SLS009 Territory. We and GenFleet also have entered into a supply agreement and related quality agreement pursuant to which GenFleet is manufacturing, or having manufactured, and supplying us with all quantities of the CDK9 Licensed Product necessary for us to develop and commercialize the CDK9 Licensed Products in the SLS009 Territory.

The GenFleet Agreement will expire on a CDK9 Licensed Product-by-CDK9 Licensed Product and region-by-region basis on the date of the expiration of all of our payment obligations to GenFleet. Upon expiration of the GenFleet Agreement, the license granted to us will become fully paid-up, perpetual and irrevocable. Either party may terminate the GenFleet Agreement for the other party's material breach following a cure period or upon certain insolvency events. During the period from the first anniversary of the GenFleet Agreement Effective Date until the first regulatory approval of a CDK9 Licensed Product in any country within the SLS009 Territory, we will have the right to terminate the GenFleet Agreement upon 180 days' prior written notice to GenFleet if a clinical failure, as described in the GenFleet Agreement, occurs. If we terminate the GenFleet Agreement before the first day of the 15th calendar month following the GenFleet Agreement Effective Date, then we will be required to pay to GenFleet the remainder of the $10 million initial payment upon the first day of the 15th calendar month following the GenFleet Agreement Effective Date. Upon receipt of the first regulatory approval of a CDK9 Licensed Product and continuing throughout the term of the GenFleet Agreement, we will have the right to terminate the GenFleet Agreement upon one year's prior written notice to GenFleet. In addition, we may terminate the GenFleet Agreement upon 90 days' notice to GenFleet upon the occurrence of certain safety events described in the GenFleet Agreement.

GenFleet may terminate the GenFleet Agreement upon notice to us if we become in arrears in any payments due pursuant to the GenFleet Agreement and we fail to make the required payment within 60 days after the delivery of written notice from GenFleet. In addition, if we fail to meet the deadline for a diligence milestone event (as described in the GenFleet Agreement), GenFleet may treat such failure as a material breach which has not been cured and GenFleet will be entitled to terminate the GenFleet Agreement if such material breach is not cured within 90 days of receiving notice of such material breach.

At GenFleet's request within 30 days of termination of the GenFleet Agreement, other than termination by us for GenFleet's material breach following a cure period, we will grant GenFleet an option to enter into negotiations with us with respect to a license agreement pursuant to which we would grant GenFleet a non-exclusive, royalty-bearing, worldwide license for certain of our intellectual property that is necessary and used to develop, commercialize and manufacture the terminated products.

Manufacturing

We do not own or operate manufacturing facilities for the production of our product candidates, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We currently depend on third-party contract manufacturers for all of our required raw materials, active pharmaceutical ingredients, and finished product candidate for our clinical trials. We do not have any current contractual arrangements for the manufacture of commercial supplies of any product candidates. We currently employ internal resources and third-party consultants to manage our manufacturing contractors.

GPS

Our sole CMO for GPS drug substance peptides is Polypeptide Group. Our sole CMO for GPS drug product is Lyophilization Services of New England, Inc. (PCI Pharma Services). Our CMOs comply with cGMP requirements and manufacture product batches used in ongoing clinical trials. We anticipate the same CMOs to manufacture commercial batches. All batches for clinical trials meet release criteria and are monitored for long-term and accelerated stability.

We have significantly advanced the chemistry, manufacturing, and controls, or CMC, objectives in support of the GPS clinical development program and for licensure, including:

- Manufacturing lyophilized clinical GMP batches;
- Qualifying processes;
- Validating analytical methods; and
- Monitoring the stability program.

In the third quarter of 2023, based upon this work, we concluded a Type C meeting with the FDA regarding the CMC sections in a potential BLA for GPS. We had submitted a briefing package to FDA which provided an up-to-date overview of the extensive work we have completed for the GPS CMC program, including commercial manufacturing and regulatory plans. Following review of the package and accompanying questions to FDA, the FDA responded with positive guidance, including agreement on our proposed potency assay and manufacturing processes validation and our stability data generation plan for the commercial presentation of GPS. The current storage condition of GPS drug product is -20°C and we are collecting stability data to allow GPS to be stored in 2-8°C (36° – 46°F), which would be more optimal for supply chain logistics and would make it more accessible for end-users.

SLS009

In October 2022, we entered into a Clinical Supply Agreement with GenFleet pursuant to which GenFleet will manufacture and/or have manufactured through third parties (with which GenFleet entered into agreements and to which we have access, as necessary), and supply SLS009 and any back-up molecule or intermediary related to SLS009 (including all methods, forms, presentations, dosage strengths, dosage forms, and formulations), for our use in all research and development activities necessary to obtain, maintain or expand regulatory approval worldwide, except Greater China.

Sales and Marketing

The infrastructure required to commercialize oncology products is market and product dependent. For a rare disease, such as AML, a relatively focused infrastructure may be sufficient which would make it cost-effective for us to internally develop a marketing, access and reimbursement function, and field-based sales force. We will potentially build the infrastructure to commercialize our product candidates in North America and, possibly, Europe, if GPS or our other product candidates are approved by the FDA and other regulatory authorities. However, we will remain opportunistic in seeking strategic partnerships in these and other markets when advantageous and increase shareholder value.

The commercial infrastructure of specialty oncology products typically consists of a targeted, specialty sales force that calls on a limited and focused group of physicians supported by sales management, internal sales support, an internal marketing group, and distribution support. As GPS and our other product candidates may initially be developed for orphan indications with a relatively small number of treating physicians, we anticipate that a reduced infrastructure, including a small, targeted sales force, will be sufficient to support our sales and marketing objectives. We continue to assess the infrastructure and resources needed to establish our commercial operations and support other relevant commercial matters, such as pricing and market access.

We may elect in the future to utilize strategic partners, distributors, or contract sales forces and clinical nurse educators to assist in the commercialization of our products.

In December 2020, we entered into the 3D Medicines Agreement for the development and commercialization of GPS, as well as the Company's next generation heptavalent immunotherapeutic GPS+, which is at preclinical stage, across all therapeutic and diagnostic uses in Greater China. We have retained sole rights to GPS and GPS+ outside of Greater China. See *Strategic Collaborations and License Agreements*.

Intellectual Property

Our commercial success depends in part on our ability to avoid infringing the proprietary rights of third parties, our ability to obtain and maintain proprietary protection for our product candidates, technologies and know-how, and our ability to prevent others from infringing our proprietary rights. We seek to protect our proprietary position by, among other methods, evaluating relevant patents, establishing defensive positions, monitoring post grant proceedings in the US and foreign jurisdictions and pending intellectual property rights, preparing litigation strategies in view of the U.S. legislative framework, filing U.S. and international patent applications on technologies, inventions and improvements that are important to our business and maintaining our issued patents. We also include restrictions regarding use and disclosure of our proprietary information in our contracts with third parties, and utilize customary confidentiality and invention assignment agreements with our employees, consultants, clinical investigators, and scientific advisors to protect our confidential information and know-how. Together with our licensors, we also rely on trade secrets to protect our combined technology especially where we do not believe patent protection is appropriate or obtainable. It is our policy to operate without knowingly infringing on, or misappropriating, the proprietary rights of others.

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

The patent term of a patent that covers an FDA-approved drug may also be eligible for patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. Patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, and only one patent applicable to an approved drug may be extended. Similar provisions are available in Europe and certain other foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our product candidates receive approval by the FDA or foreign regulatory authorities, we expect to apply for patent term extensions on issued patents covering those products, depending upon the length of the clinical trials for each drug and other factors.

Our patent portfolio includes the following:

Patents and patent applications covering GPS and WT1-targeting peptides:

- Patents and patent applications co-owned by us and MSK:
    - Patent applications covering a heptavalent (7-peptide) immunotherapy composition and methods of use for treating, reducing the incidence of, or inducing an immune response against a WT1-expressing cancer pending in the United States, Australia, Canada, China, European Patent Office (or EPO), Hong Kong, India, Japan, South Korea, and Mexico, which, if granted, are expected to expire in 2040.
    - Patents covering a heptavalent (7-peptide) immunotherapy composition and uses thereof for treating, reducing the incidence of, or inducing an immune response against a WT1-expressing cancer in Israel and Russia, which are expected to expire in 2040.

- Patents and patent applications in-licensed from MSK:
  - Composition-of-matter patents covering certain WT1-targeting peptides and methods of use in the United States, which are expected to expire in 2034; and a composition-of-matter patent covering additional WT1-targeting peptides and methods of use in the United States, which is expected to expire in 2035;
  - Composition-of-matter patents covering certain WT1-targeting peptides and methods of use in Australia, Canada, China, Hong Kong, several countries in Europe, and Japan, which are expected to expire in 2034;
  - Patent applications covering certain WT1-targeting peptides and methods of use pending in the United States, Australia, the EPO, Canada, China, and Hong Kong, which, if granted, are expected to expire in 2034;
  - Patents covering methods for treating, reducing the incidence of, or inducing an immune response against a WT1-expressing cancer, using the peptides of GPS in combination with anti-PD-1 antibody checkpoint inhibitors in the United States, Australia, China, Hong Kong, several countries in Europe, South Korea, and Japan, which are expected to expire in 2037 (United States) and 2036 (Australia, China, Hong Kong, Europe and Japan);
  - Patent applications covering methods for treating, reducing the incidence of, or inducing an immune response against a WT1-expressing cancer, using the peptides of GPS in combination with immune checkpoint inhibitors pending in the United States, Australia, Canada, China, Hong Kong, the EPO, South Korea, and Japan, which, if granted, are expected to expire in 2036;
  - Composition-of-matter patents covering the WT1-A1 peptide of GPS in the United States, which are expected to expire in 2026;
  - Composition-of-matter patent covering the WT1-427 long and WT1-331 long peptides of GPS issued in the United States, which is expected to expire in 2031, and patents covering the methods of use in the United States, which are expected to expire in 2026; a patent covering nucleic acids encoding the WT1-427 long and WT1-331 long peptides of GPS and methods of use thereof in the United States, which are expected to expire in 2026; a patent covering peptide conjugates of the WT1-427 long peptide or WT1-331 long peptide in the United States, which is expected to expire in 2027; a patent covering nucleic acids encoding peptide conjugates of the WT1-427 long peptide or WT1-331 long peptide and methods of use thereof in the United States, which is expected to expire in 2029; and a patent application covering peptide conjugates of the WT1-427 long peptide or WT1-331 long peptide pending in the United States, which, if granted, is expected to expire in 2026;
  - Composition-of-matter patents covering the WT1-427 long peptide of GPS and WT1-331 long peptide of GPS, and methods of use, in Australia, Canada, several countries in Europe, and Hong Kong, which are expected to expire in 2026;
  - Composition-of-matter patent covering a WT1-specific peptide in the United States, which is expected to expire in 2026;
  - Composition-of-matter patent covering the WT1-122A1 long peptide of GPS in the United States which is expected to expire in 2033; patent covering methods of using the WT1-122A1 long peptide of GPS in the United States, which is expected to expire in 2029; and patent application covering the WT1-122A1 long peptide of GPS and methods of use thereof pending in the United States, which, if granted, is expected to expire in 2027; and
  - Composition-of-matter patent covering the WT1-122A1 long peptide of GPS and methods of use in several countries in Europe, which is expected to expire in 2027, and patent applications covering the WT1-122A1 long peptide of GPS and methods of use pending in the EPO and Canada, which, if granted, are expected to expire in 2027.

Patents and patent applications covering SLS009:

- Patents and patent applications in-licensed from GenFleet:
    - Composition-of-matter patents covering SLS009 and use thereof in the treatment or amelioration of cancer in the United States, Australia, Brazil, Canada, Japan, Russia, South Korea, and several countries in Europe, which are expected to expire in 2038; and
    - Patents covering maleate and fumarate polymorphs of SLS009 and uses thereof in prevention or treatment of CDK9-related diseases, including cancer, in the United States, Australia, Canada, Eurasian Patent Office, South Korea, and Japan, which are expected to expire in 2042 (United States) and 2040 (Australia, Canada, Eurasian Patent Office, South Korea, and Japan); patent applications covering maleate and fumarate salt forms and polymorphs of SLS009, syntheses thereof, and use thereof in prevention or treatment of CDK9-related diseases, including cancer, pending in the United States, Brazil, the EPO, and the Eurasian Patent Office, which, if granted, are expected to expire in 2040.
- Patents and patent applications owned by us:
    - Patent applications covering methods of treating cancer in a subject having an ASXL1 mutation using CDK9 inhibitors in the Patent Cooperation Treaty (PCT) and Taiwan, which, if granted, are expected to expire in 2045.

Competition

Oncology in general, and specifically, cancer immunotherapy, is a significant growth area for the biopharmaceutical industry, attracting large pharmaceutical companies as well as small niche players. While we believe that our scientific knowledge, assets, development experience and ability to attract experienced commercial professionals provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, which either alone or together with their collaborative partners, have substantially greater resources than we have.

Generally, our competitors in the oncology therapeutic market are large and mid-sized companies with approved oncology therapeutic products and companies currently engaged in clinical development of such products. Any product candidates that we successfully develop and commercialize may compete with these existing therapies and new therapies that may become available in the future.

Companies developing novel products with similar indications to those we are pursuing and may pursue are expected to influence our ability to penetrate and maintain market share. Principal competitors for AML broadly include companies with currently marketed products, such as AbbVie/Genentech (Venclexta), Pfizer (Mylotarg), Daiichi-Sankyo (Vanflyta), Rigel Pharmaceuticals (Rezlidhia), Syndax Pharmaceuticals (Revumenib) and Bristol Myers Squibb (Vidaza and Onureg), among others. There are also companies developing therapies to treat AML in the r/r setting, which are in earlier stages of clinical development, including emavusertib, which is in a Phase 1/2 trial in AML and being developed by Curis, and later-stage clinical development candidates which may enter the market before our potential products, such as Delta-Fly Pharma (DFP-10917) and AROG Pharmaceuticals (crenolanib).

With respect to WT1-targeting therapies, we do not believe GPS has direct competition in AML in the maintenance setting after CR2 at this time. While there are companies engaged in the clinical development of WT-1 targeting therapies, they are not currently focused on AML or have since discontinued or paused their development of WT-1 targeting therapies.

With respect to SLS009, we anticipate competition from companies who have been engaged in the clinical development of selective CKD9-targeting therapies. There are other companies which are in early development stages for their CDK9 inhibitors and targeting other hematologic malignancies or solid tumors, including Sumitomo Dainippon Pharma (TP-1287), Cothera Bioscience (zotiraciclib), and Prelude Therapeutics (PRT2527).

With regard to both GPS and SLS009, many of our competitors, either alone or with their strategic partners, may have substantially greater resources and expertise in research and development, manufacturing, preclinical testing, obtaining regulatory approvals, and marketing approved products than we have. Mergers and acquisitions in the biotechnology, pharmaceutical and diagnostics industries may result in even more resources being concentrated among a smaller number of our competitors. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel, the ability to work with specific clinical contract organizations due to conflict of interest, and also the conduct of trials in the ability to recruit clinical trial sites and subjects for our clinical trials. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These activities may lead to consolidated efforts that allow for more rapid development of cancer immunotherapy product candidates.

We expect the key competitive factors that could affect the success of any products that we develop and commercialize are likely to be efficacy, safety, price, level of generic competition, placement (or lack thereof) in clinical treatment guidelines and the availability of reimbursement from government and other third-party payors. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are viewed as safer, more convenient or less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for our current product candidates or any other future product candidate, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to complete may be affected by insurers or other third-party payors seeking to encourage the use of generic or biosimilar products. If our therapeutic product candidates are approved, we believe that they would be priced at a premium over competitive generic products.

Employees and Human Capital

We have assembled a management team of biopharmaceutical experts with extensive experience in building and operating organizations that develop and deliver innovative medicines to patients with cancer. Our management team has broad expertise and successful track records in clinical development and approval of cancer therapies.

As of March 1, 2026, we had 13 full-time employees. In addition to our full-time employees, we engage various independent consultants and advisors to support key areas of our business. None of our employees are represented by a labor union or covered by collective bargaining agreements. We believe our relationship with our employees is good.

Our employees have various backgrounds, experience, and perspectives. For example, as of March 1, 2026, of our 13 employees, 54% are women, 31% are racial or ethnic minorities, and 54% have advanced degrees. In addition, two of our six Board of Director members are women. We believe we have built and continue to build a strong diverse and inclusive culture of cooperation, respect and acceptance.

We are committed to identifying, retaining, and incentivizing highly skilled employees, and we are able to recruit talented individuals through our competitive benefits, compensation packages and health and wellness initiatives, which are based on peer company benchmarks.

Government Regulation

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

A biologic candidate is licensed by the FDA through approval of a biologics license application, or BLA. Assuming we receive positive data from our REGAL clinical trial of GPS in patients with AML, we will submit a BLA to the FDA. A drug candidate must be approved by the FDA through a new drug application, or NDA. For SLS009, we will seek marketing approval through the submission of an NDA to the FDA. The process required by the FDA before drug or biological product candidates may be marketed in the United States generally involves the following:

- completion of extensive nonclinical laboratory tests and animal studies performed in accordance with the FDA's current good laboratory practice, or GLP, regulations and other applicable regulations;
- submission to the FDA of an IND application, which must become effective before clinical trials may begin and must be updated annually or when significant changes are made;
- approval by an institutional review board, or IRB, or ethics committee at each clinical site before the trial is initiated at such sites;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practice, or GCP, and other clinical-trial related regulations to establish the safety and efficacy of the investigational product candidate for its proposed indication;
- preparation of and submission to the FDA of an NDA or BLA, after completion of all pivotal clinical trials;
- a determination by the FDA within 60 days of its receipt of an NDA or BLA to file the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with current good manufacturing practice, or cGMP, regulations and to assure that the facilities, methods and controls are adequate to preserve the product's continued identity, strength, quality and purity for a drug and safety, purity and potency for a biologic;
- potential audit of selected clinical trial sites to assess compliance with GCP and the integrity of the clinical data submitted in support of the NDA or BLA; and
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- FDA review and approval of the NDA or BLA to permit commercial marketing of the product for particular indications for use in the United States.

The testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our current or future product candidates will be granted on a timely basis, if at all.

Preclinical testing

Before testing any drug or biological product candidate, including our product candidates, in humans, the product candidate must undergo rigorous preclinical testing. Nonclinical studies during the preclinical development stage include laboratory evaluation of product chemistry and formulation and typically include in vitro and animal studies to assess the potential for adverse events and in some cases to establish a rationale for therapeutic use. The Consolidated Appropriations Act for 2023, signed into law on December 29, 2022, (P.L. 117-328) amended the Food, Drug, and Cosmetic Act, or the FDCA, and the Public Health Service Act to specify that nonclinical testing for drugs and biologics may, but is not required to, include in vivo animal testing. According to the amended language,

a sponsor may fulfill nonclinical testing requirements by completing various in vitro assays (e.g., cell-based assays, organ chips, or microphysiological systems), in silico studies (i.e., computer modeling), other human or nonhuman biology-based tests (e.g., bioprinting), or in vivo animal tests. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations for safety/toxicology studies. Some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue after an IND for an investigational drug or biologic candidate is submitted to the FDA and human clinical trials have been initiated.

Prior to beginning the first clinical trial with a product candidate, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. The IND also includes the results of the nonclinical studies of the product candidate, together with manufacturing information, analytical data, any available clinical data or literature. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, issues a notice expressly authorizing the proposed trial to proceed or raises safety concerns or questions about the proposed clinical trial. If the FDA raises concerns or places the trial on clinical hold, the IND may be placed on clinical hold and the IND sponsor and the agency must resolve any outstanding concerns or questions before the proposed trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

Human clinical trials in support of an NDA or BLA

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCP and other trial-related regulations, which include, among other things, the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site and must monitor the clinical trial until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent data safety monitoring board, or DSMB, organized by the clinical trial sponsor, which at designated check points based on access to certain data from the clinical trial may recommend that the sponsor halt the trial if the DSMB determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy.

Information about certain clinical trials, including details of the protocol and eventually study results, also must be submitted within specific timeframes to the NIH for public dissemination on the ClinicalTrials.gov data registry. Information related to the product, patient population, phase of investigation, study site locations and other aspects of the clinical trial is made public as part of the registration of the clinical trial. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed in some cases for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs. Failure to timely register a covered clinical trial or to submit study results as provided for in the law can give rise to civil monetary penalties and also prevent the non-compliant party from receiving future grant funds from the federal government. The NIH Final Rule on ClinicalTrials.gov registration and reporting requirements became effective in 2017, and both NIH and FDA have brought enforcement actions against non-compliant clinical trial sponsors.

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

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

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

- **Phase 3**-The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval and labeling. These trials may include comparisons with placebo and/or other comparator treatments. The duration of treatment is often extended to mimic the actual use of a product during marketing.

- **Phase 4**-In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain additional information and experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow up. These so-called Phase 4 studies may be made a condition to approval of the BLA or NDA.

In the Consolidated Appropriations Act for 2023, Congress amended the FDCA to require sponsors of a Phase 3 clinical trial, or other “pivotal study” of a new drug to support marketing authorization, to submit a diversity action plan for such clinical trial. The action plan must include the sponsor’s diversity goals for enrollment, as well as a rationale for the goals and a description of how the sponsor will meet them. A sponsor must submit a diversity action plan to FDA by the time the sponsor submits the trial protocol to the agency for review. The FDA may grant a waiver for some or all of the requirements for a diversity action plan. To grant a waiver, FDA must determine that the prevalence or incidence of the disease or condition being studied makes it impracticable to conduct a clinical trial in accordance with a diversity action plan, or that a waiver is necessary to protect public health during a public health emergency. Our Phase 3 REGAL trial of GPS for AML patients who have achieved CR2 was initiated before this requirement became effective, but for any future Phase 3 trials we plan to conduct, we must submit a diversity action plan to the FDA by the time we submit plans for such Phase 3, or pivotal study, protocol to the agency for review as part of an IND, unless we are able to obtain a waiver for some or all of the requirements for a diversity action plan. If FDA objects to a sponsor’s diversity action plan and requires the sponsor to amend the plan or take other actions, it may delay trial initiation.

Phase 1, Phase 2 and Phase 3 testing may not be completed successfully within a specified period, if at all, and there can be no assurance that the data collected will support FDA approval or licensure of the product.

Progress reports detailing the progress of and safety data from the clinical trials must be submitted at least annually to the FDA and more frequently if unexpected serious adverse events, or SAEs, occur. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the clinical protocol, GCP regulations, or other IRB requirements or if the drug has been associated with unexpected serious harm to patients.

Concurrent with clinical trials, companies may complete additional nonclinical studies and develop additional information about the biological characteristics of the product candidate and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must incorporate methods for testing the identity, strength, quality and purity of the final product, or for biologics, the safety, purity and potency. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

Marketing Application Submission and Review by the FDA

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, preclinical studies and clinical trials are submitted to the FDA as part of an NDA or BLA requesting approval to market the product for one or more indications. The NDA or BLA must contain proof of the product candidate's safety and substantial evidence of effectiveness for its proposed indication or indications in the form of relevant data available from pertinent preclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. In particular, a marketing application must demonstrate that the manufacturing methods and quality controls used to produce the drug or biological product are adequate to preserve the drug's identity, strength, quality, and purity for an NDA or a biologic's safety, purity, and potency for a BLA. Data can come from company-sponsored clinical studies intended to test the safety and effectiveness of a use of the product, or from a number of alternative sources, including studies initiated by investigators. FDA approval of an NDA or BLA must be obtained before the corresponding drug or biologic may be marketed in the United States.

Under federal law, the fee for the submission of an NDA or BLA for which clinical data is submitted and analyzed is substantial, and the sponsor of an approved NDA or BLA is also subject to an annual program fee. These fees are typically increased annually, but exemptions and waivers may be available under certain circumstances (such as a waiver for the first human drug application submitted by a qualifying small business and exemptions for orphan products).

The FDA reviews all submitted NDAs and BLAs to determine if they are substantially complete before it accepts them for filing and may request additional information rather than accepting a submission for filing. The FDA must make a decision on accepting an NDA or BLA for filing within 60 days of receipt and must inform the sponsor by the 74th day after the FDA's receipt of the submission whether the application is sufficiently complete to permit substantive review. The FDA may refuse to file any submission that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the marketing application must be resubmitted with the additional information requested by the agency. The resubmitted application is also subject to review before the FDA accepts it for filing.

Once an NDA or BLA is accepted for filing, the FDA's goal is to review the application within 10 months after it accepts the application for filing, or, if the application meets the criteria for "priority review", within six months after the FDA accepts the application for filing. The review process is often significantly extended by FDA requests for additional information or clarification after the NDA or BLA has been accepted for filing. The review process may be extended by the FDA for three additional months to consider new information or in the case of a clarification provided by the applicant to address an outstanding deficiency identified by the FDA following the original submission.

During the review process, the FDA reviews the NDA or BLA to determine, among other things, whether the product is safe, effective, pure and potent and whether the facility in which it is manufactured, processed, packed, or held meets standards designed to assure the product's continued safety, quality, purity and potency. The FDA may refer any NDA or BLA, including applications for novel drug or biologic candidates which present difficult questions of safety or efficacy, to an advisory committee to provide clinical insight on application review questions. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendation of an advisory committee, but it considers such recommendations carefully when making final decisions on approval.

Before approving an NDA or BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA or BLA, the FDA will typically inspect one or more clinical trial sites to assure compliance with GCP and integrity of the trial data. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies as part of the review process and often will request additional testing or information. Notwithstanding the submission of

any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

Under the Pediatric Research Equity Act, or PREA, amendments to the FDCA, an NDA or BLA or supplement to such applications must contain data that are adequate to assess the safety and efficacy of the product candidate for the claimed indications in all relevant pediatric populations and to support dosing and administration for each pediatric population for which the product is safe and effective. The FDA may grant deferrals for submission of pediatric data or full or partial waivers. The PREA requires a sponsor that is planning to submit a marketing application for a product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration to submit an initial Pediatric Study Plan, or PSP, within 60 days of an end of-Phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2/3 clinical trial. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including trial objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach an agreement on the PSP. A sponsor can submit amendments to an agreed upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early-phase clinical trials or other clinical development programs.

The testing and approval process requires substantial time, effort and financial resources, and each may take several years to complete. The FDA may not grant approval on a timely basis, or at all, and we may encounter difficulties or unanticipated costs in our efforts to secure necessary governmental approvals, which could delay or preclude us from marketing our products. After the FDA evaluates an NDA or BLA and conducts inspections of the manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response Letter, or CRL. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A CRL indicates that the review cycle of the application is complete and the application will not be approved in its present form. A CRL generally outlines the deficiencies in the submission and may require substantial additional testing, information or clarification for FDA to reconsider the application. The FDA may delay or refuse approval of an NDA or BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product. In September 2025, the FDA began publishing CRLs soon after issuing them to the respective sponsors, breaking with long standing agency tradition of publishing CRLs with approval documentation after the product is approved. If a CRL is issued, the applicant may either resubmit the NDA or BLA, addressing all of the deficiencies identified in the letter, or withdraw the application. If and when the deficiencies have been addressed to the FDA's satisfaction in a resubmission of the marketing application, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in response to an issued CRL in either two or six months depending on the type of information included. Even if such data and information are submitted, the FDA may ultimately decide that the NDA or BLA does not satisfy the criteria for approval.

If regulatory approval of a product is granted, such approval is limited to the conditions of use (e.g., patient population, indication) described in the application and may entail further limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the NDA or BLA with a Risk Evaluation and Mitigation Strategy, or REMS, plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA determines the requirement for a REMS, as well as the specific REMS provisions, on a case-by-case basis. If the FDA concludes a REMS plan is needed, the sponsor of the NDA or BLA must submit a proposed REMS. The FDA will not approve an NDA or BLA without a REMS, if one is required. The FDA also may condition approval on, among other things, changes to proposed labeling (e.g., adding contraindications, warnings or precautions) or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing regulatory standards is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization and may limit further marketing of the product based on the results of these post-marketing studies. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval. In addition, new government requirements, including those resulting from new legislation,

may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

Fast Track, Priority Review, and Breakthrough Therapy Designations

A sponsor may seek approval of its product candidate under programs designed to accelerate FDA's review and approval of new drugs and biological products that meet certain criteria. Specifically, new drugs and biological products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. Fast Track designation provides increased opportunities for sponsor interactions with the FDA during preclinical and clinical development, in addition to the potential for rolling review once a marketing application is filed, meaning that the FDA may consider for review sections of the NDA or 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 NDA or BLA, the FDA agrees to accept sections of the marketing application and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application. A Fast Track designated product candidate may also qualify for accelerated approval (described below) or priority review, under which the FDA sets the target date for FDA action on the NDA or BLA at six months after the FDA accepts the application for filing. We have obtained Fast Track designation for GPS in AML, MPM and MM, and for SLS009 in r/r AML and r/r PTCL.

Priority review is granted when there is evidence that the proposed product would be a significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of a serious condition. 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. If criteria are not met for priority review, the application is subject to the standard FDA review period of ten months after FDA accepts the application for filing.

A sponsor may seek FDA designation of its product candidate as a Breakthrough Therapy, if the product candidate is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the therapy may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Breakthrough Therapy designation provides all the features of Fast Track designation in addition to intensive guidance on an efficient development program beginning as early as Phase 1, and FDA organizational commitment to expedited development, including involvement of senior managers and experienced review and regulatory staff in a proactive, collaborative, cross-disciplinary review, where appropriate. A drug designated as Breakthrough Therapy is also eligible for accelerated approval if the relevant criteria are met.

In 2025, the FDA created a new voucher program called the Commissioner's National Priority Voucher ("CNPV") with the goal of radically expediting the drug and biological product review and approval process. The agency may award a CNPV to a company or a specific product candidate that demonstrates alignment with certain national health priorities. The FDA aims to take action on a marketing application for which a CNPV is used within one to two months after the filing date.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. None of these programs changes the scientific or medical standards for approval or the quality of evidence necessary to support approval but may expedite the development or approval process.

Accelerated Approval

In addition, products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval from the FDA and may be approved on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant

accelerated approval for such a drug or biologic when it has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, or IMM, and that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug or biologic receiving accelerated approval perform post-marketing clinical trials to verify and describe the predicted effect on IMM or other clinical endpoint, and the product may be subject to expedited withdrawal procedures. Drugs and biologics granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

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. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a drug or biologic, such as an effect on IMM. The FDA has limited experience with accelerated approvals based on intermediate clinical endpoints but has indicated that such endpoints generally may support accelerated approval when the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate long-term clinical benefit of a drug or biologic.

The accelerated approval pathway is most often used in settings in which the course of a disease is long and an extended period of time is required to measure the intended clinical benefit of a drug, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. For example, accelerated approval has been used extensively in the development and approval of drugs and biologics for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large clinical trials to demonstrate a clinical or survival benefit.

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the product candidate's clinical benefit. As a result, a product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or to confirm the predicted clinical benefit of the product during post-marketing studies, would allow the FDA to withdraw approval of the product. As part of the Consolidated
Appropriations Act for 2023, Congress provided the FDA additional statutory authority to mitigate potential risks to
patients from continued marketing of ineffective drugs or biologics previously granted accelerated approval. Under
the act's amendments to the FDCA, the FDA may require the sponsor of a product being considered for accelerated approval to have a confirmatory trial underway prior to approval. The sponsor must also submit progress reports on a confirmatory trial every six months until the trial is complete, and such reports are published on the FDA's website. The amendments also give the FDA the option of using expedited procedures to withdraw product approval if the sponsor's confirmatory trial fails to verify the claimed clinical benefits of the product.

All promotional materials for product candidates being considered and approved under the accelerated approval program are subject to prior review by the FDA.

Orphan Drugs

Under the Orphan Drug Act, the FDA may grant Orphan Drug Product Designation to a drug or biologic intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 individuals in the United States and when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the United States will be recovered from sales in the United States for that drug or biologic. Orphan Drug Product Designation must be requested before submitting an NDA or BLA. After the FDA grants Orphan Drug Product Designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA.

If a drug or biologic product that has Orphan Drug Product Designation subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a full NDA or BLA, to market the same drug or biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan product exclusivity or if FDA finds that the holder of the orphan product exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan product to meet the needs of patients with the disease or condition for which the drug or biologic was designated. Orphan product exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of Orphan Drug Product Designation are tax credits for certain research and a waiver of NDA or the BLA application user fee.

A drug or biologic with Orphan Drug Product Designation may not receive orphan product exclusivity if it is approved for a use that is broader than the indication for which it received Orphan Drug Product Designation. In addition, orphan product exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Court cases have challenged FDA's approach to determining the scope of orphan drug exclusivity; however, at this time the agency continues to apply its long-standing interpretation of the governing regulations and has stated that it does not plan to change any orphan drug implementing regulations.

We have obtained Orphan Drug Product Designation in the United States for GPS in AML, MPM and MM and for SLS009 for AML and PTCL.

Pediatric exclusivity

Pediatric exclusivity is a type of non-patent marketing exclusivity available in the United States and, if granted, it provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity or listed patents. This six-month exclusivity may be granted if an NDA or BLA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application. The issuance of a written request does not require the sponsor to undertake the described studies.

Patent term restoration

Depending upon the timing, duration and specifics of FDA approval of the use of our product candidates, some of our United States patents may be eligible for limited patent term extension under the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product candidate's approval date. The patent term restoration period is generally one half of the time between the effective date of an IND and the submission date of an NDA or BLA, plus the time between the submission date of the NDA or BLA and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved product candidate is eligible for the extension and the application for extension must be made prior to expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we intend to apply for restorations of patent term for some of our currently owned or licensed patents to add patent life beyond their current expiration date, depending on the expected length of clinical trials and other factors involved in the submission of the relevant NDA or BLA.

Abbreviated new drug applications for generic drugs

In 1984, with passage of the Drug Price Competition and Patent Term Restoration Act, or Hatch-Waxman Act, which established an abbreviated regulatory scheme authorizing the FDA to approve generic drugs based on an innovator or "reference" product, Congress also enacted Section 505(b)(2) of the FDCA, which provides a hybrid pathway combining features of a traditional NDA and a generic drug application. To obtain approval of a generic drug, an applicant must submit an abbreviated new drug application, or ANDA, to the agency. ANDAs are "abbreviated" because they do not include preclinical and clinical data to demonstrate safety and effectiveness.

Instead, in support of such applications, a generic manufacturer may rely on the preclinical and clinical testing previously conducted for a drug product previously approved under an NDA, known as the reference-listed drug, or RLD.

Specifically, in order for an ANDA to be approved, the FDA must find that the generic version is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form, and the strength of the drug. At the same time, the FDA must also determine that the generic drug is "bioequivalent" to the innovator drug. Under the statute, a generic drug is bioequivalent to an RLD if "the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug."

Upon approval of an ANDA, the FDA indicates whether the generic product is "therapeutically equivalent" to the RLD in its publication Approved Drug Products with Therapeutic Equivalence Evaluations, also referred to as the Orange Book. Clinicians and pharmacists consider a therapeutic equivalent generic drug to be fully substitutable for the RLD. In addition, by operation of certain state laws and numerous health insurance programs, the FDA's designation of therapeutic equivalence often results in substitution of the generic drug without the knowledge or consent of either the prescribing clinicians or patient.

In contrast, Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. A Section 505(b)(2) applicant may eliminate the need to conduct certain preclinical or clinical studies, if it can establish that reliance on studies conducted for a previously approved product is scientifically appropriate. Unlike the ANDA pathway used by developers of bioequivalent versions of innovator drugs, the 505(b)(2) regulatory pathway does not preclude the possibility that a follow-on applicant would need to conduct additional clinical trials or nonclinical studies; for example, they may be seeking approval to market a previously approved drug for new indications or for a new patient population that would require new clinical data to demonstrate safety or effectiveness.

In addition, under the Hatch-Waxman Act, the FDA might not approve an ANDA or 505(b)(2) NDA until any applicable period of non-patent exclusivity for the RLD has expired. These market exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a period of five years of non-patent data exclusivity for a new drug containing a new chemical entity. For the purposes of this provision, a new chemical entity, or NCE, is a drug that contains no active moiety that has previously been approved by the FDA in any other NDA. An active moiety is the molecule or ion responsible for the physiological or pharmacological action of the drug substance. In cases where such NCE exclusivity has been granted, an ANDA or 505(b)(2) NDA may not be filed with the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification (described below), in which case the applicant may submit its application four years following the original product approval.

The FDCA also provides for a period of three years of exclusivity for an NDA, 505(b)(2) NDA or supplement thereto if one or more new clinical investigations, other than bioavailability or bioequivalence studies, that were conducted by or for the applicant are deemed by the FDA to be essential to the approval of the application. This three-year exclusivity period often protects changes to a previously approved drug product, such as a new dosage form, route of administration, combination or indication. The three-year exclusivity covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving follow-on applications for drugs containing the original active agent. Five-year and three-year exclusivity also will not delay the submission or approval of a traditional NDA filed under Section 505(b)(1) of the FDCA. However, an applicant submitting a traditional NDA would be required to either conduct or obtain a right of reference to all of the preclinical studies and
adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Hatch-Waxman patent certification and the 30-month stay

Upon approval of an NDA or a supplement thereto, NDA sponsors are required to list with the FDA each patent with claims that cover the applicant's product or an approved method of using the product. Each of the patents listed by the NDA sponsor is published in the Orange Book. When an ANDA applicant files its application with the FDA, the applicant is required to certify to the FDA concerning any patents listed for the reference product in the Orange Book, except for patents covering methods of use for which the ANDA applicant is not seeking approval. To the extent that the Section 505(b)(2) NDA applicant is relying on studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would.

Specifically, the applicant must certify with respect to each patent that:

I. the required patent information has not been filed by the original applicant;
II. the listed patent has expired;
III. the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or
IV. the listed patent is invalid, unenforceable or will not be infringed by the manufacture, use or sale of the new product.

If a Paragraph I or II certification is filed, the FDA may make approval of the application effective immediately upon completion of its review. If a Paragraph III certification is filed, the approval may be made effective on the patent expiration date specified in the application, although a tentative approval may be issued before that time. If an application contains a Paragraph IV certification, a series of events will be triggered, the outcome of which will determine the effective date of approval of the ANDA or 505(b)(2) application.

If the follow-on applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the follow-on application in question has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA or 505(b)(2) NDA until the earlier of 30 months after the receipt of the Paragraph IV notice, expiration of the patent, or a decision in the infringement case that is favorable to the ANDA or 505(b)(2) applicant. Alternatively, if the listed patent holder does not file a patent infringement lawsuit within the required 45-day period, the follow-on applicant's ANDA or 505(b)(2) NDA will not be subject to the 30-month stay.

Reference a product exclusivity for biological products

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, amended the PHSA to authorize the FDA to approve similar versions of innovative biologics such as ours, which are also known as "reference biological products." The new pathway authorized under the BPCIA allows FDA to approve, under an abbreviated application, a biological product that are demonstrated to be "biosimilar" or "interchangeable" with an FDA-licensed reference biological product. Biosimilarity to an approved reference product requires that there be no differences in mechanism of action for the conditions of use, route of administration, dosage form, and strength, and no clinically meaningful differences between the follow-on biological product and the reference product in terms of safety, purity, and potency. Biosimilarity is demonstrated in steps beginning with rigorous analytical studies or "fingerprinting," *in vitro* studies, *in vivo* animal studies, and for some biosimilar products, at least one clinical study, absent a waiver from the FDA. The biosimilarity exercise tests the hypothesis that the investigational product and the reference product are the same. If at any point in the stepwise biosimilarity process a significant difference is observed, then the products are not biosimilar, and the development of a standalone BLA for the follow-on biological product is necessary. In order to meet the higher hurdle of interchangeability, a sponsor must demonstrate that the biosimilar product can be expected to produce the same clinical result as the reference product, and for a product that is administered more than once, that the risk of switching between the reference product and biosimilar product is not greater than the risk of maintaining the patient on the reference product. Complexities associated with the larger,

and often more complex, structures of biological products, as well as the process by which such products are manufactured, pose significant hurdles to implementation that are still being evaluated by the FDA.

Under the BPCIA, a reference biological product is granted 12 years of data exclusivity from the date of first licensure of the product, which means that the FDA is barred from approving biosimilar applications for 12 years after the reference biological product receives initial marketing approval. The first approved interchangeable biological product will be granted an exclusivity period of up to one year after it is first commercially marketed, and as part of the Consolidated Appropriations Act for 2023, Congress amended the PHSA in order to permit multiple interchangeable products approved on the same day to receive and benefit from this one-year exclusivity period. In addition, the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. “First licensure” typically means the initial date the particular product at issue was licensed in the United States. Date of first licensure does not include the date of licensure of (and a new period of exclusivity is not available for) a supplement for the reference product for a subsequent application filed by the same sponsor or manufacturer of the reference product (or licensor, predecessor in interest or other related entity) for a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength or for a modification to the structure of the biological product that does not result in a change in safety, purity or potency. Therefore, one must determine whether a new product includes a modification to the structure of a previously licensed product that results in a change in safety, purity or potency to assess whether the licensure of the new product is a first licensure that triggers its own period of exclusivity. Whether a subsequent application, if approved, warrants exclusivity as the “first licensure” of a biological product is determined on a case-by-case basis with data submitted by the sponsor.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, some government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact, implementation and meaning of the BPCIA continues to be subject to significant uncertainty.

Post-approval requirements

Following approval of a new product, the manufacturer and the approved product are subject to pervasive and continuing regulation by the FDA, including, among other things, monitoring and recordkeeping activities, reporting of adverse experiences with the product, product sampling and distribution restrictions, complying with promotion and advertising requirements, which include restrictions on promoting drugs for unapproved uses or patient populations (i.e., “off-label use”) and limitations on industry-sponsored scientific and educational activities. The manufacturer and its products are also subject to similar post-approval requirements by regulatory authorities comparable to FDA in jurisdictions outside of the United States where the products are approved. Although physicians may prescribe legally available products for off-label uses, manufacturers may not market or promote such uses. 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. If there are any modifications to the product, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA or BLA or a supplement thereto, which may require the applicant to develop additional data or conduct additional preclinical studies and clinical trials. The FDA may also place other conditions on approvals including the requirement for a REMS to assure the safe use of the product. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMP. The cGMP regulations include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports and returned or salvaged products. The manufacturing facilities for our product candidates must meet applicable cGMP

requirements to the FDA's or comparable foreign regulatory authorities' satisfaction before any product is approved and our commercial products can be manufactured. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products in accordance with cGMP regulations. These manufacturers must comply with cGMP regulations that require, among other things, quality control and quality assurance, the maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved drugs or biologics are required to register their establishments with the FDA and certain state agencies and are subject to periodic prescheduled or unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. Future inspections by the FDA and other regulatory agencies may identify compliance issues at the facilities of our CMOs that may disrupt production or distribution or require substantial resources to correct. In addition, the discovery of conditions that violate these rules, including failure to conform to cGMP, could result in enforcement actions, and the discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved BLA, including voluntary recall and regulatory sanctions as described below.

Once an approval of a drug or biologic is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in mandatory revisions to the approved labeling to add new safety information; imposition of post-market or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or other enforcement-related letters or clinical holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or BLAs or supplements to approved marketing authorizations, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- injunctions or the imposition of civil or criminal penalties; and
- consent decrees, corporate integrity agreements, debarment, or exclusion from federal health care programs; or mandated modification of promotional materials and labeling and the issuance of corrective information.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drugs and drug samples at the federal level and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution. Furthermore, the Drug Supply Chain Security Act, or DSCSA, was enacted with the aim of building an electronic system to identify and trace certain prescription drugs distributed in the United States, including most biological products. The DSCSA mandates resource-intensive obligations for pharmaceutical manufacturers, wholesale distributors, and dispensers. From time to time, new legislation and regulations may be implemented that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. It is impossible to predict whether further legislative or regulatory changes will be enacted, whether FDA regulations, guidance or interpretations will be changed or what the impact of such changes, if any, may be.

Other Health Care Laws and Compliance Requirements

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

The federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving, or paying remuneration, directly or indirectly, in cash or in kind, in exchange for or to induce or reward either the referral of patients for, or the purchase, order or recommendation of, any good or service that may be paid for in whole or part by Medicare, Medicaid or other federal health care programs. Remuneration has been broadly defined to include anything of value, including cash, improper discounts, and free or reduced-price items and services. The government has enforced the Anti-Kickback Statute to reach large settlements with health care companies based on sham research or consulting and other financial arrangements with physicians. Further, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. Many states have similar laws that apply to their state health care programs as well as private payors.

The FCA imposes liability on persons who, among other things, (i) knowingly present or cause to be presented false or fraudulent claims for payment or approval by a federal health care program, (ii) knowingly make, use, or cause to be made or used a false record or statement material to a false or fraudulent claim to the federal government, or (iii) avoid, decrease, or conceal an obligation to pay money to the federal government. The FCA has been used to prosecute persons submitting claims for payment that are inaccurate or fraudulent, that are for services not provided as claimed, or for services that are not medically necessary. Actions under the FCA may be brought by the U.S. Attorney General or as a qui tam action by a private individual in the name of the government. Violations of the FCA can result in significant monetary penalties and treble damages. The federal government is using the FCA, and the accompanying threat of significant liability, in its investigation and prosecution of pharmaceutical and biotechnology companies throughout the country, for example, in connection with the promotion of products for unapproved uses and other sales and marketing practices. The government has obtained multi-million and multi-billion dollar settlements under the FCA in addition to individual criminal convictions under applicable criminal statutes. Conviction or civil judgment for violating the FCA may result in exclusion from federal health care programs, and suspension and debarment from government contracts, and refusal of orders under existing government contracts. In addition, companies have been forced to implement extensive corrective action plans and have often become subject to consent decrees or corporate integrity agreements, restricting the manner in which they conduct their business. The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, also created federal criminal statutes that prohibit, among other things, knowingly and willfully executing a scheme to defraud any health care benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services. Given the significant size of actual and potential settlements, it is expected that the government will continue to devote substantial resources to investigating health care providers' and manufacturers' compliance with applicable fraud and abuse laws.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians and other health care providers. The federal Physician Payments Sunshine Act, enacted as part of the Patient Protection and Affordable Care Act of 2010, or the ACA, requires manufacturers of FDA-approved drugs, devices, biologics and medical supplies covered by Medicare, Medicaid or the Children's Health Insurance Program to report, on an annual basis, to CMS information related to payments or other transfers of value made by them to U.S.-licensed physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain advanced non-physician health care practitioners and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to submit required information may result in civil monetary penalties**.** Certain states also mandate implementation of commercial compliance programs, impose restrictions on drug manufacturer marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to physicians and other health care professionals.

The federal criminal statutes enacted under HIPAA impose criminal liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any health care benefit program, including private third-party payors, 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 health care benefit program; knowingly and willfully embezzling or stealing from a health care benefit program; willfully preventing, obstructing, misleading, or delaying a criminal investigation of a health care offense; and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of or payment for health care benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity need not have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

We may also be subject to data privacy and security regulation by both the federal government and the states in which it conducts its business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their respective implementing regulations impose specific requirements on covered entities relating to the privacy, security and transmission of individually identifiable health information, known as protected health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates," defined as independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity for a function or activity regulated by HIPAA. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. We are not a covered entity or a business associate under HIPAA; however, we are indirectly affected by HIPAA because the protected health information held by investigators conducting our clinical trials is subject to HIPAA and can only be used for our clinical research consistent with HIPAA requirements imposed on those investigators. In addition, state laws, such as the California Consumer Privacy Act, or the CCPA, govern the privacy and security of the personal information of individuals residing in such states, and may in certain circumstances, apply to health information. In addition to California, other states have implemented laws protecting identifiable health and personal information, and many of these laws differ from each other in significant ways and may not be preempted by HIPAA, thus complicating compliance efforts.

We may also be subject to analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving health care items or services reimbursed by non-governmental third-party payors, including private insurers, and may be broader in scope than their federal equivalents. The laws of some U.S. states and foreign jurisdictions require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to health care providers. In addition, certain state and foreign laws and regulations require disclosures to regulatory agencies and/or commercial purchasers with respect to certain price increases that exceed a certain level as identified in the relevant statutes, require drug manufacturers to report information related to payments and other transfers of value to physicians and other health care providers, and restrict marketing practices or require disclosure of marketing expenditures and pricing information. Some U.S. states also require registration of pharmaceutical sales representatives.

If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to it, we may be subject to penalties, including, without limitation, civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, exclusion from participation in federal and state health care programs and imprisonment, any of which could adversely affect our ability to operate our business and our financial results. Also, the U.S. Foreign Corrupt Practices Act and similar worldwide anti-bribery laws generally prohibit companies and their intermediaries from making improper payments to foreign officials for the purpose of obtaining or retaining business. We cannot assure you that our internal control policies and procedures will protect us from reckless or negligent acts committed by our employees, future distributors, partners, collaborators or agents. Violations of these laws, or allegations of such violations, could result in fines, penalties or prosecution and have a negative impact on our business, results of operations and reputation.

General Data Protection Regulation

The collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the EU, including personal health data, is subject to the EU's General Data Protection Regulation, or GDPR, which became effective on May 25, 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the EU, including the U.S., and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global turnover, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. The Company must comply with the GDPR in the performance of its clinical trials in the EU and relies on its CROs to implement appropriate safeguards and procedures relating to informed consent in order to ensure that trials are conducted in a manner consistent with the GDPR.

In July 2023, the European Commission adopted an adequacy decision for a new mechanism for transferring personal data from the EU to the United States – the EU-U.S. Data Privacy Framework, which provides EU individuals with several new rights, including the right to obtain access to their data, or obtain correction or deletion of incorrect or unlawfully handled data. In addition, the EU-U.S. Data Privacy Framework offers additional redress avenues for violations, including free of charge independent dispute resolution mechanisms and an arbitration panel. The adequacy decision followed the U.S.' signing of an executive order introducing new binding safeguards to address the points raised by the Court of Justice of the EU in its decision on a case known as *Schrems II*, which invalidated the previous EU-U.S. Privacy Shield. Notably, the new obligations were geared to ensure that data can be accessed by U.S. intelligence agencies only to the extent necessary and proportionate and to establish an independent and impartial redress mechanism to handle complaints from Europeans concerning the collection of their data for national security purposes. The European Commission will continually review developments in the United States along with its adequacy decision. Adequacy decisions can be adapted or even withdrawn in the event of developments affecting the level of protection in the applicable jurisdiction. Future actions of EU data protection authorities are difficult to predict. Some customers or other service providers may respond to these evolving laws and regulations by asking us to make certain privacy or data-related contractual commitments that we are unable or unwilling to make. This could lead to the loss of current or prospective customers or other business relationships.

Coverage and Reimbursement

Sales of our products approved for marketing by the FDA and foreign regulatory authorities will depend, in part, on the extent to which our products will be covered by third-party payors, such as government health programs, commercial or private insurance and managed care organizations. The process for determining whether a payor will provide coverage for a drug or biological product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the drug or biological product. Third-party payors may limit coverage to specific drug or biological products on an approved list, or formulary, which might not include all of the FDA-approved drug or biological products for a particular indication. Third-party payors are increasingly challenging drug prices and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable regulatory approvals. Our drug or biological candidates may or may not be considered medically necessary or cost-effective or may require prior authorizations before use. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Moreover, eligibility for reimbursement may not be available at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the product and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost products and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates

required by third-party payors and by any future relaxation of laws that presently restrict imports of products from countries where they may be sold at lower prices than in the United States. In the United States, third-party payors often rely upon CMS coverage policy and payment limitations in setting their own reimbursement policies, but they also have their own methods and approval processes apart from CMS coverage and reimbursement determinations. Accordingly, one third-party payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product.

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 granted at all. The process for determining whether a payor will cover and provide reimbursement for a product may be separate from the process of seeking approval for or setting the price of the product. Even if reimbursement is provided, market acceptance of our products may be adversely affected if the amount of payment for our products proves to be unprofitable for health care providers or less profitable than alternative treatments or if administrative burdens make our products less desirable to use.

Additionally, the United States government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid health care costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. For example, the ACA contains provisions that may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on biopharmaceutical companies' share of sales to federal health care programs. Adoption of general controls and measures, coupled with the tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for drugs and biologics. The Medicaid Drug Rebate Program requires biopharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of the DHHS as a condition for states to receive federal matching funds for the manufacturer's outpatient therapeutic products furnished to Medicaid patients. The ACA made several changes to the Medicaid Drug Rebate Program, including increasing biopharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on most branded prescription drugs from 15.1% of average manufacturer price, or AMP, to 23.1% of AMP and adding a new rebate calculation for "line extensions" (i.e., new formulations, such as extended release formulations) of solid oral dosage forms of branded products, as well as potentially impacting their rebate liability by modifying the statutory definition of AMP. The ACA also expanded the universe of Medicaid utilization subject to drug rebates by requiring biopharmaceutical manufacturers to pay rebates on Medicaid managed care utilization and by enlarging the population potentially eligible for Medicaid drug benefits. As another example, the 2021 Consolidated Appropriations Act, signed into law on December 27, 2020, incorporated extensive health care provisions and amendments to existing laws, including a requirement that all manufacturers of drugs and biological products covered under Medicare Part B report the product's average sales price, or ASP, to the DHHS beginning on January 1, 2022, subject to enforcement via civil money penalties.

Under currently applicable U.S. law, certain products that are not self-administered by the patient (including injectable drugs) may be eligible for coverage under Medicare through Medicare Part B. Medicare Part B is administered by Medicare Administrative Contractors, which generally have the responsibility of making coverage decisions. Subject to certain payment adjustments and limits, Medicare generally pays for a Part B-covered drug or biologic based on a percentage of manufacturer-reported Average Sales Price, which is regularly updated. For a drug or biological product to receive federal reimbursement under the Medicaid or Medicare Part B programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B Drug Pricing Program. The maximum amount that a manufacturer may charge a 340B covered entity for a given product is the AMP reduced by the rebate amount paid by the manufacturer to Medicaid for each unit of that product. As 340B drug pricing is determined based on AMP and Medicaid rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discount to increase.

There has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several 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 drug products. For example, the 2021 Consolidated Appropriations Act signed into law on December 27, 2020 incorporated extensive health care provisions and amendments to existing laws, including new requirements for (1) all manufacturers of drugs and biological products covered under Medicare Part B to report the product's ASP, to the DHHS beginning on January 1, 2022, subject to enforcement via civil money penalties, (2) certain Medicare plans to develop tools to display Medicare Part D prescription drug benefit information in real time, and (3) for group and health insurance issuers to report information on pharmacy benefit and drug costs to the Secretaries of the DHHS, the Department of Labor and the Department of the Treasury.

More recently, in August 2022 the Inflation Reduction Act of 2022, or the IRA, was signed into law. Among other things, the IRA has multiple provisions that may impact the prices of drug products that are both sold into the Medicare program and throughout the United States. For example, a manufacturer of a drug or biological product covered by Medicare Parts B or D must pay a rebate to the federal government if the drug product's price increases faster than the rate of inflation. This calculation is made on a product-by-product basis and the amount of the rebate owed to the federal government is directly dependent on the volume of a drug product that is paid for by Medicare Parts B or D. Additionally, CMS will negotiate drug prices annually for a select number of single-source Part D drugs without generic or biosimilar competition. CMS will also negotiate drug prices for a select number of Part B drugs starting for payment year 2028. If a drug product is selected by CMS for negotiation, it is expected that the revenue generated from such drug will decrease. CMS has begun to implement these new authorities, announcing the first round of negotiated prices for the first 10 drug products in August 2024, which will become applicable for payment year 2026. The second round of negotiated prices for 15 drug products was announced in November 2025. However, the IRA's impact on the pharmaceutical industry in the United States remains uncertain, in part because multiple large pharmaceutical companies and other stakeholders (e.g., the U.S. Chamber of Commerce) have initiated federal lawsuits against CMS arguing the program is unconstitutional for a variety of reasons, among other complaints. Those lawsuits are currently ongoing.

Separately, the Trump Administration announced the creation of a government website called TrumpRx, which will allow consumers to purchase certain drugs at reduced prices as negotiated between the drug manufacturers and the administration. As of December 2025, the Trump Administration secured deals with five major drug manufacturers to offer certain drugs at most-favored-nation prices.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control drug 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. For example, in recent years, several states have formed prescription drug affordability boards, or PDABs. Much like the IRA's drug price negotiation program, these PDABs have attempted to implement upper payment limits, or UPLs, on drugs sold in their respective states in both public and commercial health plans. For example, in August 2023, Colorado's PDAB announced a list of five prescription drugs that would undergo an affordability review. The effects of these efforts remain uncertain pending the outcomes of several federal lawsuits challenging state authority to regulate prescription drug payment limits. We expect that federal, state and local governments in the United States will continue to consider legislation directed at lowering the total cost of health care.

In December 2020, the U.S. Supreme Court held unanimously that federal law does not preempt the states' ability to regulate pharmacy benefit managers, or PBMs, and other members of the health care and pharmaceutical supply chain, an important decision that may lead to further and more aggressive efforts by states in this area. The FTC in mid-2022 also launched sweeping investigations in the practices of the PBM industry that could lead to additional federal and state legislative or regulatory proposals targeting such entities' operations, pharmacy networks, or financial arrangements. Significant efforts to change the PBM industry as it currently exists in the United States may affect the entire pharmaceutical supply chain and the business of other stakeholders, including biopharmaceutical developers like us.

As noted above, the marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. An increasing emphasis on cost containment measures in the United States has increased and we expect will continue to increase the pressure on drug or biological product 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 receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

In some foreign countries, proposed pricing for drug and biological products must be approved before the product may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. Some countries provide that drug and biological products may be marketed only after agreement on a reimbursement price has been reached. Some countries may require additional studies that compare the cost-effectiveness of our product candidate to currently available therapies (so called health technology assessment, or HTA) in order to obtain reimbursement or pricing approval. For example, the EU provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicines. A member state may approve a specific price for the 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 drug prices but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. There can be no assurance that any country that has price controls or reimbursement limitations for drug and biological products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the EU do not follow price structures of the United States and generally tend to be priced significantly lower.

Foreign Regulation

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

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in non-U.S. countries prior to the commencement of clinical trials or marketing of the product in those countries. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Similar to the United States, the various phases of non-clinical and clinical research that takes place in other countries are subject to significant regulatory controls. For example, the EU's Clinical Trials Regulation, which took effect in January 2022, was enacted to simplify and streamline the approval of clinical trials in the region. The main characteristics of the regulation include: a streamlined application procedure via a single entry point, the "EU portal" or Clinical Trial Information System; a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors; and a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts. Part I, which contains scientific and medicinal product documentation, is assessed by the competent authorities of all EU member states in which an application for authorization of a clinical trial has been submitted. Part II, which contains the national and patient-level documentation, will be assessed individually by each such EU member state. Any substantial changes to the trial protocol or other information submitted with the CTA must be notified to or approved by the relevant competent authorities and ethics committees. Medicines used in clinical trials must be manufactured in accordance with applicable cGMP requirements. Other national and EU-wide regulatory requirements may also apply.

The requirements and processes governing the conduct of clinical trials, product licensing, pricing and reimbursement in Europe vary from country to country, even though there is already some degree of legal harmonization in the EU member states resulting from the national implementation of underlying EU legislation. In all cases, the clinical trials must be conducted in accordance with GCP and other applicable regulatory requirements. To obtain regulatory approval of a new drug or medicinal product in the EU, a sponsor must obtain approval of a marketing authorization application. The way in which a medicinal product can be approved in the EU depends on the nature of the medicinal product.

The centralized procedure results in a single marketing authorization granted by the European Commission that is valid across the EU, as well as in Iceland, Liechtenstein and Norway, or the European Economic Area, or EEA. The centralized procedure is compulsory for human medicines that are: (i) derived from biotechnology processes, such

as genetic engineering, (ii) contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative diseases, autoimmune and other immune dysfunctions and viral diseases, (iii) officially designated as orphan medicinal product and (iv) advanced-therapy medicines, such as gene-therapy, somatic cell-therapy or tissue-engineered medicines. The centralized procedure may at the request of the applicant also be used for human medicines which do not fall within the above mentioned categories if the medicinal product contains a new active substance which has not been previously authorized in the EEA, the product constitutes a significant therapeutic, scientific or technical innovation, or where the granting of authorization in the centralized procedure is in the interests of public health in the EEA.

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

There are also two other possible routes to authorize medicinal products in several EU countries, which are available for investigational medicinal products for which the centralized procedure is not obligatory: the decentralized procedure and the mutual recognition procedure, or MRP. Using the decentralized procedure, an applicant may apply for simultaneous authorization in more than one EU country of a medicinal product that has not yet been authorized in any EU country and that does not fall within the mandatory scope of the centralized procedure.

The MRP is applicable to the majority of conventional medicinal products and is based on the principle of recognition of an already existing national marketing authorization by one or more member states. In the MRP process, a marketing authorization for a drug already exists in one or more member states of the EU and subsequently marketing authorization applications are made in other EU member states by referring to the initial marketing authorization. The member state in which the marketing authorization was first granted will then act as the reference member state. The member states where the marketing authorization is subsequently applied for act as concerned member states. After the reference state completes its medicinal product assessment, copies of the report are sent to all member states, together with the approved summary of product characteristics, labeling and package leaflet. The concerned member states then have 90 days to recognize the decision of the reference member state and the summary of product characteristics, labeling and package leaflet. National marketing authorizations shall be granted within 30 days after acknowledgement of the agreement.

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

Only products for which marketing authorizations have been granted may be sold in the EU. A marketing authorization is valid for five years in principle and the marketing authorization may be renewed after the initial five-year period on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the authorizing member state. To this end, the marketing authorization holder must provide the EMA, or the applicable competent authority, with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least six months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization is valid for an unlimited period, unless the European Commission, or the applicable competent authority, decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal. Any marketing authorization which is not followed by the actual placing of the drug on the market in the EU (in case of centralized procedure) or on the

market in the authorizing member state within three years after authorization ceases to be valid (the so-called sunset clause).

In the EU, new chemical entities, sometimes referred to as new active substances, qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity. The data exclusivity, if granted, prevents regulatory authorities in the EU from referencing the innovator's data to assess a generic or biosimilar application for eight years, after which generic marketing authorization can be submitted, and the innovator's data may be referenced, but not approved for two years. The overall ten-year period can be extended to a maximum of 11 years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are determined to bring a significant clinical benefit in comparison with currently approved therapies.

The criteria for designating an orphan medicinal product in the EU are similar in principle to those in the United States. Under Article 3 of Regulation (EC) 141/2000, a medicinal product may be designated as orphan if (1) it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either (a) such condition affects no more than five in 10,000 persons in the EU when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the EU to justify investment; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU, or if such a method exists, the product will be of significant benefit to those affected by the condition, as defined in Regulation (EC) 847/2000. Orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers and are, upon grant of a marketing authorization, entitled to ten years of market exclusivity for the approved therapeutic indication. The application for orphan designation must be submitted before the application for marketing authorization. The applicant will receive a fee reduction for the marketing authorization application if the orphan designation has been granted, but not if the designation is still pending at the time the marketing authorization is submitted. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The 10-year market exclusivity for orphan products in the EU may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation, for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. Additionally, marketing authorization may be granted to a similar product for the same indication at any time if:

- the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior;
- the applicant consents to a second orphan medicinal product application; or
- the applicant cannot supply enough orphan medicinal product.

We have obtained Orphan Medicinal Product Designations from the EMA for GPS in AML, MPM and MM.

In April 2023, the European Commission issued a proposal to revise and replace the existing general pharmaceutical legislation. As of January 2026, the three EU institutions, the European Commission, the European Parliament and the Council of the EU are in the process of negotiating the final content of the new Directive and Regulation. Once negotiations are complete, the European Parliament and the Council of the EU will vote on whether to approve the Directive and Regulation. If adopted and implemented as currently proposed, these revisions will significantly change several aspects of drug development and approval in the EU.

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

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

Health Care Reform in the U.S. and Potential Changes to Health Care Laws

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the health care system that could prevent or delay marketing approval of product and therapeutic candidates, restrict or regulate post-approval activities, and affect the ability to profitably sell product and therapeutic candidates that obtain marketing approval. The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product and therapeutic candidates. In addition, future legislative and regulatory proposals may materially impact the ability of the FDA and other regulatory agencies to operate as they have historically operated. We cannot be sure whether additional legislative changes will be enacted, or whether any of the FDA's regulations, guidances or interpretations will be changed, or what the impact of such changes on the agency and its scientific review staff, if any, may be. For example, negotiations on the next FDA user fee reauthorization package began in mid-2025, and the resulting agreement is expected to be sent to Congress in early 2027 for purposes of initiating the legislative process. Reauthorization of the prescription drug user fee program must be finalized by Congress by the end of September 2027 in order to avoid a disruption in FDA's review goals for NDAs and other activities supported by user fees assessed against industry.

As previously mentioned, the primary trend in the US health care industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products and services, implementing reductions in Medicare and other health care funding and applying new payment methodologies. In addition to the sweeping reforms contained in the ACA (summarized above in the section entitled "Coverage and Reimbursement"), other legislative changes have been proposed and adopted in the United States that may affect health care expenditures. For example, the 2020 Further Consolidated Appropriations Act (P.L. 116-94) included a piece of bipartisan legislation called the Creating and Restoring Equal Access to Equivalent Samples Act of 2019, or the CREATES Act. The CREATES Act was enacted to address the concern articulated by both the FDA and industry stakeholders that some brand manufacturers improperly restrict the distribution of their products, including by invoking the existence of a REMS for certain products, to deny generic and biosimilar product developers access to samples of the brand products. Because generic and biosimilar product developers need samples to conduct certain comparative testing required by the FDA, some attributed the inability to timely obtain samples as a cause of delay in the entry of generic and biosimilar products. To remedy this concern, the CREATES Act established a private cause of action that permits a generic or biosimilar product developer to sue the brand manufacturer to compel it to furnish the necessary samples on "commercially reasonable, market-based terms." Although lawsuits have been filed under the CREATES Act since its enactment, those lawsuits have settled privately; therefore, to date no federal court has reviewed or opined on the statutory language and there continues to be uncertainty regarding the scope and application of the law. The Consolidated Appropriations Act of 2021 also includes, among other things, a new requirement for patent information to be submitted to the FDA and published in a "Purple Book" that contains detailed information about each FDA-licensed biological product, analogous to the Orange Book that provides information about approved small-molecule drug products and their patent and exclusivity information under the Hatch-Waxman Act.

In the EU, many member states have increased the amount of discounts required on pharmaceuticals and these efforts could continue as countries attempt to manage health care expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the EU. The downward pressure on health care costs in general, particularly prescription products, has become intense. As a result, increasingly high barriers are being erected to the entry of new medicinal products. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU member states, and parallel trade, i.e., arbitrage between low-priced and high-priced member states, can further reduce prices. There can be no assurance that any country that has price controls or reimbursement limitations for medicinal products will allow favorable reimbursement and pricing arrangements for any products, if approved in those countries.

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. We expect that additional state and federal health care reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for health care products and services. Moreover, if we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, our therapeutic candidates may lose any marketing approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

Corporate Information

Our principal executive offices are located at 7 Times Square, Suite 2503, New York, NY 10036, and our phone number is (646) 200-5278. Our website address is www.sellaslifesciences.com. We do not incorporate the information on our website into this Annual Report on Form 10-K, and you should not consider such information part of this Annual Report on Form 10-K.

We were incorporated on April 3, 2006 in Delaware as Argonaut Pharmaceuticals, Inc. On November 28, 2006, we changed our name to RXi Pharmaceuticals Corporation and began operations January 2007. On September 26, 2011, we changed our name to Galena Biopharma, Inc., or Galena. In December 2017, we completed a business combination, or the Merger, with SELLAS Life Sciences Group, Ltd., a privately held Bermuda exempted company, or Private SELLAS, and changed our name to "SELLAS Life Sciences Group, Inc."

A copy of our Corporate Governance Guidelines, Code of Business Conduct and Ethics and the charters of the Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee are posted on our website, www.sellaslifesciences.com, under "Investors – Corporate Governance."

ITEM 1A. RISK FACTORS

You should carefully consider the risks and uncertainties described below, together with all of the other information in this Annual Report on Form 10-K. We operate in a dynamic and rapidly changing industry that involves numerous risks and uncertainties. The risks and uncertainties described below are not the only ones we face. Other risks and uncertainties, including those that we do not currently consider material, may impair our business. If any of the risks discussed below actually occur, our business, financial condition, operating results or cash flows could be materially adversely affected. This Annual Report on Form 10-K also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including the risks we face as described below and elsewhere in this Annual Report on Form 10-K.

Risks Related to Our Financial Position and Capital Needs

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

Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate will fail to prove effective, gain regulatory approval or become commercially viable. We do not have any products approved by regulatory authorities, have not generated any product revenues to date, and have incurred significant research, development and other expenses related to our ongoing operations. As a result, we have not been profitable and have incurred significant operating losses in every reporting period since our inception. For the years ended December 31, 2025 and 2024, we reported a net loss of $26.9 million and $30.9 million, respectively. As of December 31, 2025 and 2024, we had an accumulated deficit of $275.0 million and $248.1 million, respectively.

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

- conduct additional clinical trials of our lead product, GPS, including the Phase 3 clinical trial evaluating GPS for AML, and our second clinical candidate, SLS009;
- seek marketing approval for any of our product candidates that successfully complete clinical trials;

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

We currently have no source of revenues from product sales. We may never generate such revenues or achieve profitability.

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

- successfully complete development activities, including the necessary clinical trials;
- complete and submit BLAs and NDAs to the FDA and obtain U.S. regulatory approval for indications for which there is a commercial market;
- complete and submit applications to foreign regulatory authorities in Europe, Asia and other jurisdictions;
- obtain regulatory approval in territories with viable market sizes;
- obtain coverage and adequate reimbursement from third parties, including government and private payors;
- set commercially viable prices for our products, if any;
- establish and maintain supply and manufacturing relationships with reliable third parties and/or build our own manufacturing facility and ensure adequate, legally globally compliant manufacturing of bulk drug substances and drug products to maintain that supply;
- develop distribution processes for our product candidates;
- develop commercial quantities of our product candidates, once approved, at acceptable cost levels;
- obtain additional funding, if required to develop and commercialize our product candidates;
- develop a commercial organization capable of sales, marketing and distribution for any products we intend to sell ourselves, in the markets in which we choose to commercialize on our own, and successfully enter into arrangements with third parties to sell, market, and distribute our products in markets where we choose not to commercialize on our own;
- achieve market acceptance of our products;
- attract, hire and retain qualified personnel; and

- protect our rights in our intellectual property portfolio.

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

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

We expect to expend substantial resources for the foreseeable future to continue the clinical development and manufacturing of GPS, in particular the Phase 3 study of GPS in AML, and SLS009. Our existing cash will not be sufficient to complete such development activities and obtain regulatory approval for our product candidates and, if we receive regulatory approval for our product candidates, commence commercialization activities, and we will need to raise significant additional capital to help us do so. In addition, our operating plan may change as a result of factors currently unknown to us, and we may need additional funds sooner than planned. If we are unable to obtain sufficient funding for our operations, we may be delayed in pursuing our development programs for GPS and SLS009.

Our future capital requirements depend on many factors, including:

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

Additional funds may not be available when we need them on terms that are acceptable to us, or at all. Moreover, global and domestic events, such as public health crises, geopolitical unrest and domestic political events, have caused and could continue to cause uncertainty and volatility in the capital markets which could impact our ability to raise capital. If adequate funds are not available to us on a timely basis, we may not be able to continue as a going concern or we may be required to delay, limit, reduce or terminate preclinical studies, clinical trials or other development activities for one or more of our product candidates or target indications, or delay, limit, reduce or terminate our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates.

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

We may seek additional capital through a variety of means, including through private and public equity offerings and debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, or through the issuance of shares under management or other types of contracts, or upon the exercise or conversion of outstanding derivative securities, the ownership interests of our stockholders will be diluted, and the terms of such financings may include liquidation or other preferences, anti-dilution rights, conversion and exercise price adjustments and other provisions that adversely affect the rights of our stockholders, including rights, preferences and privileges that are senior to those of our holders of common stock in the event of a liquidation. In such event, there is a possibility that once all senior claims are settled, there may be no assets remaining to pay out to the holders of our common stock. Debt financing, if available, could include covenants limiting or restricting our ability to take certain actions, such as incurring additional debt, making capital expenditures, entering into licensing arrangements, or declaring dividends and may require us to grant security interests in our assets, including our intellectual property, and for our subsidiaries to guarantee our obligations. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves. If we raise additional funds through collaborations, strategic alliances, or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, products or product candidates or grant licenses on terms that may not be favorable to us.

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

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

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

- designing, conducting and successfully completing preclinical development activities, including preclinical efficacy and IND-enabling studies, for our product candidates or product candidates we are interested in in-licensing or acquiring;
- designing, conducting and completing clinical trials for our product candidates with positive results;
- receipt of regulatory approvals from applicable authorities;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- making arrangements with third-party manufacturers, receiving regulatory approval of our manufacturing processes and our third-party manufacturers' facilities from applicable regulatory authorities and ensuring adequate supply of drug product;
- manufacturing our product candidates at an acceptable cost;

- effectively launching commercial sales of our product candidates, if approved, whether alone or in collaboration with others;
- achieving acceptance of our product candidates, if approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- if our products candidates are approved, obtaining and maintaining coverage and adequate reimbursement by third-party payors, including government payors, for our product candidates;
- complying with all applicable regulatory requirements, including FDA GCP and cGMP requirements, as well as, standards, rules and regulations governing promotional and other marketing activities;
- maintaining a continued acceptable safety profile of the products during development and following approval; and
- maintaining and growing an organization of scientists and businesspeople who can develop and commercialize our product candidates.

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

Our lead product candidate, GPS, represents a new therapeutic approach that presents significant challenges.

Our future success is substantially dependent on the successful development of WT1 peptide immunotherapies in general and GPS in particular. Because this program represents a new approach to cancer immunotherapy for the treatment of cancer and other diseases, developing and commercializing GPS subjects us to a number of challenges, including:

- obtaining regulatory approval from the FDA and other regulatory authorities, which have very limited experience with the development and commercialization of WT1 cancer immunotherapies;
- obtaining the components required for the administration of GPS (i.e., GPS, GM-CSF, Montanide, and device connector for mixing) from separate sources, the subsequent separate storage requirements for each of these components and the separate delivery of these components to the administration location;
- utilizing GPS in combination with other therapies, which may increase the risk of adverse side effects;
- sourcing clinical and, if approved, commercial supplies for the materials used to manufacture and process GPS;
- developing a manufacturing process used in connection with GPS that will yield a satisfactory product that is safe, effective, scalable and profitable;
- establishing sales and marketing capabilities after obtaining any regulatory approval to gain market acceptance; and
- obtaining coverage and adequate reimbursement from third-party payors and government authorities.

Moreover, public perception of safety issues, including adoption of new therapeutics or novel approaches to treatment, may adversely influence the willingness of subjects to participate in clinical trials, or if approved, of physicians to subscribe to the novel treatment mechanics. Physicians, hospitals and third-party payors often are slow to adopt new products, technologies and treatment practices that require additional educational upfront costs

and training. Physicians may not be willing to undergo training to adopt this novel therapy, may decide the therapy is too complex to adopt without appropriate training and may choose not to administer the therapy. Based on these and other factors, hospitals and payors may decide that the benefits of this new therapy do not or will not outweigh their costs.

The limited number of patients who have the diseases for which our product candidates are being studied, has made it more difficult to enroll patients in our clinical trials, which could delay or prevent the start of clinical trials for our product candidates.

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

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

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

The indication being studied in our Phase 3 clinical trial for GPS, i.e., patients with AML who have achieved CR2, is an orphan indication. In addition, only those CR2 patients who meet specific inclusion criteria are eligible to participate in the study. Primary entry restrictions include demonstrating adequate hematologic recovery and not being candidates for bone marrow transplants. The estimated prevalence of newly diagnosed AML patients is approximately 20,000 cases in the United States annually (across all ages) with only a subset of this group having achieved CR2 and only a further subset of the CR2 subset satisfying the enrollment criteria for our AML Phase 3 clinical trial.

We may not be able to initiate or continue to support clinical trials of our product candidates for one or more indications, or any future product candidates if we are unable to locate and enroll a sufficient number of eligible participants in these trials as required by the FDA or other regulatory authorities. Even if we are able to enroll a

sufficient number of patients in our clinical trials, if the pace of enrollment is slower than we expect, the development costs for our product candidates may increase and the completion of our trials may be delayed or our trials could become too expensive to complete.

Congress also recently amended the FDCA to require sponsors of a Phase 3 clinical trial, or other "pivotal study" of a new drug or biologic to support marketing authorization, to design and submit a diversity action plan for such clinical trial. The action plan must describe appropriate diversity goals for enrollment, as well as a rationale for the goals and a description of how the sponsor will meet them. Our Phase 3 REGAL trial of GPS for AML patients who have achieved CR2 was initiated before this requirement became effective, but for any future Phase 3 trials we plan to conduct, including any registrational study for SLS009, we must submit a diversity action plan to the FDA by the time we submit plans for such Phase 3, or pivotal study, protocol to the agency for review as part of an IND, unless we are able to obtain a waiver for some or all of the requirements for a diversity action plan. Initiation of our future Phase 3 trials may be delayed if the FDA objects to our proposed diversity action plans for any future Phase 3 trial for our product candidates. We may experience difficulties recruiting a diverse population of patients in attempting to fulfill the requirements of any approved diversity action plan.

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

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

Success in preclinical studies and early clinical trials does not ensure that later clinical trials will generate adequate data to demonstrate the efficacy and safety of an investigational drug. A number of companies in the pharmaceutical and biotechnology industries, including those with greater resources and experience than us, have suffered significant setbacks in clinical trials, even after seeing promising results in earlier preclinical studies or clinical trials. Any of our product candidates that are in, or may advance to, clinical trials may not succeed in clinical trials despite promising preclinical data. For example, with respect to GPS, a broadly similar anti-cancer peptide immunotherapeutic against melanoma-specific antigen being developed by GlaxoSmithKline for advanced unresectable melanoma initially produced positive efficacy data in a Phase 2 clinical study, but subsequently failed to prove more beneficial than placebo in a controlled, blinded and randomized Phase 3, registration-enabling clinical trial in the same indication in patients after tumor resection.

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

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

From time to time, we may publicly disclose preliminary, interim or topline data from our clinical trials. These interim updates are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to a 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 evaluate all data. As a result, the topline results or preliminary data 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. Topline 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, topline data should be viewed with caution until the final data are available. In addition, we may report interim analyses of only certain endpoints rather than all endpoints. Interim data from clinical trials that we complete are subject to the risk that one or more of the clinical outcomes may materially change as more patient data becomes available. Adverse changes between interim data and final data could adversely affect our business and prospects and could result in volatility in the price of our common stock.

We are developing and may continue to develop our programs in combination with other therapies, which exposes us to additional risks.

We are currently investigating SLS009 in combination with aza/ven in a Phase 2 clinical trial and we may continue to develop clinical candidates in combination with one or more currently approved cancer therapies or therapies currently in clinical development. Patients may not be able to tolerate our product candidates in combination with other therapies or dosing of our product candidates in combination with other therapies may have unexpected consequences. Even if any of our product candidates were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA, EMA or other comparable foreign regulatory authorities could revoke approval of the therapy used in combination with any of our product candidates, or safety, efficacy, manufacturing or supply issues could arise with these existing therapies. In addition, it is possible that existing therapies with which our product candidates may be approved for use could themselves fall out of favor or be relegated to later lines of treatment. This could result in the need to identify other combination therapies for our product candidates or our own products being less successful commercially.

We may also evaluate our product candidates in combination with one or more other cancer therapies that have not yet been approved for marketing by the FDA, EMA or comparable foreign regulatory authorities. If the FDA, EMA or other comparable foreign regulatory authorities do not approve or revoke their approval of these other therapies, or if safety, efficacy, commercial adoption, manufacturing or supply issues arise with the therapies we choose to evaluate in combination with our product candidates, we may be unable to obtain approval of or successfully market our product candidates.

Additionally, if the third-party providers of therapies or therapies in development used in combination with our product candidates are unable to produce sufficient quantities for clinical trials or commercialization of our product candidates, or if the cost of combination therapies are prohibitive, our development and commercialization efforts would be impaired, which would have an adverse impact on our business, financial condition, results of operations and growth prospects.

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

Clinical testing is expensive and can take many years to complete, with the outcome inherently uncertain. Failure can occur at any time during the clinical trial process. Before obtaining approval from regulatory authorities for the sale of any product candidate, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Prior to initiating clinical trials, a sponsor must complete extensive preclinical testing of a product candidate, including, in most cases, preclinical efficacy experiments as well IND-enabling toxicology studies. These experiments and studies may be time-consuming and expensive to complete. The necessary preclinical testing may not be completed successfully for a preclinical product candidate and a potentially promising product candidate may therefore never be tested in humans. Once it commences, clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. We may experience numerous unforeseen events during drug development that could delay or prevent

our ability to receive marketing approval or commercialize our product candidates. In particular, clinical trials of our product candidates may produce inconclusive or negative results. We have limited data regarding the safety, tolerability and efficacy of GPS administered as monotherapy or in combination with PD-1 inhibitors or for SLS009 as monotherapy and in combination with other therapeutics, including aza/ven. For a further discussion of the safety risks in our trials, see the risk factor herein entitled "Our current and future product candidates, the methods used to deliver them or their dosage levels may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following any regulatory approval."

Clinical trials also require the review and oversight of an IRB. An inability or delay in obtaining IRB approval could prevent or delay the initiation and completion of clinical trials, and the FDA may decide not to consider any data or information derived from a clinical investigation not subject to initial and continuing IRB review and approval.

We may experience delays in our ongoing or future clinical trials, and we do not know whether planned clinical trials will begin or enroll subjects on time, will need to be redesigned or will be completed on schedule, if at all. There can be no assurance that the FDA will not put clinical trials of any of our product candidates on clinical hold in the future. Clinical trials may be delayed, suspended or prematurely terminated for a variety of reasons, such as:

- delay or failure in reaching agreement with the FDA or a comparable foreign regulatory authority on a clinical trial design that we are able to execute;
- delay or failure in obtaining authorization to commence a trial or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a trial;
- delay or failure in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delay or failure in obtaining IRB approval or the approval of other reviewing entities, including comparable foreign regulatory authorities, to conduct a clinical trial at each site;
- withdrawal of clinical trial sites from our clinical trials or the ineligibility of a site to participate in our clinical trials;
- clinical sites and investigators deviating from trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial;
- inability to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs, including some that may be for the same indication;
- failure of our third-party clinical trial managers, CROs, clinical trial sites, contracted laboratories or other third-party vendors to satisfy their contractual duties, meet expected deadlines or return trustworthy data;
- delay or failure in adding new trial sites;
- delay or failure in recruiting and enrolling suitable subjects to participate in a trial;
- delay or failure in subjects completing a trial or returning for post-treatment follow-up;
- interim results or data that are ambiguous or negative or are inconsistent with earlier results or data;
- alteration of trial design necessitated by re-evaluation of design assumptions based upon observed data;
- feedback from the FDA, or foreign regulatory authority, the IRB, or DSMB, or results from earlier stage or concurrent preclinical studies and clinical trials, that might require modification to the protocol for a trial;

- a decision by the FDA or foreign regulatory authority, the IRB, or us, or a recommendation by a DSMB or comparable foreign regulatory authority, to suspend or terminate clinical trials at any time for safety issues or for any other reason;
- unacceptable risk-benefit profile, unforeseen safety issues or adverse side effects;
- failure to demonstrate a benefit from using a product candidate;
- difficulties in manufacturing or obtaining from third parties sufficient quantities of a product candidate to start or to use in clinical trials;
- lack of adequate funding to continue a trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional studies or increased expenses associated with the services of our CROs and other third parties; or
- changes in governmental regulations or administrative actions or lack of adequate funding to continue a clinical trial.

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

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

For certain of our clinical trials, we have clinical sites in countries outside of the United States. Consequently, we may be subject to risks related to operating in foreign countries. Risks associated with conducting operations in foreign countries include:

- differing regulatory requirements for drug approvals and regulation of approved drugs in foreign countries; more stringent privacy requirements for data to be supplied to our operations in the United States, *e.g.*, GDPR in the EU;
- unexpected changes in tariffs, trade barriers and regulatory requirements; economic weakness, including inflation, or political instability in particular foreign economies and markets; compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; foreign taxes, including withholding of payroll taxes;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems and price controls;
- foreign currency fluctuations, which could result in increased operating expenses or reduced revenues, and other obligations incident to doing business or operating in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- continued uncertainties related to the withdrawal of the United Kingdom from the EU (known as "Brexit") and its financial, trade, regulatory and legal implications, which could lead to legal uncertainty and potentially divergent national laws and regulations as the United Kingdom determines which EU laws to replace or replicate, and which may further create global economic uncertainty, which could materially adversely affect our business, business opportunities, results of operations, financial condition, and cash flows;

- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad, including those that may result from a pandemic or global health emergency; and

- business interruptions resulting from geopolitical actions, including war and terrorism.

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

The results of our operations could be adversely affected by general conditions in the global economy, the global financial markets and the global political conditions. The United States and global economies have recently faced growing inflation, higher interest rates and a potential recession. Furthermore, a prolonged economic downturn, including a recession or depression resulting from public health crises such as a pandemic or ongoing political disruption such as the war between Ukraine and Russia, the conflicts in the Middle East, tensions between China and Taiwan and other geopolitical events could result in a variety of risks to our business, including weakened demand for our programs and development candidates, if approved, relationships with any vendors or business partners located in affected geographies and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy or political disruption, including any international trade disputes, particularly between the United States and China, could also strain our existing or future partnerships, manufacturers or suppliers, possibly resulting in disruption to our clinical trials or supply, or cause our customers to delay making payments for our potential products. Any of the foregoing could seriously harm our business, and we cannot anticipate all of the ways in which the political or economic climate and financial market conditions could seriously harm our business.

Although we do not currently have any clinical study sites in Russia or Ukraine, economic, political and social conditions resulting from Russia's invasion of Ukraine could materially disrupt our clinical trials, increase our costs and may disrupt planned clinical development activities. For example, we had clinical sites for our REGAL study in Poland, a country that borders Ukraine and has been impacted by an influx of Ukrainian refugees resulting from Russia's invasion of Ukraine. Furthermore, we rely on suppliers in the EU. To the extent the conflict between Ukraine and Russia adversely impacts the ability of our suppliers to distribute the supplies we need for our clinical trials, or such distribution cannot be done on a timely basis, the timing for completing our clinical trials may be adversely impacted.

Continued increases in inflation could raise our costs for commodities, labor, materials and services and other costs required to grow and operate our business, and failure to secure these on reasonable terms may adversely impact our financial condition. Additionally, increases in inflation, along with the uncertainties surrounding geopolitical developments and global supply chain disruptions, have caused, and may in the future cause, global economic uncertainty and uncertainty about the interest rate environment. A failure to adequately respond to these risks could have a material adverse impact on our financial condition, results of operations or cash flows. In response to high levels of inflation and recession fears, the U.S. Federal Reserve, the European Central Bank, and the Bank of England have raised, and may continue to raise, interest rates and implement fiscal policy interventions. Even if these interventions lower inflation, they may also reduce economic growth rates, create a recession, and have other similar effects.

Changes in U.S. federal policy that affect the geopolitical landscape, including tariffs, quotas, trade agreements or other trade restrictions, could give rise to circumstances outside our control that could have negative impacts on our business. For example, in April 2025, the U.S. government announced a 10% tariff on product imports from almost all countries and individualized higher tariffs on certain other countries, including a 145% tariff on product imports from China. Several tariff announcements have been followed by announcements of limited exemptions and temporary pauses. Historically, tariffs have led to increased trade and political tensions, between not only the United States and China, but also between the United States and other countries in the international community. In response to tariffs, other countries have implemented retaliatory tariffs on U.S. goods. Political tensions as a result of trade policies could reduce trade volume, investment, technological exchange and other economic activities between major international economies, resulting in a material adverse effect on global economic conditions and the stability of global financial markets. Any changes in political, trade, regulatory, and economic conditions, including U.S. trade policies, could have a material adverse effect on our financial condition or results of operations.

The U.S. debt ceiling and budget deficit concerns have increased the possibility of credit-rating downgrades and economic slowdowns, or a recession in the United States. Although U.S. lawmakers have previously passed legislation to raise the federal debt ceiling on multiple occasions, there is a history of ratings agencies lowering or threatening to lower the long-term sovereign credit rating on the United States given such uncertainty. Since August 1, 2023, Fitch Ratings downgraded and has maintained the United States' long-term foreign currency issuer default rating to AA+ from AAA as a result of these repeated debt ceiling and budget deficit concerns. The impact of this or any further downgrades to the U.S. government's sovereign credit rating or its perceived creditworthiness could adversely affect the U.S. and global financial markets and economic conditions.

If the equity and credit markets deteriorate, it may make any necessary equity or debt financing more difficult to secure, more costly or more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could harm our growth strategy, financial performance and stock price and could require us to delay or abandon plans with respect to our business, including clinical development plans. Further, recent developments in the banking industry could adversely affect our business. If the financial institutions with which we do business enter receivership or become insolvent in the future, there is no guarantee that the Department of the Treasury, the Federal Reserve and the FDIC will intercede to provide us and other depositors with access to balances in excess of the $250,000 FDIC insurance limit, that we would be able to access our existing cash, cash equivalents and investments, that we would be able to maintain any required letters of credit or other credit support arrangements, or that we would be able to adequately fund our business for a prolonged period of time or at all, any of which could have a material adverse effect on our business, financial condition and results of operations. We cannot predict the impact that the high market volatility and instability of the banking sector more broadly could have on economic activity and our business in particular. In addition, there is a risk that one or more of our current service providers, manufacturers or other third parties with which we conduct business may not survive difficult economic times, the ongoing conflict between Russia and Ukraine, the conflicts in the Middle East, tensions between China and Taiwan and other geopolitical events, the instability of the banking sector, and the uncertainty associated with current worldwide economic conditions, which could directly affect our ability to attain our operating goals on schedule and on budget.

Our partnerships in China subject us to risks and uncertainties relating to the laws and regulations of China and the changes in relations between the United States and China.

Under its current leadership, the government of China has been pursuing economic reform policies, including by encouraging foreign trade and investment. However, there is no assurance that the Chinese government will continue to pursue such policies, that such policies will be successfully implemented, that such policies will not be significantly altered, or that such policies will be beneficial to our partnerships in China. China's system of laws can be unpredictable, especially with respect to foreign investment and foreign trade. The U.S. government has called for substantial changes to foreign trade policy with China and has raised, and has proposed to further raise in the future, tariffs on several Chinese goods. China has retaliated with increased tariffs on U.S. goods. Moreover, China's legislature has adopted a national security law to substantially change the way Hong Kong has been governed since the territory was handed over by the United Kingdom to China in 1997. This law increases the power of the central government in Beijing over Hong Kong, limit the civil liberties of residents of Hong Kong and could restrict the ability of businesses in Hong Kong to continue to conduct business or to continue to with business as previously conducted. The U.S. State Department has indicated that the United States no longer considers Hong Kong to have significant autonomy from China. The U.S. State Department also previously enacted sanctions related to China's governing of Hong Kong, and the United States may impose the same tariffs and other trade restrictions on exports from Hong Kong that it places on goods from mainland China. Any further changes in U.S. trade policy could trigger retaliatory actions by affected countries, including China, resulting in trade wars. For example, the Uyghur Forced Labor Prevention Act bans imports from China's Xinjiang Uyghur Autonomous Region unless it can be shown that the goods were not produced using forced labor and this legislation may have an adverse effect on global supply chains which could adversely impact our business and results of operations. Additionally, the biopharmaceutical industry in particular in China is strictly regulated by the Chinese government. Changes to Chinese regulations affecting biopharmaceutical companies are also unpredictable. Any regulatory changes and changes in United States and China relations may have a material adverse effect on our partnerships in China which could materially harm our business and financial condition.

More recently, the National Defense Authorization Act for Fiscal Year 2026 includes a section titled, “Prohibition on Contracting with Certain Biotechnology Providers,” aimed at discouraging federal contracting with certain biotechnology companies for biotechnology equipment or services in China and other countries of concern. The statute prohibits federal executive agencies from procuring any biotechnology equipment or service from a biotechnology company of concern or contracting with any such company or any entity that procures or uses equipment or services from a biotechnology company of concern. Such prohibitions may limit our ability to partner with Chinese entities offering biotechnology equipment or services in connection with the development, testing, manufacturing or distribution of our product candidates or future products, if approved.

Climate change or legal, regulatory or market measures to address climate change may negatively affect our business, results of operations, cash flows and prospects.

Climate change may potentially negatively affect our business and results of operations, cash flows and prospects in the future. We could be exposed to physical risks (such as extreme weather conditions or rising sea levels), risks in transitioning to a low-carbon economy (such as additional legal or regulatory requirements, changes in technology, market risk and reputational risk), and social and human effects (such as population dislocations and harm to health and well-being) associated with climate change. These risks can be either acute (short-term) or chronic (long-term).

Extreme weather and sea-level rise could pose physical risks to facilities of our suppliers. Such risks include losses incurred as a result of physical damage to facilities, loss or spoilage of inventory, and business interruption caused by such natural disasters and extreme weather events which could disrupt our operations and supply chains that may result in increased costs.

New legal or regulatory requirements may be enacted to prevent, mitigate, or adapt to the implications of a changing climate and its effects on the environment. These regulations, which may differ across jurisdictions, could result in us being subject to new or expanded carbon pricing or taxes, increased compliance costs, restrictions on greenhouse gas emissions, investment in new technologies, increased carbon disclosure and transparency, upgrade of facilities to meet new building codes, and the redesign of utility systems, which could increase our operating costs, including the cost of electricity and energy used by us. Our supply chain would likely be subject to these same transitional risks and would likely pass along any increased costs to us.

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

Undesirable side effects caused by our current or future product candidates, their delivery methods or dosage levels could cause us, the IRB, DSMB, or the FDA or comparable regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval or termination of clinical trials. For example, although no high-grade delayed type hypersensitivity in the skin or systemic anaphylaxis events have been noted after GPS administration in patients treated in our clinical studies to date, it is theoretically possible that such toxicities, or other type of adverse events, may occur in future clinical studies. As a result of safety or toxicity issues that we may experience in our clinical trials, or negative or inconclusive results from the clinical trials of others for drug candidates similar to our own, we may not receive approval to market any product candidates, which could prevent us from ever generating revenues or achieving profitability. Results of our trials could reveal an unacceptably high severity and incidence of side effects. In such an event, our trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug-related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Any of these occurrences may have a material adverse effect on our business, results of operations, financial condition, cash flows and future prospects.

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

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

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

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

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

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

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

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

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

Our current and future product candidates could fail to receive regulatory approval from the FDA or comparable foreign regulatory authorities.

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

- disagreement with the regulatory authorities regarding the scope, design or implementation of our clinical trials;
- failure to demonstrate that a product candidate is safe and effective for our proposed indication;
- failure of clinical trials to meet the level of statistical significance required for approval;
- failure to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- disagreement with our interpretation of data from preclinical studies or clinical trials;
- the insufficiency of data collected from clinical trials of our product candidates to support the submission and filing of a BLA, NDA or other submission or to obtain regulatory approval;
- the insufficiency of a single pivotal or Phase 3 clinical trial of our product candidate(s) for regulatory approval in an indication;
- the failure to meet product quality standards or comply with cGMP regulations;
- failure to obtain approval of our manufacturing processes or facilities of third-party manufacturers with whom we contract for clinical and commercial supplies or our own manufacturing facility; or
- changes in the approval policies or regulations that render our preclinical and clinical data insufficient for approval.

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

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

We currently have orphan designation for GPS and SLS009 for certain indications, which might not provide the intended benefit thereof.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as Orphan Drug Products. Under the Orphan Drug Act, the FDA may designate a product as an Orphan Drug Product if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States. We have received orphan designations from the FDA and the EMA for GPS in AML, MPM and MM. In addition, we have received orphan designations from the FDA and the EMA for SLS009 for the treatment of AML and PTCL. Although we have received orphan designations for GPS and SLS009, there is no guarantee that any of these indications for GPS or SLS009 will be successfully approved by the FDA or the EMA, that GPS or SLS009 will be commercially successful

in the marketplace, or that another product will not be approved for the same indication ahead of our product candidate.

Even if we obtain orphan product exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same disease or condition. Even after an Orphan Drug Product is approved, the FDA can subsequently approve another drug or biologic for the same disease or condition if the FDA concludes that the later product is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In addition, Orphan product exclusivity may be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

We currently have Fast Track designation for GPS and SLS009 and may seek Fast Track designation for additional product candidates, or indications, which might not be received or provide the intended benefits thereof.

If a product candidate is intended for the treatment of a serious condition and nonclinical or clinical data demonstrate the potential to address unmet medical need for this condition, a product sponsor may apply to the FDA for Fast Track designation, which may or may not be granted by the FDA. We have received Fast Track designation from the FDA for GPS in AML, MPM and MM and Fast Track designation for SLS009 for the treatment of r/r AML and r/r PTCL.

However, Fast Track designation does not ensure that we will receive marketing approval or that approval will be granted within any particular timeframe. We may not experience a faster development or regulatory review or approval process with Fast Track designation compared to conventional FDA procedures. In addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast Track designation alone does not guarantee qualification for the FDA's accelerated approval or priority review procedures.

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

In addition to regulations in the United States, to market and sell our product candidates in the EU, United Kingdom, many Asian countries and other jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. The approval procedures vary among countries and can involve additional nonclinical or clinical testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. We may not be able to obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Clinical trials accepted in one country may not be accepted by regulatory authorities in other countries. In addition, many countries outside the United States require that a product be approved for reimbursement before it can be approved for sale in that country. A product candidate that has been approved for sale in a particular country may not receive reimbursement approval in that country, or may receive reimbursement at a level that is not commercially viable.

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

Even if our current and future product candidates receive regulatory approval, they may still face future development and regulatory difficulties.

Any regulatory approvals we receive for any of our product candidates may be subject to limitations on the approved indicated uses for which the product candidate may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials. In addition, any such regulatory approvals would be subject to ongoing requirements by the FDA and comparable foreign regulatory authorities governing the manufacture, quality control, further development, labeling, packaging, storage, distribution, adverse event reporting, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting of safety and other post-marketing information. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance by us and/or our CMOs with respect to product quality and manufacturing operations and our CROs for any post-approval clinical trials that we may conduct. The safety profile of any product will continue to be closely monitored by the FDA and comparable foreign regulatory authorities after approval. If the FDA or comparable foreign regulatory authorities become aware of new safety information after approval of any of our product candidates, they may require labeling changes or establishment of a REMS, 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 new legislation addressing drug safety issues could result in delays in product development or commercialization, or increased costs to assure compliance. If our original marketing approval for a product candidate was obtained through an accelerated approval pathway, we could be required to conduct a successful post-marketing clinical trial to confirm the clinical benefit for our products. An unsuccessful post-marketing clinical trial or failure to complete such a trial could result in the withdrawal of marketing approval.

In addition, manufacturers and manufacturers' facilities are required to continuously comply with FDA and comparable foreign regulatory authority requirements, including ensuring quality control and manufacturing procedures conform to cGMP regulations and corresponding foreign regulatory manufacturing requirements. Accordingly, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any BLA or NDA submission to the FDA or any other type of domestic or foreign marketing authorization application. We or our third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. If any of our third-party suppliers fails to comply with cGMP or other applicable manufacturing regulations, our ability to develop and commercialize our product candidates could suffer significant interruptions. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may take the following actions, any of which could significantly and adversely affect supplies of our products:

- issue Form 483 notices of observations, warning letters or untitled letters;
- mandate modifications to promotional materials or require us to provide corrective information to health care practitioners;
- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications filed by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products, refuse to permit the import or export of products, or require us to initiate a product recall.

Any government investigation of alleged violations of law would require us to expend significant time and resources in response and could generate adverse publicity. The occurrence of any event or penalty described above may inhibit our ability to successfully commercialize our products and generate revenues.

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

Risks Related to Our Manufacturing

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

We currently have direct or indirect agreements or arrangements with various third-party manufacturing facilities for production of our product candidates for research and development and testing purposes. For example, for SLS009 we are party to a supply agreement with GenFleet who has agreements with third-party manufacturers for the manufacture of SLS009. We depend on these manufacturers to meet our deadlines, quality standards and specifications. Reliance on third-party providers may expose us to more risk than if we were to manufacture our product candidates ourselves. We do not control the manufacturing processes of the CMOs we rely on and are dependent on those third parties for the production of our product candidates in accordance with relevant applicable regulations, such as cGMP, which includes, among other things, quality control, quality assurance and the maintenance of records and documentation. Our reliance on third parties for the manufacture of our active pharmaceutical ingredients and investigational drug products and, in the future, any approved products, creates a dependency that could severely disrupt our research and development, our clinical testing, and ultimately our sales and marketing efforts if the source of such supply proves to be unreliable or unavailable. If the contracted manufacturing source is unreliable or unavailable, we may not be able to manufacture clinical supplies of our product candidates, and our preclinical and clinical testing programs may not be able to move forward and our entire business plan could fail.

The third-party manufacturers we rely on for the manufacture of our product candidates are subject to inspection and approval by regulatory authorities before we can commence the manufacture and sale of any of our product candidates, and thereafter are subject to ongoing inspection from time to time. Our third-party manufacturers may not be able to comply with applicable cGMP regulations or similar regulatory requirements outside of the United States. In complying with the manufacturing regulations of the FDA and other comparable foreign regulatory authorities, we and our third-party suppliers must spend significant time, money and effort in the areas of design and development, testing, production, record-keeping and quality control to assure that the products meet applicable specifications and other regulatory requirements. If either we or the CMOs we rely on fail to comply with these requirements, our ability to develop and commercialize our product candidates could suffer significant interruptions, and we may be subject to regulatory enforcement action, including the seizure of products and shutting down of production.

Both the active pharmaceutical ingredient and drug product for our product candidates are currently single-sourced. We believe these single sources are currently capable of supplying all anticipated needs of our proposed clinical studies, as well as initial commercial introduction should such product candidates received regulatory approval. If we are able to commercialize our products in the future, there is no assurance that our manufacturers will be able to meet commercialized scale production requirements in a timely manner or in accordance with applicable standards or cGMP. Once the nature and scope of additional indications and their commensurate drug product demands are established, we will seek secondary suppliers of both the active pharmaceutical ingredients and drug products for our product candidates, but we cannot assure that such secondary suppliers will be found on terms acceptable to us, or in a timely manner, or at all.

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

We and the CMOs we rely on will need to conduct phase appropriate development work for each product candidate for each target indication for studies, trials and commercial launch readiness. We intend to improve the existing processes for GPS in connection with more advanced clinical trials or commercialization efforts we may undertake in the future. Developing commercially viable manufacturing processes is a difficult, expensive and uncertain task, and there are risks associated with scaling to the level required for advanced clinical trials or commercialization, including cost overruns, potential problems with process scale-up, process reproducibility, stability issues, storage issues, consistency and timely availability of reagents or raw materials. The manufacturing facilities in which our product candidates will be made could be adversely affected by infectious disease outbreaks, pandemics, earthquakes and other natural disasters, equipment failures, labor shortages, lack of adequate temperature controls, power failures, and numerous other factors. We currently estimate that we have sufficient clinical supplies to support our clinical trials, however, this estimate is dependent on patient enrollment rates and a number of other factors and, accordingly, could change. Moreover, current clinical supplies may not be adequate for future clinical studies.

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

- product loss due to contamination, equipment failure or improper installation or operation of equipment, or vendor or operator error;
- product loss or manufacturing failure due to failure of temperature controls in production, storage or transit;
- product loss, which may not be covered by insurance, due to global conflict and unrest, including related inoperability of shipping lanes;
- reduced production yields, product defects, and other supply disruptions due to deviations, even minor, from normal manufacturing and distribution processes;
- inability to procure or delay in procuring raw materials and reagents for manufacturing products;
- unexpected product defects;
- microbial, viral, or other contaminations in our product candidates or in the manufacturing facilities in which our product candidates are made, which may result in the closure of such manufacturing facilities for an extended period of time to allow for the investigation and remediation of the contamination; and
- adverse impact on the manufacturing of GPS as a result of potential contamination from excess humidity and oxygen which can lead to higher than acceptable levels of impurities resulting in the drug product being unacceptable for use.

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

In our GPS clinical trials, GM-CSF and Montanide are also administered in addition to GPS and their availability is dependent upon third-party manufacturers, which may or may not reliably provide GM-CSF or Montanide, thus jeopardizing the completion of the trials.

GPS is administered in combination with GM-CSF, which is available exclusively from one manufacturer, and Montanide, which is exclusively available from another supplier. We will continue to be dependent on these manufacturers for our supply of these materials in connection with the ongoing GPS trials and the potential commercial manufacture of GPS. We have not entered into a dedicated supply agreement with the manufacturers for GM-CSF or Montanide, and instead rely on purchase orders to meet our supply needs. Any temporary interruptions or discontinuation of the availability of these materials, or any determination by us to change their use with GPS, could have a material adverse effect on our clinical trials and any commercialization of the assets.

If any of the clinical manufacturing facilities of CMOs we rely on for clinical supply are damaged or destroyed or production at such facilities is otherwise interrupted, our business and prospects would be negatively affected.

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

Although we currently maintain insurance coverage against damage to our property and to cover business interruption and research and development restoration expenses, our insurance coverage may not reimburse us, or may not be sufficient to reimburse us, for any expenses or losses we may suffer. In addition, our clinical trials insurance coverage has exclusions for global conflict and unrest of the type currently ongoing in Ukraine. We may be unable to meet our requirements for our product candidates if there were a catastrophic event or failure of our current manufacturing facility or processes.

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

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

Our internal capacity for clinical trial execution and management is limited and therefore we rely heavily on third parties. We have relied upon and plan to continue to rely upon third-party CROs, vendors and contractors to monitor and manage data for our ongoing preclinical and clinical programs. We currently rely on and plan to continue to rely on a CRO for our Phase 3 trial for GPS in AML and well as all of our ongoing and contemplated clinical studies, with services to be rendered by such CROs and vendors ranging from specific and need-tailored (*e.g.*, data management and biostatistics) to, in the case of our Phase 3 trial for GPS in AML, all-encompassing. We rely on these parties for the execution of our preclinical studies and clinical trials, including the proper and timely conduct of our clinical trials, and we control only some aspects of their activities. Outsourcing these functions involves risk that third parties may not perform to our standards, may not produce results or data in a timely manner or may fail to perform at all.

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

If we or any of our partners or CROs fail to comply with applicable regulations and GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our regulatory applications. Upon inspection by a given regulatory authority, such regulatory authority could determine that any of our clinical trials are not in compliance with applicable requirements. In addition, our clinical trials must be conducted with product candidates produced

under cGMP and other requirements. We are also required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within a specified timeframe. Failure to comply also would violate federal requirements in the United States and could result in other penalties, which would delay the regulatory approval process and result in adverse publicity.

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

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

If any of our relationships with our third-party CROs, third-party vendors or contractors terminate, we may not be able to enter into arrangements with alternative CROs, third-party vendors or contractors on a timely basis, on commercially reasonable terms or at all.

Our CROs, third-party vendors and contractors have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs, third-party vendors and contractors have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated. Identifying, qualifying and managing performance of third-party service providers can be difficult, time consuming and cause delays in our development programs. In addition, there is a natural transition period when a new CRO, third-party vendor or contractor commences work and the new CRO, third-party vendor or contractor may not provide the same type or level of services as the original provider.

We have in-licensed a significant portion of our intellectual property from MSK. If we breach our license agreement with MSK, we could lose the ability to continue the development and potential commercialization of GPS.

GPS is in-licensed from MSK and includes an exclusive license to U.S. and foreign patent applications. Under the MSK license agreement, we are subject to various obligations, including diligence obligations with respect to funding, development and commercialization activities, payment obligations upon achievement of certain milestones and royalties on product sales, as well as other material obligations. If there is any conflict, dispute, disagreement or issue of nonperformance between us and MSK regarding our rights or obligations under the license agreements, including any such conflict, dispute or disagreement arising from our failure to satisfy diligence or payment obligations under any such agreement, we may be liable to pay damages and MSK may have a right to terminate the affected license. The loss of our license agreement with MSK could materially adversely affect our ability to proceed to utilize the affected intellectual property in our development efforts, our ability to enter into future collaboration, licensing and/or marketing agreements for GPS and our ability to commercialize GPS.

We rely on a license agreement with GenFleet for the development of SLS009, and if this license is breached or otherwise terminated, we could lose the ability to continue the development and potential commercialization of SLS009.

We have entered into a license agreement with GenFleet under which we have an exclusive license to develop and commercialize SLS009 worldwide, other than in mainland China, Hong Kong, Macau and Taiwan. Under the license agreement, we are subject to various obligations, including diligence obligations with respect to development and commercialization activities, payment obligations upon achievement of certain milestones, and royalties on annual net sales (if the product candidate is ultimately commercialized), as well as other material obligations. If there is any conflict, dispute, disagreement, or issue of nonperformance between us and GenFleet regarding our rights or obligations under the license agreement, including any such conflict, dispute, or disagreement arising from our failure to satisfy diligence or payment obligations under the license agreement, we may be liable to pay damages and GenFleet may have a right to terminate the license. The loss of the license agreement could prevent us from developing, commercializing, or entering into future strategic transactions relating to SLS009.

The risks described elsewhere pertaining to our patents and other intellectual property rights also apply to the intellectual property rights that we license, and any failure by us or our licensors to obtain, maintain and enforce these rights could have a material adverse effect on our business. In addition, our business depends on our ability to license additional therapeutic compounds from third parties. If we fail to meet our obligations under our current license agreements, we may lose the ability to enter into licenses for the development of additional product candidates in the future, which would adversely affect our business.

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

We may form strategic alliances, create joint ventures or collaborations or enter into licensing arrangements with third parties that we believe will complement or augment our existing business, such as our license agreement with 3D Medicines and our license agreement with GenFleet. These relationships, or those like them, may require us to incur nonrecurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic alliances and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic alliance or other alternative arrangements for any future product candidates and programs because our research and development pipeline may be insufficient, our product candidates and programs may be deemed to be at too early a stage of development for collaborative effort and third parties may not view our product candidates and programs as having the requisite potential to demonstrate safety and efficacy. If we license products or acquire businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. We cannot be certain that, following a strategic transaction or license, we will achieve the revenues or specific net income that justifies such transaction. Any delays in entering into new strategic alliances or license agreements related to our product candidates could also delay the development and commercialization of our product candidates and reduce their competitiveness even if they reach the market.

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

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

We may not be able to establish or maintain the third-party relationships that are necessary to develop or potentially commercialize some or all of our product candidates, including our relationship with 3D Medicines.

We expect to depend on collaborators, partners, licensees, clinical research organizations and other third parties to support our discovery efforts, to formulate product candidates, to manufacture our product candidates, to conduct clinical trials for some or all of our product candidates and to commercialize our product candidates if approved. For example, in December 2020 we entered into an Exclusive License Agreement with 3D Medicines pursuant to which we granted commercialization rights in Greater China to 3D Medicines. In accordance with the 3D Medicines Agreement and Side Letter, we expected that 3D Medicines would begin enrolling patients in mainland China in the REGAL study in the second half of 2023. To date, no patients have been enrolled in mainland China. However, patients were enrolled in the REGAL study in Taiwan, which is part of the Greater China territory, prior to the second half of 2023. Thus, we and 3D Medicines are currently engaged in a dispute regarding, among other things, the trigger and payment of the relevant milestone payments due to us as well as 3D Medicines' failure to use commercially reasonable best efforts to develop GPS in the Greater China territory, and particularly in mainland China. Over the last three to four months of 2023, we attempted to resolve the aforementioned matters in good faith under the dispute resolution provisions of the 3D Medicines Agreement with 3D Medicines but we were unable to reach a resolution. Accordingly, we commenced a binding arbitration proceeding administered by the Hong Kong International Arbitration Centre governed by New York State law as per the 3D Medicines Agreement in December 2023. We are unable at this time to predict with certainty the outcome of the arbitration proceeding, or the timing of the receipt of any milestone payments and other damages it is seeking in the arbitration proceeding, if at all.

Additionally, we cannot guarantee that we will be able to successfully negotiate future agreements for or maintain relationships with collaborators, partners, licensees, clinical investigators, vendors and other third parties on favorable terms, if at all. Our ability to successfully negotiate such agreements will depend on, among other things, potential partners' evaluation of the superiority of our technology over competing technologies and the quality of the preclinical and clinical data that we have generated, and the perceived risks specific to developing our product candidates. If we are unable to obtain or maintain these agreements, we may not be able to clinically develop, formulate, manufacture, obtain regulatory approvals for or commercialize our product candidates. We cannot necessarily control the amount or timing of resources that our contract partners, including 3D Medicines, will devote to our research and development programs, product candidates or potential product candidates, and we cannot guarantee that these parties will fulfill their obligations to us under these arrangements in a timely fashion, if at all. We may not be able to readily terminate any such agreements with contract partners even if such contract partners do not fulfill their obligations to us.

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

Risks Related to Our Intellectual Property

We may not be able to obtain and enforce patent rights or other intellectual property rights that cover our product candidates and that are of sufficient breadth to prevent third parties from competing against us.

Our success with respect to our product candidates will depend in part on our ability to obtain and maintain patent protection in the United States and abroad, to preserve our trade secrets, and to prevent third parties from infringing upon our proprietary rights. We seek to protect our proprietary position by filing in the United States and in certain foreign jurisdictions patent applications related to our novel technologies and product candidates that are important to our business. The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. In addition, we may not pursue or obtain patent protection in all major markets. Moreover, in some circumstances, we do not have the right to control the preparation, filing or prosecution of patent

applications, or to maintain the patents, covering technology that we license from third parties or covering technology that a collaboration or commercialization partner may develop. In some circumstances, our licensors have the right to prosecute and/or enforce the licensed patents without our involvement or consent, or to decide not to enforce or to allow us to enforce the licensed patents. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. If any such licensors fail to maintain such patents, or lose rights to those patents, the rights that we have licensed may be reduced or eliminated and our ability to develop and commercialize any of our products that are the subject of such licensed rights could be adversely affected.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign jurisdictions may not protect our rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than U.S. law does. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions. Moreover, the U.S. Patent and Trademark Office, or USPTO, might require that the term of a patent issuing from a pending patent application be disclaimed and limited to the term of another patent that is commonly owned or names a common inventor. As a result, the issuance, scope, validity, term, enforceability and commercial value of our patent rights are highly uncertain.

Our pending and future patent applications, and any collaboration or commercialization partner's pending and future patent applications, may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products.

During prosecution of any patent application, the issuance of any patents based on the application may depend upon our or our partners' ability to generate additional preclinical or clinical data that support the patentability of our proposed claims. We or any collaboration or commercialization partner may not be able to generate sufficient additional data on a timely basis, or at all. Moreover, changes in either the patent laws or interpretation of the patent laws in the United States or other countries may diminish the value of our or a collaboration or commercialization partner's patents or narrow the scope of our or their patent protection.

Changes in the patent laws, regulations, or interpretations thereof in the United States or abroad may diminish the value of our intellectual property.

The following are potential factors that could affect the scope our intellectual property:

Patent Reform Legislation: The United States Congress periodically considers patent reform legislation aimed at modifying the standards for patentability, patent enforcement procedures, or the rights of patent holders. Such legislative changes could introduce stricter requirements for patent eligibility, limit the scope of patent protection, or streamline patent challenges. Any of these changes may weaken the enforceability or value of our existing patents or make it more difficult to obtain new patents for our products or technologies.

Judicial Interpretations: Court decisions, particularly those from the United States Supreme Court and the Federal Circuit, play a crucial role in shaping patent law and practice. Shifts in judicial interpretations, such as alterations to the criteria for patent eligibility or obviousness-type double patenting, or the standard for proving patent infringement, may impact prosecution, defense, and enforcement of certain patent claims in our patent portfolio.

International Harmonization: Changes in patent laws or regulations in foreign jurisdictions where we hold or seek patent protection may also impact the value of our intellectual property. Harmonization efforts or shifts in international standards for patentability criteria, enforcement mechanisms, or patent term extensions could affect our ability to protect and monetize our intellectual property in key markets outside the United States.

Patent Regulations and Patent Office Practices: Alterations in patent examination procedures or policies at the United States Patent and Trademark Office, or USPTO, or foreign patent offices could influence the strength and scope of our patent rights. Changes in patent office practices related to patent eligibility or patentability standards, or the handling of post-grant proceedings such as inter partes reviews, or IPRs, may weaken our ability to obtain some patent claims or to enforce patents that may issue to us in the future. Moreover, changes in regulations governing patent rights, such as those related to government-funded programs, may affect our current or future intellectual property rights.

While we continuously monitor developments in patent laws and regulations, there can be no assurance that changes in patent laws, regulations, or interpretations thereof will not adversely affect the value of our intellectual property.

While we intend to take actions reasonably necessary to enforce our patent rights, we may not be able to detect infringement of our own or in-licensed patents, which may be especially difficult for methods of manufacturing or formulation products.

We depend, in part, on our licensors and collaborators to protect a substantial portion of our proprietary rights. In addition, third parties may challenge our in-licensed patents and any of our own patents that we may obtain, which could result in the invalidation or unenforceability of some or all of the relevant patent claims. Litigation or other proceedings to enforce or defend intellectual property rights is very complex, expensive, and may divert our management's attention from our core business and may result in unfavorable results that could adversely affect our ability to prevent third parties from competing with us.

If another party has reason to assert a substantial new question of patentability against any of our claims in our own and in-licensed patents, the third party can request that the patent claims be reexamined, which may result in a loss of scope of some claims or a loss of the entire patent. In addition to potential infringement suits, and interference and reexamination proceedings, we may become a party to *inter partes* and post-grant review proceedings in the United States and patent opposition proceedings outside the United States, where either the patentability of our patents is challenged, or we are challenging the patents of others. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful. As the medical device, biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that others may assert our commercial product and/or product candidates infringe their patent rights. If a third-party's patents were found to cover our commercial product and product candidates, proprietary technologies, or our uses, we or our collaborators could be enjoined by a court and required to pay damages and could be unable to continue to commercialize our products or use our proprietary technologies unless we or such collaborators obtained a license to the patent. A license may not be available to us or our collaborators on acceptable terms, if at all. In addition, during litigation, the patent holder could obtain a preliminary injunction or other equitable relief, which could prohibit us from making, using or selling our commercial product and product candidates pending a trial on the merits, which could be years away.

SLS009 may face generic competition sooner than expected before the expiration of our composition of matter patent protection.

Even if we are successful in achieving regulatory approval to commercialize SLS009, our product candidate may face generic competition. Once an NDA is approved, the product covered thereby becomes a "reference listed drug" in the FDA's Orange Book. In the United States, manufacturers may seek approval of generic versions of reference listed drugs through submission of an ANDA or approval through a 505(b)(2) NDA. In support of an ANDA, a generic manufacturer need not conduct clinical trials to assess safety and efficacy. Rather, the applicant generally must show that its product has the same active ingredient(s), dosage form, strength, route of administration and conditions of use or labelling as the reference listed drug and that the generic version is bioequivalent to the reference listed drug, meaning it is absorbed in the body at the same rate and to the same extent. Generic products may be significantly less costly to bring to market than the reference listed drug and companies that produce generic products are generally able to offer them at lower prices. Thus, following introduction of a generic drug, a significant percentage of the sales of any branded drug is typically lost to the generic product. In contrast, Section 505(b)(2) enables the applicant to rely, in part, on the FDA's prior findings of safety and efficacy data for an existing product, or published literature, in support of its application. Section 505(b)(2) provides an alternate path to FDA approval for new or improved formulations or new uses of previously approved products; for example, a follow-on

applicant may be seeking approval to market a previously approved drug for new indications or for a new patient population that would require new clinical data to demonstrate safety or effectiveness. Competition that our products could face from follow-on versions of our products could materially and adversely affect our future revenue, profitability and cash flows and substantially limit our ability to obtain a return on the investments we have made in those products. Because SLS009 has not been previously approved as an active ingredient, we expect the Hatch-Waxman Act to provide a five-year period of new chemical entity, or NCE, exclusivity following its approval during which time generic competitors cannot file an ANDA for a generic version of SLS009 or a 505(b)(2) NDA for SLS009, unless the submission contains a Paragraph IV Certification that one or more patents listed in the Orange Book for SLS009 are invalid, unenforceable or will not be infringed by a proposed ANDA product, in which case the submission may be made four years following the original drug approval. If a Paragraph IV Certification is made, the follow-on applicant is required to provide a Paragraph IV Notice Letter advising of the certification. If that occurs, we will have the opportunity to bring a patent infringement action against the follow-on applicant. If such a suit is filed within the 45-day period following receipt of the Paragraph IV Notice Letter, the Hatch-Waxman Act provides for a 30-month stay on FDA's ability to grant final approval of the proposed follow-on product. The 30-month stay generally runs from the date the Paragraph IV Notice Letter is received. However, when a Paragraph IV certification is received during the five-year period of NCE exclusivity following the date of first NDA approval, the 30-month stay extends from five years after the date that product was first approved. The 30-month stay may be shortened or lengthened, including due to a settlement of a lawsuit, a court order (including a decision by the district court on the merits of the case), or patent expiration. The party filing the ANDA or 505(b)(2) NDA may also counterclaim in the litigation that one or more of our patents are invalid, unenforceable, and/or not infringed. If all of the asserted SLS009 patents were found invalid, enforceable, and/or not infringed, a competing generic product could be marketed prior to expiration of those patents, our business could be harmed.

Settlements and related licensing agreements resulting from Hatch-Waxman litigation can be challenged and have the potential to generate additional litigation which can be costly. The success of such litigation depends on the strength of the patents covering our branded products and our ability to prove that the follow-on applicant's product would infringe one or more such patents. The outcome of such litigation is inherently uncertain and may result in potential loss of market exclusivity for SLS009, which may have a significant financial impact on our business. Furthermore, the Federal Trade Commission, or FTC, has brought successful lawsuits challenging Hatch-Waxman litigation settlements as anti-competitive, and such decisions have been upheld by federal circuit courts. If we engage in Hatch-Waxman litigation, we may also face an FTC challenge with respect to any proposed settlement related to such litigation, which may result in additional expense or penalty. The FTC also has more recently been questioning pharmaceutical company patent listings in the Orange Book and raising concerns about "improper" listings that may be intended to discourage competition by follow-on drug developers, and certain members of Congress have been investigating similar issues. Accordingly, there could be future changes to federal laws, regulations, or guidelines related to Hatch-Waxman requirements or procedures that could have a material adverse impact on all pharmaceutical innovators, including us.

If the FDA, EMA or other foreign regulatory authorities approve generic or biosimilar versions of any of our product candidates that receive marketing approval, or such authorities do not grant our products appropriate periods of exclusivity before approving generic or biosimilar versions of those products, the sales of our products, if approved, could be adversely affected.

Even if we are successful in achieving regulatory approval to commercialize a biologic product candidate ahead of our competitors, our product candidates may face competition from biosimilar and generic products. Most biological products are licensed for marketing by FDA via a BLA, under authorities in the Public Health Service Act, or PHSA. Assuming that we receive positive data from the REGAL trial, we will file a BLA in order to obtain marketing authorization for GPS. In 2010, the BPCIA, enacted as Title VII of the ACA, established an abbreviated pathway under the PHSA for licensure of biosimilar biologics (i.e., biosimilars, sometimes referred to as follow-on biologics). A biosimilar is a biological product that is demonstrated to be "highly similar" (i.e., biosimilar), but not identical, to an FDA-licensed biological product (i.e., the reference product).

The BPCIA also establishes periods of exclusivity for a brand-name biologic (the reference product), one with a duration of four years and the other with a duration of 12 years. These periods of regulatory exclusivity initiate upon licensure of the new biological product if certain requirements are met. During the four-year exclusivity period, an abbreviated BLA for a biosimilar referencing the protected brand-name biologic may not be submitted to FDA. During the 12-year exclusivity period, approval of an abbreviated BLA for a biosimilar referencing the protected

brand-name biologic may not be made effective, which means FDA may not approve the biosimilar application until 12 years after the date on which the reference product was first licensed.

In addition, the BPCIA provides for a process for disclosure and negotiation between the biosimilar applicant and reference product sponsor, sometimes referred to as the “patent dance.” Although not mandatory on the party of the biosimilar applicant, the dance involves several rounds of informational exchanges concerning potential disputes over the biosimilar applicant’s infringement of the reference product sponsor’s patents. Also, biosimilar licensure under the BPCIA is not contingent upon resolution of patent disputes. Therefore, the FDA may approve a biosimilar despite unresolved patent issues between the reference product sponsor and the biosimilar applicant.

We believe that GPS will qualify for four years of data exclusivity and 12 years of market exclusivity under the BPCIA. The law is complex and continues to be interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our product candidates. There is also a risk that the U.S. Congress could amend the BPCIA to shorten the 12-year market exclusivity period or that the FDA will not consider our product candidates to be reference biological products pursuant to its interpretation of the exclusivity provisions of the BPCIA for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated after the expiration of our patent protection. Moreover, the extent to which a biosimilar, once approved, will be substituted for any reference product 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. Under the BPCIA as well as state pharmacy laws, only interchangeable biosimilar products are considered substitutable for the reference biological product without the intervention of the health care provider who prescribed the original biological product. However, as with all prescribing decisions made in the context of a patient-provider relationship and a patient’s specific medical needs, health care providers are not restricted from prescribing biosimilar products in an off-label manner.

Even if, as we expect, GPS is considered to be reference products eligible for 12 years of exclusivity under the BPCIA, a competitor could decide to forego the abbreviated approval pathway available for biosimilar products and to submit a full BLA for product licensure after completing its own preclinical studies and clinical trials. In such a situation, any exclusivity to which we may be eligible under the BPCIA would not prevent the competitor from marketing its biological product as soon as it is approved.

In Europe, the European Commission has granted marketing authorizations for multiple biosimilar products pursuant to a set of general and product class-specific guidelines for biosimilar approvals. In addition, companies may be developing biosimilar products in other countries that could compete with our products, if approved.

The regulatory, or non-patent, exclusivity available to drugs or biologics in some countries is less than that provided by the United States. For instance, Canada currently provides for an eight-year period of exclusivity for new biological products, and Mexico provides for a five-year period of exclusivity. Furthermore, in some countries outside of the United States, peptide vaccines, such as GPS, are regulated as chemical drugs rather than as biologics and may or may not be eligible for non-patent exclusivity.

If competitors are able to obtain marketing approval for biosimilars referencing our therapeutic candidates, if approved, our future products may become subject to competition from such biosimilars, whether or not they are designated as interchangeable, with the attendant competitive pressure and potential adverse consequences. Such competitive products may be able to immediately compete with us in each indication for which our therapeutic candidates may have received approval.

If we are sued for infringing the intellectual property rights of third parties, such litigation could be costly and time-consuming and could prevent or delay our development and commercialization efforts.

Our commercial success depends, in part, on us and our collaborators not infringing the patents and proprietary rights of third parties. There is a substantial amount of litigation and other adversarial proceedings, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interference or derivation proceedings,

oppositions, and *inter partes* and post-grant review proceedings before the USPTO and non-U.S. patent offices. Numerous U.S. and non-U.S. issued patents and pending patent applications owned by third parties exist in the fields in which we are developing and may develop our current and future product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as our product pipeline grows, the risk increases that our product candidates may be subject to claims of infringement of third parties' patent rights as it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform or predictable.

If we are sued for patent infringement, we would need to demonstrate that our product candidates, products and methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Proving that a patent is invalid is difficult. If any issued third-party patents were held by a court of competent jurisdiction to cover aspects of our materials, formulations, methods of manufacture or methods for treatment, we could be forced, including by court order, to cease developing, manufacturing or commercializing the relevant product candidate until such patent expired. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and to continue developing, manufacturing or marketing the infringing product candidate. We could be prevented from commercializing a product candidate or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms. In addition, parties making claims against us may also obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates.

Defending against claims of patent infringement or misappropriation of trade secrets could be costly and time consuming, regardless of the outcome. Thus, even if we were to ultimately prevail, or to settle at an early stage, such litigation could burden us with substantial unanticipated costs. In addition, litigation or threatened litigation could result in significant demands on the time and attention of our management team, distracting them from the pursuit of other company business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent, or to redesign our infringing product candidates, which may be impossible or require substantial time and monetary expenditure. We may also elect to enter into license agreements in order to settle patent infringement claims prior to litigation, and any such license agreement may require us to pay royalties and other fees that could be significant. During the course of any patent or other intellectual property litigation, there could be public announcements of the results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our product candidates, programs or intellectual property could be diminished. Accordingly, the market price of our shares of common stock may decline.

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

Filing, prosecuting, enforcing and defending patents on our current and future product candidates in all countries throughout the world would be prohibitively expensive. We or our licensors' intellectual property rights in certain countries outside the United States may be less extensive than those in the United States. In addition, the laws of certain foreign countries do not protect intellectual property rights to the same extent as laws in the United States. Consequently, we and our licensors may not be able to prevent third parties from practicing our and our licensors' inventions in countries outside the United States, or from selling or importing infringing products made using our and our licensors' inventions in and into the United States or other jurisdictions. Competitors may use our and our licensors' technologies in jurisdictions where we have not obtained patent protection or where we do not have exclusive rights under the relevant patent(s) to develop their own products and, further, may export otherwise infringing products to territories where we and our licensors have patent protection but where enforcement is not as strong as that in the United States. These infringing products may compete with our product candidates in jurisdictions where we or our licensors have no issued patents or where we do not have exclusive rights under the relevant patent(s), or our patent claims and 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 foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor

the enforcement of patents and other intellectual property protection, particularly those relating to drugs and biologics, which could make it difficult for us and our licensors to stop the infringement of our and our licensors' patents or marketing of competing products in violation of our and our licensors' proprietary rights generally. Certain governments outside the United States have indicated that compulsory licenses to patents may be sought to further their domestic policies or on the basis of national emergencies. Proceedings to enforce our and our licensors' patent rights in foreign jurisdictions could result in substantial costs and divert our attention from other aspects of our business, could put our and our licensors' patents at risk of being invalidated or interpreted narrowly, could put our and our licensors' patent applications at risk of not issuing, and could provoke third parties to assert claims against us or our licensors. We or our licensors may not prevail in any lawsuit that we or our licensors initiate, and even if we or our licensors are successful the damages or other remedies awarded, if any, may not be commercially meaningful.

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 and on our stock price.

Third parties may infringe our patents, the patents of our licensors, or misappropriate or otherwise violate our or our licensors' intellectual property rights. We and our licensors' patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent is issued from such applications, and then only to the extent the issued claims cover the technology. In the future, we or our licensors may elect to initiate legal proceedings to enforce or defend our or our licensors' intellectual property rights, to protect our or our licensors' trade secrets or to determine the validity or scope of intellectual property rights we own or control. Any claims that we assert against perceived infringers could also provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property rights or that our intellectual property rights are invalid. In addition, third parties may initiate legal proceedings against us or our licensors to challenge the validity or scope of intellectual property rights we own or control. The proceedings can be expensive and time-consuming. Many of our or our licensors' adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our licensors can. Accordingly, despite our or our licensors' efforts, we or our licensors may not be able to prevent third parties from infringing upon or misappropriating intellectual property rights we own or control, particularly in countries where the laws may not protect our rights as fully as in the United States. Litigation 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, in whole or in part, or may refuse to stop the other party from using the technology at issue on the grounds that our or our licensors' patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our or our licensors' patents at risk of being invalidated, held unenforceable or interpreted narrowly.

Interference or derivation proceedings provoked by third parties, brought by us or our licensors or collaborators, or brought by the USPTO or any non-U.S. patent authority may be necessary to determine the priority of inventions or matters of inventorship with respect to our or our licensors' patents or patent applications. We may also become involved in other proceedings, such as reexamination, reissue, or opposition proceedings, *inter partes* review, post-grant review or other pre-issuance or post-grant proceedings in the USPTO or its foreign counterparts relating to our intellectual property or the intellectual property of others. An unfavorable outcome in any such proceeding could require us or our licensors to cease using the related technology and commercializing the affected product candidate, or to attempt to license rights to it from the prevailing party.

Our business could be harmed if the prevailing party does not offer us or our licensors a license on commercially reasonable terms if any license is offered at all. Even if we or our licensors obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us or our licensors. In addition, if the breadth or strength of protection provided by our or our licensor's patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current and future product candidates. Even if we successfully defend such litigation or proceeding, we may incur substantial costs and it may distract our management and other employees. We could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of shares of our common stock. Furthermore, under Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or MMA, certain agreements, including patent litigation settlement agreements between brand and generic drug companies, must be filed with the FTC and DOJ. The Patient Right to Know Drug Prices Act amended MMA Title XI, expanding the reporting requirements to include agreements between biosimilar product applicants and biologic companies.

Although we have taken steps to protect our trade secrets and unpatented know-how by entering into confidentiality agreements with third parties and proprietary information and invention agreements with our employees and certain consultants and advisors, third parties may still obtain this information or we may be unable to protect our rights.

There can be no assurance that binding agreements will not be breached, that we would have adequate remedies for any breach, or that our trade secrets and unpatented know-how will not otherwise become known or be independently discovered by our competitors. If trade secrets are independently discovered, we would not be able to prevent their use. Enforcing a claim that a third party illegally obtained and is using our trade secrets or unpatented know-how is expensive and time-consuming, and the outcome is unpredictable.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed to us alleged trade secrets of their other clients or former employers. As is common in the biotechnology and pharmaceutical industry, certain of our employees were formerly employed by other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Moreover, we engage the services of consultants to assist us in the development of our commercial product and product candidates, many of whom were previously employed at or may have previously been or are currently providing consulting services to, other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees and consultants or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers or their former or current customers. Litigation may be necessary to defend against these types of claims. Even if we are successful in defending against any such claims, any such litigation would likely be protracted, expensive, a distraction to our management team, not viewed favorably by investors and other third parties, and may potentially result in an unfavorable outcome.

If we are unable to protect the confidentiality of our trade secrets and other proprietary information, the value of our technology could be materially adversely affected, and our business could be harmed.

Proprietary trade secrets and unpatented know-how are also very important to our business. We have limited control over the protection of trade secrets used by our licensors, collaborators and suppliers. We rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce, and other elements of our technology, discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, including by enabling them to develop and commercialize products substantially similar to or competitive with our current or future product candidates, thus eroding our competitive position in the market. Trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements and invention assignment agreements with our employees, consultants, and outside scientific advisors, contractors and collaborators. These agreements are designed to protect our proprietary information. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, or outside scientific advisors might intentionally or inadvertently disclose our trade secrets or confidential, proprietary information to competitors. In addition, competitors may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. If any of our confidential proprietary information were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position.

Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, the laws of certain foreign countries do not protect proprietary rights such as trade secrets to the same extent or in the same manner as the laws of the United States. Misappropriation or unauthorized disclosure of our trade secrets to third parties could impair our competitive advantage in the market and could materially adversely affect our business, results of operations and financial condition.

Some intellectual property that we have in-licensed, if created as a result of government funded programs, may be subject to certain federal regulations.

Some of the agreements covering the intellectual property rights we have licensed provide that to the extent that such rights are derived from the use of U.S. government funding, those rights may therefore be subject to certain federal regulations. As a result, the U.S. government may have certain rights to intellectual property embodied in our current or future product candidates pursuant to the Bayh-Dole Act of 1980, or Bayh-Dole Act. These U.S. government rights in certain inventions developed under a government-funded program include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right to require us to grant exclusive, partially exclusive or non-exclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention, (ii) government action is necessary to meet public health or safety needs or (iii) government action is necessary to meet requirements for public use under federal regulations (also referred to as "march-in rights"). The U.S. government also has the right to take title to these inventions if we, or the applicable licensor, fail to disclose the invention to the government and fail to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us or the applicable licensor to expend substantial resources. In addition, the U.S. government requires that any products embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the United States. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. manufacturers may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property. To the extent any of our current or future intellectual property is generated through the use of U.S. government funding, the provisions of the Bayh-Dole Act may similarly apply. Moreover, changes in regulations related to government-funded programs may affect how the government may exercise march-in rights and affect any of our current or future intellectual property rights derived from U.S. government funding.

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

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

Our future success depends on our ability to demonstrate and maintain a competitive advantage with respect to the design, development, and commercialization of our product candidates. Our competitors may succeed in developing competing products before we do for the same indications we are pursuing, obtaining regulatory approval for products, or gaining acceptance for the same markets that we are targeting. If we are not "first to market" with a product candidate, thereby effecting our order of entry, our competitive position could be compromised via reduced market share and higher hurdles to regulatory approval.

We expect any product candidate which we commercialize will compete with products from other companies in the biotechnology and pharmaceutical industries. There are several biopharmaceutical companies which have approved treatments options in the United States for AML broadly, with different mechanisms of action, including AbbVie/Genentech (Venclexta), Pfizer (Mylotarg), Daiichi-Sankyo (Vanflyta), Rigel Pharmaceuticals (Rezlidhia), Syndax Pharmaceuticals (Revumenib) and Bristol Myers Squibb (Vidaza and Onureg).

Key late-stage pipeline agents that are different from GPS have been granted ODD or Fast Track designation due to the unmet need in AML. Therefore, clinical late-stage companies developing late-stage clinical candidates to treat r/r AML may enter the market before our potential products, such as Delta-Fly Pharma (DFP-10917) and AROG Pharmaceuticals (crenolanib).

With respect to WT1-targeting therapies, we do not believe GPS currently has direct competition in AML in the maintenance setting after CR2. While there are companies engaged in the clinical development of WT-1 targeting therapies, they are not currently focused on AML or have since discontinued or paused their development of WT-1 targeting therapies.

With respect to our SLS009 program, we anticipate competition from companies who have been engaged in the clinical development of selective CDK9-targeting therapies. There are other companies which are in early development stages for their CDK9 inhibitors and targeting other hematological malignancies or solid tumors, including Sumitomo Dainippon Pharma (TP-1287), Cothera Bioscience (zotiraciclib), and Prelude Therapeutics (PRT2527).

Many of our competitors have substantially greater commercial infrastructures and financial, technical and personnel resources than we have. In addition, some are farther along in their clinical development programs or in collaboration with larger, established pharmaceutical companies. We may not be able to compete unless we successfully:

- design and develop products that are superior to other products in the market;
- conduct successful preclinical and clinical trials;
- attract qualified scientific, medical, sales and marketing and commercial personnel;
- obtain patent and/or other proprietary protection for our processes and product candidates;
- obtain required regulatory approvals; and
- collaborate with others in the design, development, and commercialization of new products.

Established competitors may invest heavily to quickly discover and develop novel compounds that could make our product candidates obsolete. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability, and safety to overcome price competition and to be commercially successful. If we are not able to compete effectively against our current and future competitors, our business will not grow, and our financial condition and operations will suffer.

If we obtain marketing approval, our commercial success depends on establishing or implementing our own sales, marketing, access and reimbursement, and distribution capabilities or entering into licensing or collaboration agreements for these purposes, and the timing of these.

With the exception of very few employees, including our executive officers, we have not yet built a broader team with any significant sales, marketing, access and reimbursement, or distribution experience. If we progress toward regulatory approval, we will take an efficient and measured approach to building an appropriately sized commercial infrastructure depending on whether we choose to commercialize our current and any future product candidates on our own or through licensing, distribution or collaboration agreements. We will have to invest significant amounts of financial and management resources, some of which will be committed prior to the receipt of positive data if we choose to commercialize on our own. We may need to successfully recruit, retain and train a broad complement of effective commercial staff, including, but not limited to, sales, access and reimbursement, business analytics, and diagnostics. As AML is a highly competitive space, we would expect some personnel to be sought by our competitors. Any delays in hiring an adequate number of experienced sales personnel (including support staff), inability to obtain access to key markets, and unforeseen time, cost and expenses associated with creating a separate and high performing sales and marketing organization could adversely impact commercialization of any product for which we obtain marketing approval.

We may elect to utilize other means of commercialization should the economics of the approach be deemed appropriate. This could include contract sales forces or strategic partners to support in the commercialization of our product candidates. If we enter into arrangements with third parties to perform sales, marketing and distribution services for our products, the resulting revenues or the profitability from these revenues to us are likely to be lower than if we had sold, marketed and distributed our products ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates, or do so in a timely manner, or may be unable to do so on terms that are favorable to us. We may also need the infrastructure and resources to maintain the contractual relationships and external support. If we are not able to timely and properly establish a commercial organization on our own or in collaboration with third parties, then we may not be profitable.

Our commercial success depends upon attaining significant market acceptance of our current and future product candidates, if approved, among health care providers, third-party payors and operators of major cancer clinics.

Even if we obtain regulatory approval for any of our current or future product candidates, the products may not gain market acceptance among physicians, third-party payors, patients or the medical community. For example, current cancer treatment such as chemotherapy and radiation therapy are well-established in the medical community, and health care providers may continue to rely on these treatments. The degree of market acceptance of any product candidates for which we receive approval depends on a number of factors, including:

- the efficacy and safety of such product candidates as demonstrated in clinical trials, and acceptance of such by physicians, major cancer treatment centers, and patients;
- the potential and perceived advantages and disadvantages of product candidates over alternative treatments, including the degree of clinically meaningful improvement in care, ease of administration and prevalence and severity of side effects;
- the clinical indications and patient populations for which the product candidate is approved and the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the ability to garner placement of our therapeutics in widely accepted clinical practice treatment guidelines;
- the placement, or the lack of placement, of our therapeutics in reputable and highly regarded clinical treatment guidelines;

- product labeling or product insert requirements of the FDA or other regulatory authorities and any restrictions on use with other medications;
- the timing of market introduction of our products as well as competitive products;
- the cost of treatment and coverage and reimbursement status;
- development and effectiveness of our sales and marketing, manufacturing and distribution efforts for commercial scale; and
- new healthcare legislation that could adversely affect the payor profile of our marketed assets.

If any of our current and future product candidates are approved but fail to achieve market acceptance, we will not be able to generate significant revenues, which would compromise our ability to become profitable.

Even if we are able to commercialize our current or future product candidates, the products may become subject to unfavorable pricing regulations, third-party reimbursement practices or health care reform initiatives, which could harm our business.

Significant uncertainty exists as to the coverage and reimbursement status of any drug or biological candidates for which we obtain regulatory approval. The regulations that govern marketing approvals, pricing and reimbursement (public and private) for new drug products vary widely from country to country. In the United States, recently passed legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and 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 any product successfully will also depend, in part, on the extent to which reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will cover and how much they will pay. A primary trend in the U.S. health care industry and elsewhere is cost containment. Government authorities and third-party have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product that we commercialize and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a physician. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or similar foreign regulatory authorities outside the United States. Moreover, eligibility for coverage does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government health care programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third-party commercial payors often

follow CMS coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Further, there have been, and may continue to be, legislative and regulatory proposals at the U.S. federal and state levels and in foreign jurisdictions directed at broadening the availability and containing or lowering the cost of health care. The continuing efforts of the government, insurance companies, managed care organizations and other third-party payors to contain or reduce costs of health care may adversely affect our ability to set prices for our products that would allow us to achieve or sustain profitability. In addition, governments may impose price controls on any of our products that obtain marketing approval, which may adversely affect our future profitability.

More recently, in August 2022, the IRA was signed into law. Among other things, the IRA (see above "Government Regulation—Healthcare Reform"). If a drug product is selected by CMS for negotiation, it is expected that the revenue generated from such drug will decrease. CMS has begun to implement these new authorities announcing the first round of negotiated prices for the first 10 drug products in August 2024, which will become applicable for payment year 2026. The second round of negotiated prices for 15 drug products was announced in November 2025. However, the IRA's impact on the pharmaceutical industry in the United States remains uncertain, in part because multiple large pharmaceutical companies and other stakeholders (e.g., the U.S. Chamber of Commerce) have initiated federal lawsuits against CMS arguing the program is unconstitutional for a variety of reasons, among other complaints. Those lawsuits are currently ongoing.

In some foreign countries, particularly the member states of the EU, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can be a long and expensive process after the receipt of marketing approval for a drug candidate. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. In some countries, we may be required to conduct additional clinical trials that compare the cost-effectiveness of our drug candidates to other available therapies in order to obtain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on prices or reimbursement levels within the country of publication and other countries. If reimbursement of our products is unavailable or limited in scope or amount in a particular country, or if pricing is set at unsatisfactory levels, we may be unable to successfully commercialize and achieve or sustain profitability for sales of any of our drug candidates that are approved for marketing in that country and our business could be adversely affected.

Health care policy changes may have a material adverse effect on our business and results of operations.

Our business may be affected by the efforts of government and third-party payors to contain or reduce the cost of health care through various means. For example, the recently enacted IRA requires drug manufacturers to pay a rebate to the federal government if prices for single-source drugs and biologicals covered under Medicare Part B and nearly all covered drugs under Part D increase faster than the rate of inflation (CPI-U Penalty). The Patient Protection and Affordable Care Act, and the Health Care and Education Affordability Reconciliation Act of 2010, or collectively, the ACA, enacted in March 2010, substantially changed the way health care is financed by both governmental and private insurers, and significantly impacted the pharmaceutical industry, by among other things, increasing the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; introducing a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; extending the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care plans; imposing mandatory discounts for certain Medicare Part D beneficiaries as a condition for manufacturers' outpatient drugs coverage under Medicare Part D; and establishing a Center for Medicare Innovation at the CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending. Regardless of whether or not the ACA is changed or modified by Congress or the U.S. Supreme Court, we expect both government and private

health plans to continue to require health care providers, including health care providers that may one day purchase our products, to contain costs and demonstrate the value of the therapies they provide.

Additionally, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices considering the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several 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, in May 2019, CMS issued a final rule to allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. In addition, the 2021 Consolidated Appropriations Act signed into law on December 27, 2020, incorporated extensive health care provisions and amendments to existing laws, including a requirement that all manufacturers of drug products covered under Medicare Part B report the product's average sales price to CMS beginning on January 1, 2022, subject to enforcement via civil money penalties.

Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control biopharmaceutical 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. For example, in recent years, several states have formed PDABs. Much like the IRA's drug price negotiation program, these PDABs have attempted to implement upper payment limits on drugs sold in their respective states in both public and commercial health plans. For example, in August 2023, Colorado's PDAB announced a list of five prescription drugs that would undergo an affordability review. The effects of these efforts remain uncertain pending the outcomes of several federal lawsuits challenging state authority to regulate prescription drug payment limits. In December 2020, the U.S. Supreme Court held unanimously that federal law does not preempt the states' ability to regulate pharmacy benefit managers, or PBMs, and other members of the health care and pharmaceutical supply chain, an important decision that may lead to further and more aggressive efforts by states in this area. In addition, the FTC in mid-2022 also launched sweeping investigations into the practices of the PBM industry that could lead to additional federal and state legislative or regulatory proposals targeting such entities' operations, pharmacy networks, or financial arrangements. Significant efforts to change the PBM industry as it currently exists in the United States may affect the entire pharmaceutical supply chain and the business of other stakeholders, including biopharmaceutical developers like us.

We expect that these and other health care reform measures that may be adopted in the future may result in additional reductions in Medicare and other health care funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of health care services to contain or reduce costs of health care and/or impose price controls may adversely affect:

- the demand for our product candidates, if we obtain regulatory approval;
- our ability to receive or set a price that we believe is fair for our products;
- our ability to generate revenue and achieve or maintain profitability;
- our ability to enjoy or maintain market exclusivity;
- the level of taxes that we are required to pay; and
- the availability of capital.

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

In some countries, particularly member states of the EU, the pricing of prescription drugs is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after

receipt of regulatory approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Global reference pricing used by most (if not all) EU member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. In some countries, we or our collaborators may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be adversely affected.

Risks Related to Health Care Compliance Regulations

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

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

- the federal health care Anti-Kickback Statute which prohibits, among other things, individuals and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal health care program such as Medicare or Medicaid;

- federal civil and criminal false claims laws, including the FCA that can be enforced through civil whistleblower or qui tam actions, and civil monetary penalty laws, prohibit individuals or entities from knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment or approval that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any health care benefit program and also created federal criminal laws that prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of or payment for health care benefits, items or services, and further, as amended by HITECH, imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information on entities subject to the law, such as certain health care providers, health plans, and health care clearinghouses, known as covered entities, and their respective business associates that perform services for them that involve the creation, use, maintenance or disclosure of, individually identifiable health information;

- the federal physician sunshine requirements under the ACA which requires certain manufacturers of drugs, devices, biologics and medical supplies, with certain exceptions, to report annually to HHS information related to payments and other transfers of value to physicians, certain advanced non-physician health care

practitioners, and teaching hospitals, and ownership and investment interests held by physicians and other health care providers and their immediate family members and applicable group purchasing organizations;

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving health care items or services reimbursed by non-governmental third-party payors, including private insurers; some state laws which require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other health care providers, marketing expenditures or pricing information; and certain state and local laws which require the registration of pharmaceutical sales representatives; and

- state and foreign laws govern the privacy and security of health information in specified circumstances, including the GDPR, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable health care laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other health care laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, disgorgement, exclusion from government funded health care programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, and the curtailment or restructuring of our operations. If any physicians or other health care providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded health care programs. Many health care laws and regulations are rapidly changing and legislative bodies and regulatory agencies are regularly considering amendments and supplements to existing laws and regulations, and as a result interpretations of rules and confirmation of our compliance with such rules can be ambiguous.

We may be subject to, or may in the future become subject to, U.S. federal and state, and international laws and regulations imposing obligations on how we collect, use, disclose, store and process personal information. Our actual or perceived failure to comply with such evolving privacy and data protection laws could adversely affect our business, results of operations, and financial condition.

New privacy and data security laws have been proposed in more than half of the states in the United States and in the U.S. Congress, reflecting a trend toward more stringent privacy legislation in the U.S., which trend may accelerate with increasing concerns about individual privacy. The existence of comprehensive privacy laws in different states in the U.S. may make our compliance obligations more complex and costly, may require us to modify our data processing practices and policies, and may require us to incur substantial costs and potential liability in an effort to comply.

In California, the CCPA, which became effective in 2020, broadly defines personal information, gives California residents expanded individual privacy rights and protections, provides for civil penalties for violations, and gives California residents a private right of action for data breaches in certain cases. Further, the California Privacy Rights Act, or the CPRA, which became effective in 2023 and amends the CCPA, imposes additional obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It also created a new California Privacy Protection Agency authorized to issue substantive regulations and is expected to result in increased privacy and information security enforcement. The CPRA also extends the provisions of both the CCPA and the CPRA to the personal information of California-based employees. While there is an exception for certain health information, including protected health information that is subject to HIPAA, and clinical trial data, the CCPA may impact our business activities if we become a "Business" regulated by the CCPA. Further, there continues to be some uncertainly about how certain provisions of the CCPA will be interpreted and how some areas of the law will be enforced. We will continue to monitor developments related to the CCPA and anticipate additional costs and expenses associated with compliance.

In addition to the CCPA, numerous other states have either enacted are considering enacting new comprehensive privacy laws.

Other U.S. states, such as New York and Massachusetts have enacted stringent data security laws and numerous other states have proposed similar laws. Additionally, various states, such as California and Massachusetts, have implemented similar privacy laws and regulations, such as the California Confidentiality of Medical Information Act, that impose restrictive requirements regulating the use and disclosure of health information and other personally identifiable information. These laws and regulations are not necessarily preempted by HIPAA, particularly if a state affords greater protection to individuals than HIPAA. Where state laws are more protective, we have to comply with the stricter provisions. In addition to fines and penalties imposed upon violators, some of these state laws also afford private rights of action to individuals who believe their personal information has been misused. California's patient privacy laws, for example, provide for penalties of up to $250,000 and permit injured parties to sue for damages. Similarly, as discussed above, the CCPA allows consumers a private right of action when certain personal information is subject to unauthorized access and exfiltration, theft or disclosure due to a business' failure to implement and maintain reasonable security procedures.

Furthermore, over the past few years, the number of privacy-related enforcement actions in the U.S., and in many cases the fines, have steadily increased. Failure to comply with these current and future laws, policies, industry standards, or legal obligations. or any data breach involving personal information, may result in government enforcement actions, litigation, fines, and penalties, private litigation, or adverse publicity, and could cause our customers, business partners, and investors to lose trust in us which could have a material adverse impact on our business, results of our operations, and our financial condition. We continue to face uncertainty as to the exact interpretation of the new requirements on our clinical trials and we may be unsuccessful in implementing all measures required by data protection authorities or courts in interpretation of the new law.

The interplay of federal and state laws may be subject to varying interpretations by courts and government agencies, creating complex compliance issues for us and data we receive, use and share, potentially exposing us to additional expense, adverse publicity and liability. Further, as regulatory focus on privacy issues continues to increase and laws and regulations concerning the protection of personal information expand and become more complex, these potential risks to our business could intensify. Changes in laws or regulations associated with the enhanced protection of certain types of sensitive data, for the treatment of genetic data, along with increased customer demands for enhanced data security infrastructure, could greatly increase our cost of providing our products, decrease demand for our products, reduce our revenues and/or subject us to additional liabilities.

In many activities, including the conduct of clinical trials and our regulatory and commercial operations in the EEA and the United Kingdom, or UK, we are subject to international laws and regulations governing data privacy and the protection of health-related and other personal information. The regulatory framework for collecting, using, safeguarding, sharing, transferring and other processing of information worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. The withdrawal of the UK from the EU and the subsequent separation of the data protection regimes of these territories means we are required to comply with separate data protection laws in the EU and the UK, which may lead to additional compliance costs and could increase our overall risk. Similar laws and regulations govern our processing of personal data, including the collection, access, use, analysis, modification, storage, transfer, security breach notification, destruction and disposal of personal data. For example, the collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the EU, including personal health data, is subject to the GDPR, which took effect across all Member States of the EEA on May 25, 2018, and as still in effect in the UK as the UK GDPR. On June 28, 2021, the EU Commission adopted decisions on the UK's adequacy under the EU GDPR, and the UK continues to operate under this adequacy decision. The GDPR applies to any company established in the EU as well as to those outside the EU that process personal data in connection with the offering of goods or services to individuals in the EU or the monitoring of their behavior. We currently conduct clinical trials and engage in regulatory and commercial operations in the EEA and the UK. As a result, we are subject to privacy laws, including the GDPR and UK GDPR. The GDPR imposes a broad range of data protection obligations on controllers and/or processors, as applicable, that must be complied with when processing personal data subject to the GDPR, including, for example, providing expanded disclosures about how their personal data will be used; higher standards for organizations to demonstrate that they have obtained valid consent or have another legal basis in place to justify their data processing activities; the obligation to

appoint data protection officers in certain circumstances; new rights for individuals to be “forgotten” and rights to data portability, as well as enhanced current rights (e.g., access requests); the principal of accountability and demonstrating compliance through policies, procedures, training and audit; limitations on retention of information; mandatory data breach notification requirements; ; safeguards to protect the security and confidentiality of personal data; restrictions on transfers of personal data outside of the EU to third countries deemed to lack adequate privacy protections (such as the U.S.), and onerous new obligations and liabilities on services providers or data processors. .In particular, medical or health data, genetic data and biometric data are all classified as “special category” data under the GDPR and afford greater protection and require additional compliance obligations. Further, the UK and EU member states have a broad right to impose additional conditions—including restrictions—on these data categories. This is because the GDPR allows EU member states to derogate from the requirements of the GDPR mainly in regard to specific processing situations (including special category data and processing for scientific or statistical purposes). Non-compliance with the GDPR may result in monetary penalties of up to €20 million or 4% of worldwide turnover, whichever is greater. Moreover, data subjects can claim damages resulting from infringement of the GDPR. The GDPR further grants non-profit organizations and consumer organizations the right to bring claims on behalf of data subjects. The GDPR and other changes in laws or regulations associated with the enhanced protection of certain types of personal data, such as healthcare data or other sensitive information, could greatly increase our cost of providing our products and services or even prevent us from offering certain services in jurisdictions that we may operate in. The GDPR may increase our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, including as implemented by individual EU Member States. Compliance with the GDPR is a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our EU activities.

Further, as referenced above, following the UK’s withdrawal from the EU (i.e., Brexit), and the expiry of the Brexit transition period, which ended on December 31, 2020, the EU GDPR has been implemented in the UK (as the UK GDPR). The UK GDPR sits alongside the UK Data Protection Act 2018 which implements certain derogations in the EU GDPR into UK law. Under the UK GDPR, companies not established in the UK but who process personal data in relation to the offering of goods or services to individuals in the UK, or to monitor their behavior will be subject to the UK GDPR – the requirements of which are (at this time) largely aligned with those under the EU GDPR and as such, may lead to similar compliance and operational costs. Non-compliance with the UK GDPR may result in monetary penalties of up to £17.5 million or 4% of worldwide turnover, whichever is higher.

In addition, we may be unable to transfer personal data from the EU, UK, and other jurisdictions to U.S or other countries due to limitations on cross-border data flows. In particular, the EEA and the UK have significantly regulated the transfer of personal data to the U.S and other countries whose privacy laws it believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and the UK to the U.S. in compliance with law, such as the EEA and UK’s standard contractual clauses and the newly-adopted Data Privacy 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 U.S.. If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the U.S., or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, 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 the UK to other jurisdictions, particularly to the U.S., are subject to increased scrutiny from regulators, individual litigants, and activist groups.

If we are investigated by an EEA or UK data protection authority, we may face fines and other penalties, which could have a negative effect on our existing business and on our ability to attract and retain new clients or pharmaceutical partners. We may also experience hesitancy, reluctance, or refusal by EEA, UK, or multi-national clients or pharmaceutical partners to continue to use our products due to the potential risk exposure because of the current (and future) data protection obligations imposed on them by certain data protection authorities in interpretation of current law, including the GDPR and UK GDPR. Such clients or pharmaceutical partners may also

view any alternative approaches to compliance as being too costly, too burdensome, too legally uncertain, or otherwise objectionable and therefore decide not to do business with us. Any of the foregoing could materially harm our business, prospects, financial condition, and results of operations.

In addition, many jurisdictions outside of the EEA and the UK are also considering and/or enacting comprehensive data protection legislation. For example, as of August 2020, the Brazilian General Data Protection Law imposes stringent requirements similar to GDPR with respect to personal information collected from individuals in Brazil.

In China, there have also been recent significant developments concerning privacy and data security. The Data Security Law of the People's Republic of China (Data Security Law), which took effect on September 1, 2021, requires data processing (which includes the collection, storage, use, processing, transmission, provision and publication of data), to be conducted in a legitimate and proper manner. The Data Security Law imposes data security and privacy obligations on entities and individuals carrying out data processing activities and also introduces a data classification and hierarchical protection system based on the importance of data in economic and social development and the degree of harm it may cause to national security, public interests, or legitimate rights and interests of individuals or organizations if such data are tampered with, destroyed, leaked, illegally acquired or illegally used. The appropriate level of protection measures is required to be taken for each respective category of data.

Also in China, the Personal Information Protection Law, which took effect on November 1, 2021, introduced stringent protection requirements for processing personal information, which are in many ways akin to the requirements of the GDPR. We may be required to make further significant adjustments to our business practices to comply with the personal information protection laws and regulations in China including the Personal Information Protection Law.

We also continue to see jurisdictions imposing data localization laws. These regulations may interfere with our intended business activities, inhibit our ability to expand into those markets or prohibit us from continuing to offer services in those markets without significant additional costs.

Because the interpretation and application of many domestic and international privacy and data protection laws, commercial frameworks, and standards are uncertain, it is possible that these laws, frameworks, and standards may be interpreted and applied in a manner that is inconsistent with our existing data management practices and policies. It is also possible that by complying with one law, we may be violating another. In addition to the possibility of fines, lawsuits, breach of contract claims, and other claims and penalties, we could be required to fundamentally change our business activities and practices or modify our solutions, which could have an adverse effect on our business. Failure to comply with current and future privacy and data protection laws and regulations could result in government enforcement actions (including the imposition of significant penalties), criminal and civil liability for us and our officers and directors, private litigation and/or adverse publicity that negatively affects our business. Any inability to adequately respond to privacy and security concerns, even if unfounded, or to comply with applicable privacy and data protection laws, regulations, and policies, could result in additional cost and liability to us, damage our reputation, inhibit our ability to conduct trials, and adversely affect our business.

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

We are exposed to the risk of employee fraud or other misconduct, including intentional failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, provide accurate information to the FDA or comparable foreign regulatory authorities, comply with manufacturing standards we have established, comply with federal and state health care fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, report financial information or data accurately or disclose unauthorized activities to us. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in

compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government funded health care programs, such as Medicare and Medicaid, and integrity oversight and reporting obligations.

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

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

- decreased demand for any product candidates or products that we may develop;
- termination of clinical trial sites or entire clinical trial programs;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial subjects or patients;
- loss of revenue;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize any products that we may develop.

We currently hold product liability insurance coverage at a level that we believe is customary for similarly situated companies and adequate to provide us with insurance coverage for foreseeable risks, but which may not be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. We intend to expand our insurance coverage for products to include the sale of commercial products if we obtain regulatory approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products that receive regulatory approval. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business. In addition, even in instances where we have insurance coverage, our insurance carriers may deny coverage, which could lead to the inability to recover for certain losses and costly insurance coverage disputes with our carriers.

Risks Related to our Business Operations

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reports, which would harm our business, the trading price of our common stock and our ability to raise additional capital in the future.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement

required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. Ineffective internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock, and which could impact our ability to raise capital in the future. In addition, any future testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or SOX, or any required subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our consolidated financial statements or identify other areas for further attention or improvement.

We are required, pursuant to Section 404 of SOX, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting as of December 31, 2025. However, our independent registered public accounting firm is not required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404. Under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, our management conducted an evaluation of the effectiveness of our internal control over financial reporting based on the guidelines in the Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on that evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2025. An independent assessment of the effectiveness of our internal controls could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of remediation.

We enter into various contracts in the normal course of our business in which we may be required to indemnify the other party to the contract under certain specific scenarios. In the event we have to perform under these indemnification provisions, it could have a material adverse effect on our business, financial condition and results of operations.

In the normal course of business, we periodically enter into academic, commercial, service, collaboration, licensing, consulting and other agreements that contain indemnification provisions. With respect to our academic and other research agreements, we typically agree to indemnify the institution and related parties from losses arising from claims relating to the products, processes or services made, used, sold or performed pursuant to the agreements for which we have secured licenses, and from claims arising from our or our sublicensees' exercise of rights under the agreement. With respect to our collaboration agreements, we indemnify our collaborators from any third-party product liability claims that could result from the production, use or consumption of the product, as well as for alleged infringements of any patent or other intellectual property right by a third party. With respect to consultants, we indemnify them from claims arising from the good faith performance of their services.

Should our obligations under an indemnification provision exceed applicable insurance coverage or if we were denied insurance coverage for any claim, our business, financial condition and results of operations could be adversely affected. Similarly, if we are relying on a collaborator to indemnify us and the collaborator is denied insurance coverage for the claim or the indemnification obligation exceeds the applicable insurance coverage, and if the collaborator does not have other assets available to indemnify us, our business, financial condition and results of operations could be adversely affected.

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

We rely to a large extent upon sophisticated information technology networks and systems to operate our business. In the ordinary course of business, we collect, store and transmit large amounts of confidential information (including, but not limited to, personal information and intellectual property). We also have outsourced significant elements of our operations to third parties, including significant elements of our information technology infrastructure and, as a result, we rely on third parties that process confidential information on our behalf. This includes information technology systems of MSK, our CROs, our CMOs, and other business vendors on which we rely. The size and complexity of our information technology and information security systems, and those of our third-party vendors with whom we contract, and the confidential information and data stored or processed thereon, make such systems potentially vulnerable to computer viruses, bugs, worms, or other malicious codes, malware, including as a result of advanced persistent threat intrusions, and other attacks by computer hackers, cracking, application

security attacks, social engineering, including through phishing attacks, supply chain attacks and vulnerabilities through our third-party service providers, denial-of-service attacks, such as credential stuffing, credential harvesting, personnel misconduct or error, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, and other similar threats. Such attacks are of ever-increasing levels of sophistication and are made by groups, including nation states and organized crime, and individuals with a wide range of motives (including, but not limited to, industrial espionage and market manipulation) and expertise. These threats pose a risk to the security of our systems and networks and the confidentiality, availability and integrity of our data. While we have invested significantly in the protection of data and information technology, there can be no assurance that we will be able to detect any such disruption or cybersecurity incident in a timely manner or at all, or that our efforts will prevent service interruptions or cybersecurity incidents.

While we have implemented security measures, there can be no assurances that a cybersecurity incident or any other previously identified threats will not occur. Any such event could have a material adverse effect upon our reputation, business, operations, or financial condition. For example, if such an event were to occur and cause interruptions in our operations or those of our third-parties on which we rely, it could result in a material disruption of our drug development programs and the development of our services and technologies could be delayed. Any such interruption or breach could adversely affect our business operations and/or result in the loss of critical or sensitive confidential information or intellectual property, and could result in financial, legal, business and reputational harm to us or allow third parties to gain material, inside information that they use to trade in our securities. For example, the loss of clinical trial data from completed or ongoing clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or cybersecurity incident results in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, the further development of our current and future product candidates could be delayed and our business could be otherwise adversely affected.

The costs related to significant cybersecurity incidents or disruptions could be material and could exceed the limits of the cybersecurity insurance we maintain against such risks. If the information technology systems of our third-party vendors and other contractors and consultants become subject to disruptions or cybersecurity incidents, we may have insufficient recourse against such third parties and may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring.

Furthermore, significant disruptions of our internal information technology systems or those of our third-party vendors and other contractors and consultants, or cybersecurity incidents could result in the loss, misappropriation, and/or unauthorized access, use, or disclosure of, or the prevention of access to, confidential information (including trade secrets or other intellectual property, proprietary business information, and personal information), which could result in financial, legal, business, and reputational harm to us. For instance, any such event that leads to unauthorized access to, or use, acquisition, or disclosure of personal information, including personal information regarding our customers, employees or other individuals, could harm our reputation, subject us to liability under and require us to comply with federal and/or state breach notification laws and international law equivalents, domestic or international privacy, data protection, and data security laws such as HIPAA and HITECH, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information. Such incidents could also result in legal claims or proceedings. Certain cybersecurity incidents require notice to the affected individuals, contractual partners, regulatory authorities such as the Secretary of HHS and attorneys general, and in some cases, require notice to the media. Such notice could harm our reputation and our ability to compete, result in significant legal and financial exposure and reputational damages, and loss of confidence in us, all of which could potentially have an adverse effect on our business.

Although we have implemented security measures, there is no guarantee we can protect our data from cybersecurity incidents. Cybersecurity incidents could also damage our reputation or disrupt our operations, including our ability to conduct our analyses, conduct research and development activities, collect, process and prepare company financial information, and manage the administrative aspects of our business.

Penalties for violations of these laws vary. For instance, penalties for failure to comply with a requirement of HIPAA and HITECH vary significantly, and include significant civil monetary penalties and, in certain circumstances,

criminal penalties with fines up to $250,000 per violation and/or imprisonment. A person who knowingly obtains or discloses individually identifiable health information in violation of HIPAA may face a criminal penalty of up to $50,000 and up to one-year imprisonment. The criminal penalties increase if the wrongful conduct involves false pretenses or the intent to sell, transfer or use identifiable health information for commercial advantage, personal gain or malicious harm.

Artificial intelligence presents risks and challenges that can impact our business including by posing security risks to our confidential information, proprietary information, and personal data.

Issues in the development and use of artificial intelligence, combined with an uncertain regulatory environment, may result in reputational harm, liability, or other adverse consequences to our business operations. As with many technological innovations, artificial intelligence presents risks and challenges that could impact our business. Our vendors may incorporate generative artificial intelligence tools into their offerings without disclosing this use to us, and the providers of these generative artificial intelligence tools may not meet existing or rapidly evolving regulatory or industry standards with respect to privacy and data protection and may inhibit our or our vendors' ability to maintain an adequate level of service and experience. If we, our vendors, or our third-party partners experience an actual or perceived breach or privacy or security incident because of the use of generative artificial intelligence, we may lose valuable intellectual property and confidential information and our reputation and the public perception of the effectiveness of our security measures could be harmed. Further, bad actors around the world use increasingly sophisticated methods, including the use of artificial intelligence, to engage in illegal activities involving the theft and misuse of personal information, confidential information, and intellectual property. Any of these outcomes could damage our reputation, result in the loss of valuable property and information, and adversely impact our business.

A pandemic, epidemic, or outbreak of an infectious disease, such as the COVID-19 pandemic, could materially and adversely affect our business.

Public health crises such as pandemics or similar outbreaks could adversely impact our business. Previously, our clinical trial operations were directly and indirectly adversely impacted by the COVID-19 pandemic. A new pandemic or a resurgence of the COVID-19 pandemic could have adverse economic impacts to us.

Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults or non-performance by financial institutions or transactional counterparties, could adversely affect our current and projected business operations and its financial condition and results of operations.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank, or SVB, was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation, or the FDIC, as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership. If any of our counterparties to any credit agreements, letters of credit or certain other financial instruments that we may enter into in the future were to be placed into receivership, we may be unable to access such funds. In addition, if any parties with whom we conduct business are unable to access funds pursuant to such instruments or lending arrangements with such a financial institution, such parties' ability to pay their obligations to us or to enter into new commercial arrangements requiring additional payments to us could be adversely affected. Similar impacts have occurred in the past, such as during the 2008-2010 financial crisis.

Inflation and previous increases in interest rates have led to a decline in the trading value of previously issued government securities with interest rates below current market interest rates. There is no guarantee that the U.S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion.

Although we assess our banking relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected

future business operations could be significantly impaired by factors that affect us, the financial institutions with which we have arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could involve financial institutions or financial services industry companies with which we have financial or business relationships, but could also include factors involving financial markets or the financial services industry generally.

In addition, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and/or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and/or projected business operations and financial condition and results of operations.

In addition, any further deterioration in the macroeconomic economy or financial services industry could lead to losses or defaults by parties with whom we conduct business, which in turn, could have a material adverse effect on our current and/or projected business operations and results of operations and financial condition. For example, a party with whom we conduct business may fail to make payments when due, default under their agreements with us, become insolvent or declare bankruptcy. Any bankruptcy or insolvency, or the failure to make payments when due, of any counterparty of ours, or the loss of any significant relationships, could have material adverse impacts on our liquidity and our current and/or projected business operations and financial condition and results of operations.

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

As of March 1, 2026, we had 13 full-time employees. As our development and commercialization plans and strategies continue to develop, our need for additional managerial, operational, manufacturing, regulatory, sales, marketing, financial and other resources may increase. We will need to grow the size of our organization in order to support our continued development and potential commercialization of our product candidates to complement our management and employees currently in place and to support our future growth. Future growth would impose significant added responsibilities on members of management, including:

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

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

marketing personnel. The failure to accomplish any of these tasks could prevent us from successfully growing our company.

The requirements of being a public company may strain our resources, divert management's attention and affect our ability to attract and retain qualified board members.

As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Act, the listing requirements of Nasdaq and other applicable securities rules and regulations. Compliance with these rules and regulations has increased, and will likely continue to increase, our legal and financial compliance costs, make some activities more difficult, time-consuming or costly, and place significant strain on our personnel, systems and resources. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time. This could result in continuing uncertainty regarding compliance matters, higher administrative expenses and a diversion of management's time and attention. Further, if our compliance efforts differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed. Being a public company that is subject to these rules and regulations also makes it more expensive for us to obtain and retain director and officer liability insurance, and we may in the future be required to accept reduced coverage or incur substantially higher costs to obtain or retain adequate coverage. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors and qualified executive officers.

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

We are highly dependent upon our personnel, including Dr. Angelos M. Stergiou M.D., Sc.D. h.c., our President and Chief Executive Officer, and member of our board of directors. Our employment agreement with Dr. Stergiou does not prevent him from terminating his employment with us at any time. The loss of Dr. Stergiou's services could impede the achievement of our research, development and commercialization objectives. We have not obtained, do not own, nor are we the beneficiary of, key-person life insurance. We employ our executive officers, other than Dr. Stergiou, on an at-will basis and their employment can be terminated by them or us at any time, for any reason and without notice. The loss of any member of our senior management team or the inability to hire or retain experienced senior management personnel could compromise our ability to execute our business plan and harm our operating results.

In order to retain valuable employees at our company, in addition to salary and discretionary non-equity incentive plan compensation, we provide stock options and restricted stock units, or RSUs, that vest over time. The value to our employees of stock options and RSUs could be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract offers from other companies.

Our future growth and success depend not only on our ability to retain, manage and motivate our employees but also on our ability to recruit new employees which is key to our growth. We might not be able to attract or retain qualified management and other key personnel in the future due to the intense competition for qualified talent among biotechnology, pharmaceutical and other businesses. We could have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employment recruitment and retention efforts. Many pharmaceutical and biotechnology companies with whom we compete for qualified personnel have greater financial and other resources, different risk profiles and longer histories in the industry than we do.

Legislation or other changes in U.S. tax law could adversely affect our business and financial condition.

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In

recent years, many changes have been made to applicable tax laws and changes are likely to continue to occur in the future.

It cannot be predicted whether, when, in what form or with what effective dates new tax laws may be enacted, or regulations and rulings may be enacted, promulgated or issued under existing or new tax laws, which could result in an increase in our or our shareholders' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law or in the interpretation thereof.

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

As of December 31, 2025, we had federal and state net operating loss carryforwards of approximately $77.7 million and $5.0 million, respectively. Our NOLs generated in tax years ending on or prior to December 31, 2017 are only permitted to be carried forward for 20 years under applicable U.S. tax laws, and will begin to expire, if not utilized, beginning in 2027. These NOL carryforwards could expire unused and be unavailable to offset future income tax liabilities. Federal NOLs incurred in tax years ending after December 31, 2017 may be carried forward indefinitely, but the deductibility of such federal NOLs is limited. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, and certain corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in the ownership of its equity over a three-year period, the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income may be limited. The Merger constituted an ownership change and as such, our ability to use our NOL carryforwards is materially limited, which may harm our future operating results by effectively increasing our future tax obligations.

Risks Related to Ownership of Our Common Stock

We will likely need to secure additional capital which may cause dilution to you and our existing stockholders, provide subsequent investors with rights and preference that are senior to yours, restrict our operations or require us to relinquish rights to our product candidates on unfavorable terms to us.

We will likely need to raise additional capital in the future. If we raise funds through the issuance of debt or equity, any debt securities or preferred stock issued will have rights, preferences and privileges senior to those of holders of our common stock in the event of a liquidation. In such event, there is a possibility that once all senior claims are settled, there may be no assets remaining to pay out to the holders of common stock. In addition, if we raise funds through the issuance of additional equity, whether through private placements or additional public offerings, such an issuance would dilute our stockholders and, similar to some of our past financings, may contain terms that could result in additional further significant dilution in the future. Debt financing, if available, could include covenants limiting or restricting our ability to take certain actions, such as incurring additional debt, making capital expenditures, entering into licensing arrangements, or declaring dividends, and may require us to grant security interests in our assets, including our intellectual property and for our subsidiaries to guarantee our obligations.

The market price and trading volume of shares of our common stock may be volatile.

The market price of shares of our common stock has exhibited substantial volatility. Between January 1, 2025 and December 31, 2025, the daily closing price of shares of our common stock as reported on Nasdaq ranged from a low of $0.92 to a high of $3.77. The market price of shares of our common stock could continue to fluctuate significantly for many reasons, including the following factors:

- reports of the results of our clinical trials regarding the safety or efficacy of our product candidates and surrogate markers;
- announcements of regulatory developments or technological innovations by us or our competitors;
- announcements of business or strategic transactions or our success in finalizing such a transaction;
- announcements of legal or regulatory actions against us or any adverse outcome of any such actions;

- changes in our relationships with our licensors, licensees and other strategic partners;
- low volume in the number of shares of our common stock traded on Nasdaq;
- our quarterly operating results;
- announcements of dilutive financing;
- announcements of additional potential reverse stock split;
- developments in patent or other technology ownership rights;
- additional funds may not be available on terms that are favorable to us and, in the case of equity financings, may result in dilution to our stockholders;
- government regulation of drug pricing; and
- general market conditions and other factors unrelated to our operating performance or the operating performance of our competitors, including deteriorating market conditions due to investor concerns regarding inflation and hostilities between Russia and Ukraine, the conflicts in the Middle East, tensions between China and Taiwan and other geopolitical events.

Factors beyond our control may also have an impact on the market price of shares of our common stock. For example, to the extent that other companies within our industry experience declines in their stock prices, the market price of shares of our common stock may decline as well.

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

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

Future legislative and regulatory proposals may materially impact the ability of the FDA and other regulatory agencies to operate as they have historically operated. We cannot be sure whether additional legislative changes or executive orders will be enacted, or whether any of the FDA's regulations, guidance or interpretations will be changed, or what the impact of such changes on the agency and its scientific review staff, if any, may be. For example, the FDA has experienced significant and rapid fluctuations in leadership and scientific review personnel, which may be key contributing factors in multiple reported delays in agency decision making on marketing applications and agency requests for additional data that are inconsistent with prior regulatory feedback. In addition, negotiations on the next FDA user fee reauthorization package began in mid-2025, and any agreement is expected to be sent to Congress in early 2027 for purposes of initiating the legislative process. Reauthorization of the prescription drug user fee program must be finalized by Congress by the end of September 2027 in order to avoid a disruption in FDA's review goals for BLAs and other activities supported by user fees assessed against industry.

In addition, disruptions at the FDA and other agencies may slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, political disputes in Congress may result in a shutdown of the U.S. government and in such cases certain regulatory agencies, such as the FDA and the SEC, would have to furlough critical FDA, SEC and other government employees and stop critical activities. Moreover, government shutdowns or slowdowns can increase the time needed for an agency to complete its review or make final approvals or other administrative decisions. If a

prolonged government shutdown were to occur, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business and could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Future sales of substantial amounts of our common stock, or the possibility that such sales could occur, could adversely affect the market price of our common stock.

Future sales in the public market of shares of our common stock, including shares referred to in the foregoing risk factors or shares issued upon exercise of our outstanding stock options or warrants, or the perception by the market that these sales could occur, could lower the market price of our common stock or make it difficult for us to raise additional capital.

As of December 31, 2025, we had reserved for issuance 58,481,974 shares of our common stock issuable upon the exercise of outstanding warrants at a weighted-average exercise price of $1.74 per share, 2,651,902 shares of our common stock issuable upon the exercise of outstanding stock options at a weighted-average exercise price of $3.19 per share, and 897,009 shares of our common stock issuable upon the vesting of outstanding restricted stock units with a weighted average grant date fair value of $1.09 per share. Upon exercise or conversion, the underlying shares, similar to those issued as the settlement payment, may be resold into the public market. In the case of outstanding securities that have exercise or conversion prices that are below the market price of our common stock from time to time, our stockholders would experience dilution upon the exercise or conversion of these securities.

Certain of our securityholders have registration rights and they can require us, subject to certain limitations, to register their securities for resale and to maintain such registration. Any such resales into the public market could place downward pressure on the price of our common stock.

We have issued and may issue additional preferred stock in the future, and the terms of the preferred stock may reduce the value of our common stock.

We are authorized to issue up to 5,000,000 shares of preferred stock in one or more series. Our board of directors may determine the terms of future preferred stock offerings without further action by our stockholders. If we issue shares of preferred stock, it could affect stockholder rights or reduce the market value of our outstanding common stock. In particular, specific rights granted to future holders of preferred stock may include voting rights, preferences as to dividends and liquidation, conversion and redemption rights, sinking fund provisions, and restrictions on our ability to merge with or sell our assets to a third party.

We have settled in the past and may in the future settle legal claims through the issuance of freely tradable shares of our common stock, which results in dilution to holders of our common stock and may adversely affect the market price of our common stock.

We have settled in the past and may in the future settle legal claims through the issuance of freely tradable shares of our common stock. We may issue additional shares of common stock as settlement payments in the future. Payment of these amounts in our common stock could cause significant dilution to our stockholders, and the amount of that dilution will vary depending on the price of our common stock at the time of the payment. In addition, the issuance of such a significant number of shares of our common stock may cause a decrease in the trading price of our common stock.

Anti-takeover provisions of our Amended and Restated Certificate of Incorporation and our Amended and Restated Bylaws and provisions of Delaware law could delay or prevent a change of control.

Anti-takeover provisions of our Amended and Restated Certificate of Incorporation and our Amended and Restated Bylaws may discourage, delay or prevent a merger or other change of control that stockholders may consider favorable or may impede the ability of the holders of our common stock to change our management and may be constrained by other contractual agreements with third parties. These provisions of our Amended and Restated Certificate of Incorporation and our Amended and Restated Bylaws, among other things:

- divide our Board of Directors into three classes, with members of each class to be elected for staggered three-year terms;
- limit the right of securityholders to remove directors;
- prohibit stockholders from acting by written consent;
- regulate how stockholders may present proposals or nominate directors for election at annual meetings of stockholders; and
- authorize our Board to issue preferred stock in one or more series, without stockholder approval.

In addition, Section 203 of the Delaware General Corporation Law provides that, subject to limited exceptions, persons that acquire, or are affiliated with a person that acquires, more than 15% of the outstanding voting stock of a Delaware corporation shall not engage in any business combination with that corporation, including by merger, consolidation or acquisitions of additional shares for a three-year period following the date on which that person or our affiliate crosses the 15% stock ownership threshold. Section 203 could operate to delay or prevent a change of control of us.

If our common stock becomes subject to the penny stock rules, it may be more difficult to sell our common stock.

The SEC has adopted rules that regulate broker-dealer practices in connection with transactions in penny stocks. Penny stocks are generally equity securities with a price of less than $5.00 (other than securities registered on certain national securities exchanges or authorized for quotation on certain automated quotation systems, provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system). The OTC Bulletin Board does not meet such requirements and if the price of our common stock is less than $5.00 and our common stock is no longer listed on a national securities exchange such as Nasdaq, our stock may be deemed a penny stock. The penny stock rules require a broker-dealer, at least two business days prior to a transaction in a penny stock not otherwise exempt from those rules, to deliver to the customer a standardized risk disclosure document containing specified information and to obtain from the customer a signed and date acknowledgment of receipt of that document. In addition, the penny stock rules require that prior to effecting any transaction in a penny stock not otherwise exempt from those rules, a broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive: (i) the purchaser's written acknowledgment of the receipt of a risk disclosure statement; (ii) a written agreement to transactions involving penny stocks; and (iii) a signed and dated copy of a written suitability statement. These disclosure requirements may have the effect of reducing the trading activity in the secondary market for our common stock, and therefore stockholders may have difficulty selling their shares.

Our common stock may be delisted from the Nasdaq Capital Market which could negatively impact the price of our common stock, liquidity and our ability to access the capital markets.

The listing standards of the Nasdaq Capital Market provide that a company, in order to qualify for continued listing, must maintain a minimum stock price of $1.00 and satisfy standards relative to minimum stockholders' equity, minimum market value of publicly held shares and various additional requirements. If we fail to comply with all listing standards applicable to issuers listed on the Nasdaq Capital Market, our common stock may be delisted. If our common stock is delisted, it could reduce the price of our common stock and the levels of liquidity available to our stockholders. In addition, the delisting of our common stock could materially adversely affect our access to the capital markets and any limitation on liquidity or reduction in the price of our common stock could materially adversely affect our ability to raise capital. Delisting from the Nasdaq Capital Market could also result in other negative consequences, including the potential loss of confidence by suppliers, customers and employees, the loss of institutional investor interest and fewer business development opportunities.

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

Our business requires significant funding. We currently plan to invest all available funds and future earnings in the development and growth of our business and do not anticipate paying any cash dividends on our common stock in the foreseeable future. As a result, capital appreciation, if any, of our common stock will be our stockholders' sole source of potential gain for the foreseeable future.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 1C. CYBERSECURITY

We recognize the critical importance of maintaining the trust and confidence of business partners, such as CROs and CMOs, clinical trial investigators, patients and employees toward our business and are committed to protecting the confidentiality, integrity and availability of our business operations and systems. Our board of directors is actively involved in oversight of our risk management activities, and cybersecurity represents an important element of our overall approach to risk management. In general, we seek to address cybersecurity risks through a comprehensive, cross-functional approach that is focused on preserving the confidentiality, security and availability of the information that we collect and store by identifying, preventing and mitigating cybersecurity threats and effectively responding to cybersecurity incidents when they occur.

Cybersecurity Risk Management and Strategy; Effect of Risk

We face risks related to cybersecurity, such as unauthorized access, cybersecurity attacks, and other security incidents, including perpetration by hackers and unintentional damage or disruption to hardware and software systems, loss of data, and misappropriation of confidential information. To identify and assess material risks from cybersecurity threats, we, together with our contracted third-party cybersecurity advisors, maintain a comprehensive cybersecurity program to ensure our systems are effective and prepared for information security risks, including regular oversight of our programs for security monitoring of internal and external threats to ensure the confidentiality and integrity of our information assets. We consider risks from cybersecurity threats alongside other company risks as part of our overall risk assessment process. As discussed in more detail under “Cybersecurity Governance” below, our audit committee provides oversight of our cybersecurity risk management and strategy processes, which are led by management.

We, with assistance from our contracted third-party cybersecurity advisors, identify our cybersecurity threat risks by comparing our processes to standards set by the National Institute of Standards and Technology, or NIST. To provide for the availability of critical data and systems, maintain regulatory compliance, manage our material risks from cybersecurity threats, and protect against and respond to cybersecurity incidents, we undertake the following activities:

- monitor emerging data protection laws and implement changes to our processes that are designed to comply with such laws;
- through our policies, practices, and contracts (as applicable), require employees, as well as third parties that provide services on our behalf, to treat confidential information and data with care;
- employ technical safeguards that are designed to protect our information systems from cybersecurity threats, including firewalls, intrusion prevention and detection systems, anti-malware functionality and access controls;
- provide regular, mandatory training for our employees and contractors regarding cybersecurity threats as a means to equip them with effective tools to address cybersecurity threats, and to communicate our evolving information security policies, standards, processes and practices;
- conduct regular phishing email simulations for all employees and contractors with access to our email systems to enhance awareness and responsiveness to possible threats;
- conduct cybersecurity management and incident training for employees involved in our systems and processes that handle sensitive data;
- leverage the NIST incident handling framework to help us identify, protect, detect, respond and recover when there is a potential cybersecurity incident; and

- carry information security risk insurance that provides protection against the potential losses arising from a cybersecurity incident.

Our processes also address cybersecurity threat risks associated with our selection and oversight of third-party service providers, including our suppliers and manufacturers or those who have access to patient and employee data or our systems. We generally require those third parties that could introduce significant cybersecurity risk to us to agree by contract to manage their cybersecurity risks in specified ways.

We describe whether and how risks from identified cybersecurity threats, including as a result of any previous cybersecurity incidents, have materially affected or are reasonably likely to materially affect us, including our business strategy, results of operations, or financial condition, under the heading *Significant disruptions of information technology systems, computer system failures or cybersecurity incidents could adversely affect our business*, which disclosures are incorporated by reference herein.

In the last three fiscal years, we have not experienced any material cybersecurity incidents.

Cybersecurity Governance; Management

Cybersecurity is an important part of our risk management processes and an area of focus for our Board of Directors and management. Management is responsible for the operational oversight of company-wide cybersecurity strategy, policy, and standards across relevant departments to assess and help prepare us to address cybersecurity risks.

The Audit Committee of the Board of Directors, or the Audit Committee, provides direct oversight over cybersecurity risk and periodically updates our Board of Directors on such matters. The Audit Committee receives periodic updates from management regarding cybersecurity matters, and is notified between such updates regarding any significant new cybersecurity threats or incidents.

Our cybersecurity risk management and strategy processes, which are discussed in greater detail above, are led by our Chief Financial Officer and Vice President, General Counsel and Corporate Secretary, with the assistance of our contracted third-party cybersecurity advisors. These management team members are informed about and monitor the prevention, mitigation, detection, and remediation of cybersecurity incidents through their management of, and participation in, the cybersecurity risk management and strategy processes described above, including incident response processes. As discussed above, these management team members periodically report to the Audit Committee about cybersecurity threat risks, among other cybersecurity related matters.

ITEM 2. PROPERTIES

We lease our headquarters in New York, New York. The lease covers approximately 8,455 square feet of office space and expires in September 2027. We believe that our facility is adequate for our current needs.

ITEM 3. LEGAL PROCEEDINGS

In December 2020, we entered into 3D Medicines Agreement. In November 2022, we announced that we had agreed with 3D Medicines for 3D Medicines to participate in the REGAL study through the inclusion of approximately 20 patients from mainland China.

In accordance with the terms of the 3D Medicines Agreement and the Side Letter, we had expected that 3D Medicines would begin enrolling patients in mainland China in the REGAL study in the second half of 2023 and subsequently make two development milestone payments totaling $13.0 million. Patients were enrolled in the REGAL study in Taiwan, which is part of the 3DMed Territory, prior to the second half of 2023.

On December 20, 2023, we commenced a binding arbitration proceeding against 3D Medicines, administered by the Hong Kong International Arbitration Centre and governed by New York State law as per the 3D Medicines Agreement. The arbitration proceeding involves, among other things, the trigger and payment of the relevant

milestone payments due to us as well as 3D Medicines' failure to use commercially reasonable best efforts to develop GPS in the 3DMed Territory, and particularly in mainland China.

We have engaged an international law firm with expertise in mainland China to assist us with the arbitration proceeding. While we are unable at this time to predict with certainty the outcome of the arbitration proceeding, or the timing of the receipt of any milestone payments and other damages it is seeking in the arbitration proceeding, if at all, we believe that our claims are meritorious.

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 is listed on The Nasdaq Capital Market under the symbol SLS.

Holders

As of March 18, 2026, there were approximately 10 holders of record of our common stock. Because many of our shares are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of individual stockholders represented by these holders of record.

Dividends

We have never paid any cash dividends on our common stock and do not anticipate paying any cash dividends on our common stock in the foreseeable future. We expect to retain future earnings, if any, for use in our development activities and the operation of our business. The payment of any future dividends will be subject to the discretion of our Board of Directors and will depend, among other things, upon our results of operations, financial condition, cash requirements, prospects and other factors that our Board of Directors may deem relevant. Our ability to pay future dividends may be restricted by the terms of any future securities we may issue.

Recent Sales of Unregistered Securities

During the period covered by this Annual Report on Form 10-K, there were no sales by us of unregistered securities that were not previously reported by us in a Quarterly Report on Form 10-Q or Current Report on Form 8-K.

Purchases of Equity Securities

During the year ended December 31, 2025, we did not purchase any of our equity securities. Our Board of Directors has not authorized any repurchase plan or program for the purchase of shares of our common stock or other securities on the open market or otherwise.

Equity Compensation Plan Information

The following table provides information regarding the status of our existing equity compensation plans as of December 31, 2025:

Plan Category	Number of Securities to be Issued upon Exercise of Outstanding Options, Warrants and Rights	Weighted Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance under Equity Compensation Plans (Excluding Securities Reflected in Previous Columns)
Equity compensation plans approved by security holders			
2017 Equity Incentive Plan	17,220	$ 113.00	—
2023 Amended and Restated Equity Incentive Plan	2,634,682	$ 2.47	1,369,809
Restricted Stock Units	897,009	N/A	—
2021 Employee Stock Purchase Plan	—	N/A	764,155
Equity compensation plans not approved by security holders			
None	—	—	—
Total	3,548,911	$ 3.19	2,133,964

ITEM 6. [RESERVED]

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

The purpose of this Management's Discussion and Analysis is to better allow our investors to understand and view our company from management's perspective. We are providing an overview of our business and strategy including a discussion of our financial condition and results of operations. You should read the following discussion in conjunction with the consolidated financial statements and the notes to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K. This discussion contains forward-looking statements within the meaning of federal securities laws. Such forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from those contained in such forward-looking statements, including those discussed in the section "Risk Factors" in Part I — Item 1A of this Annual Report on Form 10-K.

Overview

We are a late-stage clinical biopharmaceutical company focused on the development of novel therapeutics for a broad range of cancer indications. Our product candidates currently include galinpepimut-S, or GPS, a peptide immunotherapy directed against the Wilms tumor 1, or WT1, antigen, and SLS009 (formerly GFH009), a highly selective small molecule cyclin-dependent kinase 9, or CDK9, inhibitor.

Galinpepimut-S, or GPS: Highly Novel and Engineered Immunotherapy Targeting the WT1 Antigen

Our lead product candidate, GPS, is a cancer immunotherapeutic agent licensed from Memorial Sloan Kettering Cancer Center, or MSK, that targets the WT1 protein, which is present in 20 or more cancer types. Based on its mechanism of action as a directly immunizing agent, GPS has potential as a monotherapy or in combination with other immunotherapeutic agents to address a broad spectrum of hematologic, or blood, cancers, and solid tumor indications.

We have an ongoing open label randomized Phase 3 clinical trial, the REGAL study, for GPS monotherapy in patients with acute myeloid leukemia, or AML, in the maintenance setting after achievement of second complete remission, or CR2, following successful completion of second-line antileukemic therapy. Patients are randomized to receive either GPS or best available treatment, or BAT. We expect this study will be used as the basis for submission of a Biologics License Application, or BLA, subject to a statistically significant and clinically meaningful trial outcome and agreement with the U.S. Food and Drug Administration, or the FDA. The primary endpoint of the REGAL study is overall survival, or OS. We planned to enroll approximately 125 to 140 patients at approximately 95 clinical sites in North America, Europe and Asia with a planned interim safety, efficacy and futility analysis after 60 events (deaths). In March 2024, we announced the completion of enrollment. In December 2024, we announced that the pre-specified threshold of 60 events (deaths) per the protocol had been reached, triggering the interim analysis to be conducted by the Independent Data Monitoring Committee, or IDMC. In January 2025, we announced that the IDMC had completed pre-specified interim analysis of the REGAL study and had recommended that the study continue without modifications. The next and final analysis will be conducted once 80 events (deaths) are reached. In December 2025, we announced that our contract research organization informed us that the pooled number of events was 72 as of December 26, 2025. We remain blinded to all efficacy and survival data outcomes and, as no outcomes analyses were performed and no statistical penalty has been incurred, this one-time update on the aggregate number of events does not impact future statistical analyses. Because the final analysis is event driven, it is difficult to predict with any certainty and it may occur at a different time than currently expected. We will announce the 80th event when it occurs.

In December 2020, we entered into an exclusive license agreement, or the 3D Medicines Agreement, with 3D Medicines Inc., or 3D Medicines, a China-based biopharmaceutical company developing next-generation immuno-oncology drugs, for the development and commercialization of GPS, as well as the Company's next generation heptavalent immunotherapeutic GPS+, which is at preclinical stage, across all therapeutic and diagnostic uses in mainland China, Hong Kong, Macau and Taiwan, which we refer to as Greater China. We have retained sole rights to GPS and GPS+ outside of Greater China. In November 2022, we announced that we had agreed with 3D Medicines for 3D Medicines to participate in the REGAL study through the inclusion of approximately 20 patients from mainland China. In December 2022, we entered into a Side Letter Agreement with 3D Medicines, or Side Letter, which together with the 3D Medicines Agreement, details the terms and conditions of 3D Medicines' participation in the REGAL study. Although the REGAL study has completed enrollment as announced in March 2024, in accordance with the predetermined statistical analysis plan, 3D Medicines may still enroll patients in mainland China. The timing of such participation and patient enrollment by 3D Medicines, if at all,

cannot be predicted with certainty. As of December 31, 2025, we have received an aggregate of $10.5 million in upfront and milestone payments under our license agreement with 3D Medicines, or the 3D Medicines Agreement, and a total of $191.5 million in potential future development, regulatory and sales milestones, not including future royalties, remains under the license agreement, which milestones are variable in nature and not under our control. In December 2023, we announced that we had commenced a binding arbitration proceeding against 3D Medicines to resolve a dispute regarding, among other things, the trigger and payment of relevant milestone payments due to us under the 3D Medicines Agreement. See *Item 3. Legal Proceedings*.

GPS was granted Orphan Drug Designations, or ODD, from the FDA, as well as orphan medicines designations from the European Medicines Agency, or EMA, in AML, malignant pleural mesothelioma, or MPM, and multiple myeloma, or MM, as well as Fast Track designations for AML, MPM, and MM from the FDA. In October 2024, the FDA granted Rare Pediatric Disease, or RPD, designation to GPS for the treatment of pediatric AML.

SLS009, or Tambiciclib: Highly Selective Next Generation CDK9 Inhibitor

On March 31, 2022, we entered into an exclusive license agreement, or the GenFleet Agreement, with GenFleet Therapeutics (Shanghai), Inc., or GenFleet, a clinical-stage biotechnology company developing cutting-edge therapeutics in oncology and immunology, that grants rights to us for the development and commercialization of SLS009, a highly selective small molecule CDK9 inhibitor, across all therapeutic and diagnostic uses worldwide, except for Greater China.

CDK9 activity has been shown to correlate negatively with overall survival in a number of cancer types, including hematologic cancers, such as AML and lymphomas, as well as solid cancers, such as osteosarcoma, pediatric soft tissue sarcomas, melanoma, endometrial, lung, prostate, breast and ovarian. As demonstrated in preclinical and clinical data, to date, SLS009's high selectivity has the potential to reduce toxicity as compared to older CDK9 inhibitors and other next-generation CDK9 inhibitors currently in clinical development and to potentially be more efficacious.

We completed a Phase 1 dose-escalating clinical trial in the United States and China for SLS009 in mid-2023 and reported positive safety and efficacy data for both patient cohorts, that is relapsed and/or refractory AML and refractory lymphoma. We also established in the trial a recommended Phase 2 dose, or RP2D, of 60 mg once weekly or 30 mg twice weekly for AML and 100 mg once weekly for lymphomas.

In the second quarter of 2023, we commenced an open label, single arm, multi-center Phase 2a clinical trial with SLS009 in combination with venetoclax and azacitidine, or aza/ven, in patients with AML who failed or did not respond to treatment with venetoclax-based therapies. The trial is evaluating safety, tolerability, and efficacy at two dose levels of SLS009, 45 mg once weekly, and 60 mg once weekly or 30 mg twice a week, in combination with aza/ven. In December 2024, we announced positive data from the first 3 cohorts in the Phase 2a trial.

In July 2025, we announced that the Phase 2 trial of SLS009 in r/r AML met all primary endpoints and received FDA guidance to advance into a first-line therapy study. The overall response rate, or ORR, in 54 evaluable patients was 33% across all cohorts and dose levels, 40% for the 30 mg BIW dose level, and 44% in the 30 mg BIW dose among patients with myelodysplasia-related molecular mutations, or AML MR, all exceeding the pre-specified ORR threshold of 20%. The highest efficacy was observed among patients with ASXL1 mutations, with an ORR of 50% (9/18) at 30 mg BIW dose levels, and AML MR with Myelomonocytic/Myelomonoblastic markers, or M4/M5 per FAB classification, patients with an ORR of 50% (6/12). The median overall survival, or mOS, reached 8.9 months in patients with AML MR and 8.8 months in patients r/r to venetoclax-based regimens at a 30 mg BIW dose level, surpassing the historical benchmark of ~2.4 months. SLS009 was well-tolerated with no new safety signals observed. No dose-limiting toxicities were observed across all dose levels.

Following a productive end of Phase 2 meeting, the FDA recommended that we proceed into a clinical trial to include newly diagnosed, first-line AML patients eligible for aza/ven therapy, where the FDA noted clinical benefit might be greatest. The randomized 80-patient Phase 2 clinical trial is currently ongoing and began enrollment in the first quarter of 2026. The clinical trial will include two groups: predictive biomarker cohort (newly diagnosed patients unlikely to benefit from standard aza/ven therapy based on molecular profiling) and early venetoclax resistance cohort (patients who initiate treatment with aza/ven, but demonstrate confirmed lack of any response after two treatment cycles).

In January 2026, we announced that we entered into an agreement with IMPACT-AML, a European collaborative initiative dedicated to advancing innovative treatments for patients with AML. Under the agreement,

the IMPACT-AML network will conduct a clinical study evaluating SLS009, enabling access to multiple European clinical sites and patients. IMPACT-AML is a pan-European project and builds an inclusive clinical network (STREAM platform) that connects patients, clinicians, and researchers to test novel AML therapies and improve patient outcomes. It is part of the prestigious EU Mission Cancer program and a top-tier scientific cluster. The IMPACT-AML project is led by a consortium of major research and clinical institutions in Europe, including IRST (IRCCS Istituto Romagnolo per lo Studio dei Tumori "Dino Amadori"), the University of Bologna, IIS LA FE (Health Research Institute Hospital La Fe), several European AML collaborative groups, and supranational organizations under the umbrella of the European Leukemia Net (ELN), as well as various university hospitals across Europe. By leveraging IMPACT-AML's existing infrastructure and expertise, we expect to expand European patient access to SLS009 in a highly cost-efficient manner while supporting broader participation across the clinical program.

In November 2024, we announced data from preclinical studies identifying ASXL1 mutation as key predictor of SLS009 in response to solid cancers.

In May 2025, we announced data for pediatric acute lymphoblastic leukemia, or ALL, patients derived xenografts, or PDX. The experiment conducted and funded by the National Institute of Health, or NIH, through through the NCI Pediatric Preclinical in Vivo Testing, or PIVOT, program, included 27 patient-derived ALL tumors from pediatric patients. Tumors were xenografted in mice in two groups, vehicle control arm and SLS009 arm. Mice were treated with a fractionated dose once per week for six consecutive weeks. Treatment was well tolerated. For all models, median survival was approximately tripled in the SLS009 arm, compared to vehicle control arm. SLS009 demonstrated delayed progression in 25/27 (93%) models and more than two times longer time to progression in 15/27 (56%) of ALL models. In addition, there were complete responses, or CR, in two models and in one of the two models CR was maintained after the treatment had been completed until the end of the study (four months). Among seven KMT2A rearranged models, time to progression was extended in all seven models, and in six out of seven (86%) time to progression was more than doubled.

For SLS009, the FDA granted Orphan Drug Product designations in AML and peripheral T-cell lymphoma, or PTCL, and Fast Track designations for r/r AML and r/r PTCL. The FDA granted RPD designation to SLS009 for the treatment of pediatric acute lymphoblastic leukemia, or ALL, in June 2024 and the FDA granted RPD designation to SLS009 for the treatment of pediatric AML in July 2024. Also, the European Medicines Agency granted Orphan Drug Designation for SLS009 in AML and in PTCL in June 2024 and July 2024, respectively.

Components of Results of Operations

Research and Development

Research and development expense consists of expenses incurred in connection with the discovery and development of our product candidates. We expense research and development costs as incurred. These expenses include:

- expenses incurred under agreements with clinical research organizations, or CROs, as well as investigative sites and consultants that conduct our preclinical studies and clinical trials;
- manufacturing and clinical drug supply expenses;
- outsourced professional scientific development services;
- employee-related expenses, which include salaries, benefits and stock-based compensation;
- payments made under our license agreements, under which we acquired certain intellectual property;
- expenses relating to certain regulatory activities, including filing fees paid to regulatory agencies;
- laboratory materials and supplies used to support our research activities; and
- allocated expenses, utilities and other facility-related costs.

The successful development of our current and future product candidates is highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the remainder of the development of, or when, if ever, material net cash inflows may commence from, any current or future product candidates. This uncertainty is due to the numerous risks and uncertainties associated with the

duration and cost of our clinical trials, which vary significantly over the life of a project as a result of many factors, including:

- the number and geographical location of clinical sites included in the trials;
- the length of time required to enroll suitable patients;
- the number and geographical location of patients that ultimately participate in the trials;
- the number of doses patients receive;
- the duration of patient follow-up;
- the results of clinical trials;
- the expenses associated with manufacturing and clinical drug supply;
- the receipt of marketing approvals; and
- the commercialization of current and future product candidates.

Research and development activities are central to our business model. Oncology product candidates in the later stages of clinical development generally have higher development costs than those in the earlier stages of clinical development, primarily due to the increased size and duration of the later-stage clinical trials. We expect our research and development expenses to increase for the foreseeable future as we conduct and complete our ongoing early and late-stage clinical trials, initiate additional clinical trials, and expand regulatory activities associated with the preparation and submission of regulatory filings.

Our expenditures are subject to additional uncertainties, including the terms and timing of regulatory approvals. We may never succeed in achieving regulatory approval for any of our current or future product candidates. We may obtain unexpected results from our clinical trials. We may elect to discontinue, delay or modify clinical trials of some product candidates or target indications or focus on others. A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or other regulatory authorities were to require us to conduct clinical trials beyond those that we currently anticipate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development.

General and Administrative Expense

General and administrative expenses consist principally of salaries and related costs for personnel in executive, administrative, finance and legal functions, including stock-based compensation, travel expenses and recruiting expenses, fees for outside legal counsel, and director and officer insurance premiums. Other general and administrative expenses include facility related costs, patent filing and prosecution costs, professional fees for business development, accounting, consulting, legal and tax-related services associated with maintaining compliance with our Nasdaq listing and SEC reporting requirements, investor relations costs, and other expenses associated with being a public company.

If and when we believe that regulatory approval of a product candidate appears likely, we anticipate that an increase in general and administrative expenses will occur as a result of our preparation for commercial operations, particularly as it relates to the sales and marketing of such product candidate. Oncology product commercialization may take several years and millions of dollars in development costs.

Non-Operating Income

Non-operating income consists of interest income. Interest income primarily reflects interest earned from our cash and cash equivalents.

Results of Operations for the Years Ended December 31, 2025 and 2024

The following table summarizes our results of operations for the years ended December 31, 2025 and 2024 (amounts in thousands):

	Year ended December 31,		
	2025	2024	Change
Operating expenses:			
Research and development	$ 16,022	$ 19,096	$ (3,074)
General and administrative	12,252	12,417	(165)
Total operating expenses	28,274	31,513	(3,239)
Loss from operations	(28,274)	(31,513)	3,239
Non-operating income	1,411	632	779
Net loss	$ (26,863)	$ (30,881)	$ 4,018

Further analysis of the changes and trends in our operating results are discussed below.

Research and Development

Research and development expenses were $16.0 million for the year ended December 31, 2025 compared to $19.1 million for the year ended December 31, 2024. The following table summarizes our research and development expenses for the years ended December 31, 2025 and 2024 (amounts in thousands):

	Year ended December 31,		
	2025	2024	Change
External clinical trial expenses:			
GPS	4,257	6,669	(2,412)
SLS009	3,486	4,469	(983)
Employee related expenses	3,045	2,808	237
Stock-based compensation	434	347	87
Clinical and regulatory consulting	2,024	2,495	(471)
Manufacturing and clinical drug supply	2,093	1,742	351
Facilities and other	683	566	117
Total research and development expenses	$ 16,022	$ 19,096	$ (3,074)

The decrease in research and development expenses of approximately $3.1 million was primarily attributable to the following:

- $2.4 million of decreased external clinical trial expenses related to GPS primarily driven by the completion of enrollment in the REGAL study in the first quarter of 2024;
- $1.0 million of decreased external clinical trial expenses related to SLS009 primarily driven by the completion of enrollment in our Phase 2a trial in the current period;
- $0.5 million of decreased clinical consulting costs driven by the completion of enrollment in the REGAL study in the first quarter of 2024; partially offset by
- $0.4 million of increased manufacturing costs as we prepare for a potential BLA filing for GPS following final analysis of the REGAL study;
- $0.4 million of increased employee related expenses, stock-based compensation, and facilities and other research and development costs combined.

We anticipate that our research and development expenses will increase in the future as we continue to prepare for a potential BLA filing for GPS following the upcoming final analysis of the REGAL study and proceed into a randomized Phase 2 clinical trial to include newly diagnosed, front-line AML patients for SLS009.

General and Administrative

General and administrative expenses were $12.3 million for the year ended December 31, 2025 compared to $12.4 million for the year ended December 31, 2024. The $0.1 million decrease was primarily attributable to a $0.8 million decrease in employee related expenses which was driven by the recognition of a $1.1 million one-time severance charge in the prior period partially offset by a $0.3 million increase in non-cash stock-based compensation and a $0.7 million increase in legal fees.

Non-Operating Income

Non-operating income of $1.4 million and $0.6 million for the years ended December 31, 2025 and 2024, respectively, was related to interest income earned from our cash and cash equivalents.

Liquidity and Capital Resources

We did not generate any revenue from product sales in the years ended December 31, 2025 and 2024. Through December 31, 2025, we have only generated licensing revenue from the 3D Medicines Agreement. Since inception, we have incurred net losses, used net cash in our operations, and have funded substantially all of our operations through proceeds of the sale of equity securities and convertible notes.

Sources of Liquidity

On October 24, 2025, we entered into a Warrant Inducement Agreement, or the October 2025 Inducement, with an institutional investor and holder of certain existing warrants to cash exercise (i) warrants to purchase 6,514,658 shares of common stock at an exercise price of $1.535 per share, previously issued in March 2024, or the March 2024 Warrants, and (ii) warrants to purchase 15,849,056 shares of common stock at an exercise price of $1.325 per share, previously issued in August 2024, or the August 2024 Warrants. The March 2024 Warrants and the August 2024 Warrants were exercised at their original issuance exercise price plus $0.125 per share of common stock in accordance with Nasdaq rules. In consideration of the investor's agreement to exercise the March 2024 Warrants and the August 2024 Warrants, we agreed to issue new warrants to the investor to purchase up to 22,363,714 shares of common stock at an exercise price of $2.00 per share, or the October 2025 Warrants, which are exercisable immediately and will expire on the five year anniversary of issuance. The net proceeds to us from the October 2025 Inducement were approximately $29.1 million, after deducting financial advisory fees and related transaction expenses.

On September 10, 2025, we entered into a Warrant Inducement Agreement, or the September 2025 Inducement, with an institutional investor and holder of certain existing warrants to cash exercise warrants to purchase 19,685,040 shares of common stock, previously issued in January 2025, or the January 2025 Warrants, at the original issuance exercise price of $1.20 per share. In consideration of the investor's agreement to exercise the January 2025 Warrants, we agreed to issue new warrants to the Investor to purchase up to 19,685,040 shares of common stock at an exercise price of $1.88 per share, or the September 2025 Warrants, which are exercisable immediately and will expire on the five and one half anniversary of issuance. The net proceeds to us from the September 2025 Inducement were approximately $22.0 million, after deducting financial advisory fees and related transaction expenses.

On January 29, 2025, we consummated a registered direct offering, or the January 2025 Registered Direct Offering, with an institutional investor priced at-the-market under Nasdaq rules, pursuant to which we agreed to issue and sell 8,200,000 shares of common stock and 11,485,040 pre-funded warrants exercisable for shares of common stock, together with accompanying warrants to purchase up to 19,685,040 shares of common stock. Each share of common stock and accompanying common warrant were sold together at a combined offering price of $1.27, and each pre-funded warrant and accompanying common warrant were sold together at a combined offering price of $1.2699. The common warrants have an exercise price of $1.20 per share. The net proceeds to us from the January 2025 Registered Direct Offering were approximately $23.1 million, after deducting the placement agents' fees and related offering expenses.

During the year ended December 31, 2025, the Company received approximately $12.6 million in proceeds from the exercise of 16.8 million warrants exercisable for shares of common stock at an exercise price of $0.75 per share. Subsequent to December 31, 2025, the Company received an additional $42.6 million in proceeds from the exercise of 26.4 million warrants at a weighted-average exercise price of approximately $1.61 per share.

In December 2020, together with our wholly-owned subsidiary, SLSG Limited, LLC, we entered into the 3D Medicines Agreement pursuant to which we granted 3D Medicines a sublicensable royalty-bearing license under certain intellectual property owned or controlled by us, to develop, manufacture and have manufactured, and commercialize GPS and heptavalent GPS product candidates for all therapeutic and other diagnostic uses in the 3DMed Territory. As of December 31, 2025, we have received $10.5 million in upfront payments and certain technology transfer and regulatory milestones. A total of $191.5 million in potential future development, regulatory, and sales milestones, not including future royalties, remains under the 3D Medicines Agreement as of December 31, 2025, which milestones are all variable in nature and not under our control. In December 2023, we commenced a binding arbitration proceeding against 3D Medicines, which involves, among other things, the trigger and payment of certain milestone payments due to us. See *Part I, Item 3. Legal Proceedings.*

Funding Requirements

As of December 31, 2025, we had an accumulated deficit of $275.0 million, cash and cash equivalents of $71.8 million and restricted cash and cash equivalents of $0.1 million. In addition, we had current liabilities of $7.0 million as of December 31, 2025. We expect that our cash and cash equivalents, together with the $42.6 million in proceeds from warrant exercises received subsequent to December 31, 2025, will be sufficient to fund our current planned operations for at least the next twelve months from the date of issuance of these financial statements, although we may pursue additional capital resources through public or private equity or debt financings or by entering into additional license agreements or collaborations with other companies.

Management's expectations with respect to its ability to fund current planned operations is based on estimates that are subject to risks and uncertainties. If actual results are different from management's estimates, we may need to seek additional strategic or financing opportunities sooner than would otherwise be expected. There is no guarantee that any of these strategic or financing opportunities will be executed or executed on favorable terms, and some could be dilutive to existing stockholders. If we are unable to obtain additional funding on a timely basis, we may be forced to significantly curtail, delay, or discontinue one or more of its planned research and development programs or be unable to expand our operations or otherwise prepare for the potential regulatory approval and commercialization of its product candidates, assuming positive data.

Our future operations are highly dependent on a combination of factors, including (i) the timely and successful completion of any additional financings, (ii) our ability to complete revenue-generating partnerships with pharmaceutical and biotechnology companies, (iii) the success of our research and development activities, (iv) the development of competitive therapies by other biotechnology and pharmaceutical companies, and, ultimately, (v) regulatory approval and market acceptance of our product candidates.

Components of Cash, Cash Equivalents, Restricted Cash, and Restricted Cash Equivalents

The following table provides a reconciliation of the components of cash, cash equivalents, restricted cash, and restricted cash equivalents reported in our consolidated balance sheets to the total of the amount presented in the consolidated statements of cash flows (in thousands):

	December 31,	
	2025	2024
Cash and cash equivalents	$ 71,793	$ 13,886
Restricted cash and cash equivalents	100	100
Total cash, cash equivalents, restricted cash, and restricted cash equivalents	$ 71,893	$ 13,986

Restricted cash and cash equivalents of $0.1 million as of December 31, 2025 and 2024 relates to certificates of deposit maintained on hand with our financial institutions as collateral for our corporate credit cards.

Cash Flows

The following table summarizes our cash flows from operating, investing, and financing activities for the years ended December 31, 2025 and 2024 (in thousands):

	Year ended December 31, 2025	2024
Net cash (used in) provided by:		
Operating activities	$ (28,389)	$ (35,402)
Financing activities	86,296	46,758
Net increase in cash, cash equivalents, restricted cash, and restricted cash equivalents	$ 57,907	$ 11,356

Net Cash Used in Operating Activities

Net cash used in operating activities of $28.4 million during the year ended December 31, 2025 was primarily attributable to our net loss of $26.9 million and a $4.1 million change in our operating assets and liabilities, partially offset by non-cash charges of $2.6 million. The net change in our operating assets and liabilities is due to a decrease in accounts payable and accrued expenses and other current liabilities of approximately $2.5 million, an increase in prepaid expenses and other assets of approximately $1.0 million, and a decrease in operating lease liabilities of approximately $0.6 million. Non-cash charges were driven by approximately $2.0 million in non-cash stock-based compensation expense and $0.6 million in non-cash lease expense.

Net cash used in operating activities of $35.4 million during the year ended December 31, 2024 was primarily attributable to our net loss of $30.9 million and a $6.6 million change in our operating assets and liabilities, partially offset by various net non-cash charges of $2.1 million. The net change in our operating assets and liabilities is due to a decrease in accrued expenses and other current liabilities of approximately $2.2 million, a decrease in accounts payable of approximately $2.1 million, an increase in prepaid expenses and other assets of $1.8 million, and a decrease in operating lease liabilities of approximately $0.5 million. Net non-cash charges were driven by approximately $1.5 million in non-cash stock-based compensation expense and $0.6 million in non-cash lease expense.

Net Cash Flow from Financing Activities

We generated $86.3 million of net cash from financing activities for the year ended December 31, 2025, which was due to $51.0 million in aggregate net proceeds received from the September 2025 Warrant Inducement and October 2025 Warrant Inducement, $23.1 million in net proceeds received from the January 2025 Registered Direct Offering, $12.6 million in proceeds received from the exercise of warrants, and $0.1 million in proceeds received from the issuance of common stock under our employee stock purchase plan, partially offset by $0.5 million to satisfy tax withholding on vesting of restricted stock units.

We generated $46.8 million of net cash from financing activities for the year ended December 31, 2024, which was due to $46.2 million in aggregate net proceeds received from the January 2024 Offering, the March 2024 Registered Direct Offering, and the August 2024 Registered Direct Offering, and $0.6 million in proceeds received from the exercise of warrants, $0.1 million in aggregate net proceeds received from the issuance of common stock under our employee stock purchase plan, partially offset by $0.1 million to satisfy tax withholding on vesting of restricted stock units.

Contractual Obligations and Other Commitments

Leases

Our lease commitments reflect payments due under our lease agreement for our office space in New York, New York that expires in September 2027. As of December 31, 2025, our contractual commitment for our lease was $1.1 million, which will be paid over the remaining term of the lease. For additional information on our leases and timing of future payments, please read Note 6, *Leases*, to the consolidated financial statements included in this Form 10-K.

Other Commitments

We acquire product candidates still in development and enter into research and development arrangements with third parties that often require milestone and royalty payments to the third-party contingent upon the

occurrence of certain future events linked to the success of the product candidate in development. Milestone payments may be required, contingent upon the successful achievement of an important point in the development life-cycle of the pharmaceutical product (e.g., approval of the product for marketing by a regulatory agency). We also typically will need to make royalty payments based upon a percentage of the sales of the product candidate in the event that regulatory approval for marketing is obtained. Because of the contingent nature of these payments, they are not included in the table of contractual obligations.

These arrangements may be material individually and, in the event that multiple milestones are reached in the same period, the aggregate charge to expense could be material to the results of operations in any one period. In addition, these arrangements often give us the discretion to terminate development of the product candidate, which would allow us to avoid making the contingent payments; however, we are unlikely to cease development if the product candidate successfully achieves clinical testing objectives.

We enter into contracts in the normal course of business with various third parties for clinical trials, manufacturing, and other services and products for operating purposes. These contracts provide for termination upon notice. Payments due upon cancellation generally consist only of payments for services provided or expenses incurred, including non-cancellable obligations of our service providers, up to the date of cancellation. These payments have not been included separately within these contractual and other obligations disclosures.

Critical Accounting Policies and Estimates

Our consolidated financial statements are prepared in accordance with U.S. generally accepted accounting principles. The preparation of our consolidated financial statements and related disclosures requires our management to make estimates and judgments that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of revenues and expenses during the reported period. We base such estimates on historical experience, known trends and events and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions and conditions.

While our significant accounting policies are described in more detail in the notes to our audited consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Revenue Recognition

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

Development, Regulatory and Sales Milestones and Other Payments

At the inception of each arrangement that includes regulatory or development milestone payments, we evaluate whether the milestones are considered probable of being achieved and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue

reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of us or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. We evaluate factors such as the scientific, clinical, regulatory, commercial, and other risks that must be overcome to achieve the particular milestone in making this assessment. There is considerable judgment involved in determining whether it is probable that a significant revenue reversal would not occur. At the end of each subsequent reporting period, we reevaluate the probability of achievement of all milestones subject to constraint and, if necessary, adjust our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment.

For arrangements that include sales-based royalties, including milestone payments upon first commercial sales and milestone payments based on a level of sales, which are the result of a customer-vendor relationship and for which the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied or partially satisfied. To date, we have not recognized any royalty revenue resulting from any of our licensing arrangements.

Goodwill

Goodwill is the excess of the cost of an acquired entity over the net amounts assigned to tangible and intangible assets acquired and liabilities assumed. Goodwill is not amortized but is subject to an annual impairment test. We have a single reporting unit and all goodwill relates to that reporting unit.

We perform our annual goodwill impairment test at the reporting unit level on October 1 of each fiscal year or more frequently if changes in circumstances or the occurrence of events suggest that an impairment exists. Goodwill is evaluated for impairment using the simplified test of goodwill impairment as defined by the Financial Accounting Standards Board, or FASB, Accounting Standards Update, or ASU, No. 2017-04. Under the guidance, goodwill impairment is measured by the amount by which the carrying value of a reporting unit exceeds its fair value, without exceeding the carrying amount of goodwill allocated to that reporting unit. If the fair value of the reporting unit is less than its carrying value, an impairment loss is recorded to the extent that the implied fair value of the reporting unit’s goodwill is less than the carrying value of the reporting unit’s goodwill.

Accrued Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with applicable personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. The majority of our service providers require advance payments; however, some invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date in the consolidated financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of the estimates with the service providers and make adjustments if necessary. Examples of estimated accrued research and development expenses include fees paid to:

- Vendors in connection with clinical development activities;
- the production of clinical trial materials;
- CROs in connection with clinical trials; and
- investigative sites in connection with clinical trials.

We base our expenses related to clinical trials on our estimates of the services received and efforts expended pursuant to quotes and contracts with multiple research institutions and CROs that conduct and manage preclinical studies and clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual or prepaid accordingly.

Although we do not expect its estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, we have not made any material adjustments to our prior estimates of accrued research and development expenses.

Stock-Based Compensation

We measure stock options granted to employees and non-employee directors based on the estimated grant date fair value and recognize compensation expense on a straight-line basis over the requisite service period, which is typically the vesting period. We recognize forfeitures as they occur. We estimate the fair value of stock options on the date of grant using the Black-Scholes model. The Black-Scholes model requires us to make certain assumptions regarding: (i) the expected volatility in the market price of our shares; (ii) dividend yield; (iii) risk-free interest rates; and (iv) the period of time employees are expected to hold the award prior to exercise (referred to as the expected term). As a result, if we revise our assumptions and estimates, our stock-based compensation expense could change.

Our expected volatility is based on the historical volatility of our publicly traded common stock. The expected term of stock options is estimated using the "simplified method" for employees and non-employee directors, allowed under SEC Staff Accounting Bulletin No. 110, which assumes that stock options will be exercised evenly from vesting to expiration, as we have limited historical information from which to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior.

We recognize compensation expense for restricted stock units, or RSUs, based on the price of our shares at the grant date on a straight-line basis over the vesting period. The expense relating to RSUs that contain both a service condition and a performance condition is estimated and adjusted on a quarterly basis based upon our assessment of the probability that the performance condition would be met. As a result, if we revise such assessment, our stock-based compensation expense could change.

Recent Accounting Pronouncements

See Note 3 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for a description of recent accounting pronouncements applicable to our consolidated financial statements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The primary objective of our investment activities is to preserve capital. We do not utilize hedging contracts or similar instruments.

We are exposed to certain market risks relating primarily to interest rate risk on our cash and cash equivalents and risks relating to the financial viability of the institutions which hold our capital and through which we have invested our funds. We manage such risks by investing primarily in money market mutual funds.

In addition, we are exposed to foreign currency exchange rate fluctuations relating to payments we make to certain vendors and suppliers and license partners using foreign currencies. We do not hedge against foreign currency risks. Consequently, changes in exchange rates could adversely affect our operating results and stock price. Such losses have not been significant to date.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of
SELLAS Life Sciences Group, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of SELLAS Life Sciences Group, Inc. (the "Company") as of December 31, 2025 and 2024, the related consolidated statements of operations, stockholders' equity and cash flows for the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2025 and 2024, and the consolidated 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.

Basis for Opinion

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

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

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures to respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated 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 consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ Baker Tilly US, LLP

San Jose, California
March 19, 2026

We have served as the Company's auditor since 2018.

SELLAS LIFE SCIENCES GROUP, INC.
CONSOLIDATED BALANCE SHEETS
(Amounts in thousands, except share and per share data)

	December 31, 2025	December 31, 2024
ASSETS		
Current assets:		
Cash and cash equivalents	$ 71,793	$ 13,886
Restricted cash and cash equivalents	100	100
Prepaid expenses and other current assets	3,318	2,341
Total current assets	75,211	16,327
Operating lease right-of-use assets	963	925
Goodwill	1,914	1,914
Deposits and other assets	257	266
Total assets	$ 78,345	$ 19,432
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,948	$ 3,500
Accrued expenses and other current liabilities	3,525	5,466
Operating lease liabilities	544	544
Total current liabilities	7,017	9,510
Operating lease liabilities, non-current	457	457
Total liabilities	7,474	9,967
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Common stock, $0.0001 par value; 350,000,000 shares authorized, 153,103,459 and 73,977,459 shares issued and outstanding at December 31, 2025 and 2024, respectively	15	7
Additional paid-in capital	345,844	257,583
Accumulated deficit	(274,988)	(248,125)
Total stockholders' equity	70,871	9,465
Total liabilities and stockholders' equity	$ 78,345	$ 19,432

See accompanying notes to these consolidated financial statements.

SELLAS LIFE SCIENCES GROUP, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(Amounts in thousands, except share and per share data)

	Year Ended December 31,	
	2025	2024
Operating expenses:		
Research and development	$ 16,022	$ 19,096
General and administrative	12,252	12,417
Total operating expenses	28,274	31,513
Loss from operations	(28,274)	(31,513)
Non-operating income:		
Interest income	1,411	632
Total non-operating income	1,411	632
Net loss	$ (26,863)	$ (30,881)
Per share information:		
Net loss per common share, basic and diluted	$ (0.25)	$ (0.50)
Weighted-average common shares outstanding, basic and diluted	109,051,215	61,202,412

See accompanying notes to these consolidated financial statements.

SELLAS LIFE SCIENCES GROUP, INC.
CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY
(Amounts in thousands, except share amounts)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount			
Balance at January 1, 2024	32,132,890	$ 3	$ 209,265	$ (217,244)	$ (7,976)
Issuance of common stock, common stock warrants, and pre-funded warrants, net of issuance costs	27,500,070	3	46,161	—	46,164
Issuance of common stock upon the exercise of pre-funded warrants	13,378,302	1	—	—	1
Issuance of common stock upon the exercise of warrants	745,850	—	559	—	559
Issuance of common stock under employee stock purchase plan	103,853	—	98	—	98
Vesting of restricted stock units	172,199	—	—	—	—
Tax withholding on vesting of restricted stock units	(55,705)	—	(64)	—	(64)
Stock-based compensation	—	—	1,564	—	1,564
Net loss	—	—	—	(30,881)	(30,881)
Balance at December 31, 2024	73,977,459	7	257,583	(248,125)	9,465
Issuance of common stock upon warrant inducements, net of issuance costs	42,048,754	4	51,055	—	51,059
Issuance of common stock, common stock warrants, and pre-funded warrants, net of issuance costs	8,200,000	1	23,050	—	23,051
Issuance of common stock upon the exercise of warrants	16,823,735	2	12,615	—	12,617
Issuance of common stock upon the exercise of pre-funded warrants	11,485,040	1	—	—	1
Issuance of common stock under employee stock purchase plan	115,449	—	112	—	112
Vesting of restricted stock units	804,553	—	—	—	—
Tax withholding on vesting of restricted stock units	(351,531)	—	(527)	—	(527)
Stock-based compensation	—	—	1,956	—	1,956
Net loss	—	—	—	(26,863)	(26,863)
Balance at December 31, 2025	153,103,459	$ 15	$ 345,844	$ (274,988)	$ 70,871

See accompanying notes to these consolidated financial statements.

SELLAS LIFE SCIENCES GROUP, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Amounts in thousands)

	Year ended December 31,	
	2025	2024
Cash flows from operating activities:		
Net loss	$ (26,863)	$ (30,881)
Adjustment to reconcile net loss to net cash used in operating activities:		
Non-cash stock-based compensation	1,956	1,564
Non-cash lease expense	597	561
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(968)	(1,790)
Accounts payable	(535)	(2,139)
Accrued expenses and other current liabilities	(1,941)	(2,184)
Operating lease liabilities	(635)	(533)
Net cash used in operating activities	(28,389)	(35,402)
Cash flows from financing activities:		
Proceeds from warrant inducements, net of issuance costs	51,042	—
Proceeds from issuance of common stock, common stock warrants, and pre-funded warrants, net of issuance costs	23,051	46,164
Proceeds from the exercise of common stock warrants and pre-funded warrants	12,618	560
Proceeds from employee stock plan purchases	112	98
Tax withholding on vesting of restricted stock units	(527)	(64)
Net cash provided by financing activities	86,296	46,758
Net increase in cash, cash equivalents, restricted cash, and restricted cash equivalents	57,907	11,356
Cash, cash equivalents, restricted cash, and restricted cash equivalents at the beginning of year	13,986	2,630
Cash, cash equivalents, restricted cash, and restricted cash equivalents at the end of year	$ 71,893	$ 13,986
Supplemental disclosure of cash flow information:		
Cash received during the year for interest	$ 1,411	$ 632
Supplemental disclosures:		
Fair value of common stock warrants issued in warrant inducements	$ 67,412	$ —
Warrant modifications recorded in stockholders' equity	$ —	$ 725
Increase in operating lease right of use assets and current and non-current operating lease liabilities	$ 526	$ 526
Offering costs in accounts payable and accrued expenses	$ 17	$ —

See accompanying notes to these consolidated financial statements.

1. Organization and Description of Business

SELLAS Life Sciences Group, Inc. is a late-stage clinical biopharmaceutical company focused on novel therapeutics for a broad range of cancer indications. SELLAS' lead product candidate, galinpepimut-S ("GPS"), is a cancer immunotherapeutic agent licensed from Memorial Sloan Kettering Cancer Center ("MSK") and targets the Wilms Tumor 1 ("WT1") protein, which is present in an array of tumor types. SELLAS' second product candidate is SLS009, a small molecule, highly selective cyclin-dependent kinase 9 ("CDK9") inhibitor, which the Company licensed from GenFleet Therapeutics (Shanghai), Inc. ("GenFleet"), for all therapeutic and diagnostic uses in the world outside of mainland China, Hong Kong, Macau and Taiwan ("SLS009 Territory"). Both GPS and SLS009 have potential as monotherapies or in combination with other immunotherapeutic agents to address a broad spectrum of hematologic, or blood, cancers and solid tumor indications.

As used in this Annual Report on Form 10-K, the words the "Company," and "SELLAS" refer to SELLAS Life Sciences Group, Inc. and its consolidated subsidiaries.

2. Liquidity

On October 24, 2025, the Company entered into a Warrant Inducement Agreement (the "October 2025 Inducement") with an institutional investor and holder of certain existing warrants to cash exercise (i) warrants to purchase 6,514,658 shares of common stock at an exercise price of $1.535 per share, previously issued in March 2024 (the "March 2024 Warrants"), and (ii) warrants to purchase 15,849,056 shares of common stock at an exercise price of $1.325 per share, previously issued in August 2024 (the "August 2024 Warrants"). The March 2024 Warrants and the August 2024 Warrants were exercised at their original issuance exercise price plus $0.125 per share of common stock in accordance with Nasdaq rules. In consideration of the investor's agreement to exercise the March 2024 Warrants and the August 2024 Warrants, the Company agreed to issue new warrants to the investor to purchase up to 22,363,714 shares of common stock at an exercise price of $2.00 per share (the "October 2025 Warrants"), which are exercisable immediately and will expire on the five year anniversary of issuance. The net proceeds to the Company from the October 2025 Inducement were approximately $29.1 million, after deducting financial advisory fees and related transaction expenses.

On September 10, 2025, the Company entered into a Warrant Inducement Agreement (the “September 2025 Inducement”) with an institutional investor and holder of certain existing warrants to cash exercise warrants to purchase 19,685,040 shares of common stock, previously issued in January 2025 (the "January 2025 Warrants"), at the original issuance exercise price of $1.20 per share. In consideration of the investor’s agreement to exercise the January 2025 Warrants, the Company agreed to issue new warrants to the Investor to purchase up to 19,685,040 shares of common stock at an exercise price of $1.88 per share (the “September 2025 Warrants”), which are exercisable immediately and will expire on the five and one half anniversary of issuance. The net proceeds to the Company from the September 2025 Inducement were approximately $22.0 million, after deducting financial advisory fees and related transaction expenses.

On January 29, 2025, the Company consummated the January 2025 Registered Direct Offering with an institutional investor priced at-the-market under Nasdaq rules, pursuant to which the Company agreed to issue and sell 8,200,000 shares of common stock and 11,485,040 pre-funded warrants exercisable for shares of common stock, together with accompanying warrants to purchase up to 19,685,040 shares of common stock. Each share of common stock and accompanying common warrant were sold together at a combined offering price of $1.27, and each pre-funded warrant and accompanying common warrant were sold together at a combined offering price of $1.2699. The common warrants have an exercise price of $1.20 per share. The net proceeds to the Company from the January 2025 Registered Direct Offering were approximately $23.1 million, after deducting the placement agents' fees and related offering expenses.

During the year ended December 31, 2025, the Company received approximately $12.6 million in proceeds from the exercise of 16.8 million at an exercise price of $0.75 per share. Subsequent to December 31, 2025, the Company received an additional $42.6 million in proceeds from the exercise of 26.4 million warrants at a weighted-average exercise price of approximately $1.61 per share.

In December 2020, the Company, together with its wholly-owned subsidiary, SLSG Limited, LLC, entered into an Exclusive License Agreement (the “3D Medicines Agreement”) with 3D Medicines Inc. ("3D Medicines"), pursuant to which the Company granted 3D Medicines a sublicensable, royalty-bearing license, under certain intellectual property owned or controlled by the Company, to develop, manufacture and have manufactured, and commercialize GPS and heptavalent GPS product candidates for all therapeutic and other diagnostic uses in mainland China, Hong Kong, Macau and Taiwan ("3DMed Territory"). As of December 31, 2025, the Company has received an aggregate of $10.5 million in upfront payments and certain technology transfer and regulatory milestones. There is a total of $191.5 million in potential future development, regulatory, and sales milestones, not including future royalties, that remains under the 3D Medicines Agreement, which milestones are all variable in nature and not under the Company's control. In December 2023, the Company commenced a binding arbitration proceeding against 3D Medicines, which involves, among other things, the trigger and payment of certain milestone payments due to the Company. See *Note 6, Legal Proceedings.*

As of December 31, 2025, the Company had cash and cash equivalents of $71.8 million and restricted cash equivalents of $0.1 million. In accordance with Accounting Standards Codification ("ASC") 205-40, *Presentation of Financial Statements - Going Concern*, the Company evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about its ability to continue as a going concern within one year after the consolidated financial statements are available to be issued. The Company expects its cash and cash equivalents, together with the $42.6 million in proceeds from warrant exercises received subsequent to December 31, 2025, will be sufficient to fund its current planned operations for at least the next twelve months from the date of issuance of these financial statements, although the Company may pursue additional capital resources through public or private equity or debt financings or by entering into additional license agreements or collaborations with other companies.

Management's expectations with respect to its ability to fund current planned operations is based on estimates that are subject to risks and uncertainties. If actual results are different from management's estimates, the Company may need to seek additional strategic or financing opportunities sooner than would otherwise be expected. There is no guarantee that any of these strategic or financing opportunities will be executed or executed on favorable terms, and some could be dilutive to existing stockholders. If the Company is unable to obtain additional funding on a timely basis, it may be forced to significantly curtail, delay, or discontinue one or more of its planned research and development programs or be unable to expand its operations or otherwise prepare for the potential regulatory approval and commercialization of its product candidates, assuming positive data.

Since inception, the Company has incurred recurring losses and negative cash flows from operations and has an accumulated deficit of $275.0 million as of December 31, 2025. During the year ended December 31, 2025, the Company incurred a net loss of $26.9 million and used $28.4 million of cash in operations. The Company expects to continue to generate operating losses and negative cash flows for the next few years and will need additional funding to support its planned operating activities through profitability. The transition to profitability is dependent upon the successful development, approval, and commercialization of the Company's product candidates and the achievement of a level of revenues adequate to support its cost structure.

3. Basis of Presentation and Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States (“U.S. GAAP”). Any reference in these notes to applicable guidance is meant to refer to U.S. GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates (“ASU”) of the Financial Accounting Standards Board (“FASB”).

Principles of Consolidation

The consolidated financial statements include the financial statements of the Company and its wholly owned subsidiaries. All significant intercompany accounts and transactions have been eliminated upon consolidation. Unless the context otherwise indicates, reference in these notes to the "Company" refer to SELLAS Life Sciences Group, Inc. and its wholly owned subsidiaries, SELLAS Life Sciences Group, Ltd., a privately held

Bermuda exempted company, SLSG Limited, LLC, and Sellas Life Sciences Limited. The functional currency of the Company's non-U.S. operations is the U.S. dollar.

Use of Estimates

The preparation of these consolidated financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period.

On an ongoing basis, the Company evaluates its estimates using historical experience and other factors, including the current economic environment. Significant items subject to such estimates are assumptions used for purposes of determining stock-based compensation, carrying value of goodwill, and accounting for research and development activities. Management believes its estimates to be reasonable under the circumstances. Actual results could differ significantly from those estimates.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company's chief operating decision maker ("CODM") is the President & Chief Executive Officer.

The Company views its operations and manages its business as one operating segment, which includes all activities related to the development of novel therapeutics for a broad range of cancer indications. The determination of a single reportable segment is consistent with the consolidated financial information provided to the CODM. The CODM does not evaluate discrete financial information for each of the Company's clinical product candidates, and views and manages the Company's clinical programs as one consolidated segment for which all operations are centralized.

Segment profit or loss is measured as the Company's net loss as reported on the consolidated statement of operations. As the Company does not currently generate revenues, the CODM evaluates Company performance through the achievement of clinical development goals. The CODM also monitors the Company's cash and cash equivalents as reported on the consolidated balance sheet, net cash used in operations as reported on the consolidated statement of cash flows, and segment expense information in order to make operational decisions, allocate resources, and plan for future activities.

Segment expenses consist of the Company's functional expenses, research and development expenses and general and administrative expenses, as reported in the consolidated statement of operations. Other segment items included in the measure of segment net loss include non-operating income, which primarily relates to interest income. The measure of total segment assets is reported on the consolidated balance sheet as total assets.

The accounting policies of the Company's single reportable segment are the same as those for the consolidated financial statements described in this Note 3.

Fair Value of Financial Instruments

The Company measures certain financial assets and liabilities at fair value on a recurring basis. Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability. A three-tier fair value hierarchy is established as a basis for considering such assumptions and for inputs used in the valuation methodologies in measuring fair value:

Level 1—Quoted prices in active markets for identical assets or liabilities.

Level 2—Inputs other than quoted prices included within Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

As of December 31, 2025 and 2024, the carrying amounts of the Company's financial instruments, including cash equivalents and accounts payable, approximate fair value due to the short-term nature of those instruments and were categorized as Level 1. The Company did not transfer any financial instruments into or out of Level 3 classification during the years ended December 31, 2025 and 2024.

Concentration of Credit Risk

Financial instruments that potentially expose the Company to concentrations of credit risk consist principally of cash on deposit with financial institutions, the balances of which frequently exceed federally insured limits. If any of the financial institutions with whom we do business were to be placed into receivership, we may be unable to access to the cash we have on deposit with such institutions.

Cash and Cash Equivalents

The Company considers any highly liquid investments, such as money market funds, with an original maturity of three months or less to be cash and cash equivalents.

Restricted Cash and Cash Equivalents

Restricted cash consists of certificates of deposit on hand with the Company's financial institutions as collateral for its corporate credit cards.

The following table provides a reconciliation of the components of cash, cash equivalents, restricted cash, and restricted cash equivalents reported in the Company's consolidated balance sheets to the total amount presented in the consolidated statements of cash flows (in thousands):

	December 31,	
	2025	2024
Cash and cash equivalents	$ 71,793	$ 13,886
Restricted cash and cash equivalents	100	100
Total cash, cash equivalents, restricted cash, and restricted cash equivalents	$ 71,893	$ 13,986

As of December 31, 2025 and 2024, the Company maintained $0.1 million on hand with the Company's financial institutions as collateral for its corporate credit cards.

Goodwill

Goodwill is the excess of the cost of an acquired entity over the net amounts assigned to tangible and intangible assets acquired and liabilities assumed. Goodwill is not amortized but is subject to an annual impairment test. The Company has a single reporting unit and all goodwill relates to that reporting unit. The Company performs its annual goodwill impairment test on October 1 of each fiscal year, or more frequently if changes in circumstances or the occurrence of events suggest that an impairment exists. The Company continually evaluates financial performance, economic conditions and other relevant developments in assessing if an interim period impairment test is necessary.

The Company's goodwill balance at December 31, 2025 and 2024 was $1.9 million. The Company did not recognize any impairment of goodwill during the years ended December 31, 2025 and 2024. As of December 31, 2025 and 2024, there were no accumulated impairment losses related to goodwill.

Leases

The Company accounts for its leasing arrangements under ASU No. 2016-02, *Leases (Topic 842)* (“Topic 842”). Under Topic 842, all significant lease arrangements are generally recognized at lease commencement. Operating lease right-of-use ("ROU"), assets and lease liabilities are recognized at the commencement date. An ROU asset and corresponding lease liability is not recorded for leases with an initial term of 12 months or less (short term leases) and the Company recognizes lease expense for these leases as incurred over the lease term.

ROU assets represent the Company’s right to use an underlying asset during the reasonably certain lease terms and lease liabilities represent the Company’s obligation to make lease payments arising from the lease. The Company’s lease terms may include options to extend or terminate the lease when it is reasonably certain that the option will be exercised. Operating lease ROU assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. The Company uses its incremental borrowing rate, based on the information available at commencement date, in determining the present value of lease payments. The operating lease ROU asset also includes any lease payments related to initial direct cost and prepayments, and excludes lease incentives. Lease expense is recognized on a straight-line basis over the lease term. The Company’s lease agreements contain lease and non-lease components, which are generally accounted for separately. See Note 6 for discussion of the Company’s facility leases.

Revenue Recognition

The Company records revenue in accordance with ASC Topic 606, *Revenue From Contracts with Customers* ("Topic 606"). This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of Topic 606, the entity performs the following five-steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of Topic 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company then allocates the transaction price to each distinct performance obligation based on its relative standalone selling price. The Company recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. See Note 9 for further discussion of the Company's revenue recognition associated with the 3D Medicines Agreement.

Development, Regulatory and Sales Milestones and Other Payments

At the inception of each arrangement that includes regulatory or development milestone payments, the Company evaluates whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The Company evaluates factors such as the scientific, clinical, regulatory, commercial, and other risks that must be overcome to achieve the particular milestone in making this assessment. There is considerable judgment involved in determining whether it is probable that a significant revenue reversal would not occur. At the end of each subsequent reporting period, the Company reevaluates the probability of achievement of all milestones subject to constraint and, if necessary, adjusts its

estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment.

For arrangements that include sales-based royalties, including milestone payments upon first commercial sales and milestone payments based on a level of sales, which are the result of a customer-vendor relationship and for which the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied or partially satisfied. To date, the Company has not recognized any royalty revenue resulting from any of its licensing arrangements.

Research and Development Expenses

Research and development costs are expensed as incurred. Research and development costs that are paid in advance of performance are capitalized as a prepaid expense and recognized as research and development expenses as the services are provided. Clinical study costs, a component of research and development expenses, are accrued over the service periods specified in the contracts and adjusted as necessary based on an ongoing review of the level of effort and costs actually incurred.

Research and development expenses consist primarily of development research performed by contract research organizations ("CROs"), personnel costs, including salaries, benefits and stock-based compensation, clinical drug supply, investigator grants, materials and supplies, consulting fees, licenses and fees, preclinical studies, and overhead allocations consisting of various support and facility-related costs.

Stock-based Compensation

The Company measures employee and non-employee director share-based awards at their estimated grant-date fair value and records compensation expense on a straight-line basis over the requisite service period, which is typically the vesting term of the awards.

Estimating the fair value of share-based awards requires the input of subjective assumptions, including the expected term of the options and stock price volatility. The Company uses the Black-Scholes option pricing model to value its stock option awards. The assumptions used in estimating the fair value of share-based awards represent management’s estimate and involve inherent uncertainties and the application of management’s judgment. As a result, if factors change and management uses different assumptions, share-based compensation expense could be materially different for future awards.

The expected term of the stock options is estimated using the “simplified method,” as the Company has limited historical information from which to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior for its stock option grants. The simplified method is the midpoint between the vesting term and the contractual term of the option. The stock price volatility assumption is based on the historical volatility of the Company's publicly traded common stock. The risk-free rate is based on the U.S. Treasury yield curve commensurate with the expected term of the option. The Company accounts for forfeitures for stock option awards as they occur.

Restricted Stock Units with Performance and Service Conditions

The Company's Board of Directors has granted restricted stock units ("RSUs") to employees that vest based on performance and service conditions. The fair values of the performance-based RSUs are measured on the date of grant and are based on the Company's closing stock price on such date. Compensation expense is recognized for the number of performance-based RSUs expected to be earned, provided the requisite service period has been rendered, after assessing the probability that certain performance criteria will be met. Cumulative adjustments are recorded each quarter to reflect the estimated outcome of the performance-related conditions until the date results are determined and settled. The Company accounts for forfeitures of performance-based RSUs when they occur. If performance criteria are not met or are not expected to be met, any compensation expense previously recognized to date associated with the performance-based RSUs will be reversed.

Restricted Stock Units with Service Conditions Only

The Board of Directors has granted RSUs to certain employees that vest based on continuous service. Time-vested RSUs awarded to employees vest one-fourth per year annually over four years, provided the employee remains employed with the Company. The fair values of the time-vested RSUs are measured on the date of grant and are based on the Company's closing stock price on such date. Compensation expense for time-vested RSUs with service conditions only are recognized straight-line over the applicable service period. The Company accounts for forfeitures of time-vested RSUs when they occur. Previously recognized compensation expense for forfeited RSUs are reversed in the period the time-vested RSUs are forfeited.

Income Taxes

The Company uses the asset and liability method of accounting for income taxes. Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and credit carryforwards. 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. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. The Company recognizes the benefit of an uncertain tax position that it has taken or expects to take on its income tax returns, if such a position is more likely than not to be sustained. Potential interest and penalties associated with unrecognized tax positions are recognized in income tax expense. No interest or penalties associated with unrecognized tax positions were recognized in either of the years ended December 31, 2025 or 2024.

The Company recognizes liabilities or assets for the deferred tax consequences of temporary differences between the tax basis of assets or liabilities and their reported amounts in the consolidated financial statements in accordance with FASB ASC 740, "*Accounting for Income Taxes" ("ASC 740").* These temporary differences will result in taxable or deductible amounts in future years when the reported amounts of the assets or liabilities are recovered or settled. ASC 740 requires that a valuation allowance be established when management determines that it is more likely than not that all or a portion of a deferred asset will not be realized. The Company evaluates the realizability of its net deferred income tax assets and valuation allowances as necessary, at least on an annual basis. During this evaluation, the Company reviews its forecasts of income in conjunction with other positive and negative evidence surrounding the realizability of its deferred income tax assets to determine if a valuation allowance is required. Adjustments to the valuation allowance will increase or decrease the Company's income tax provision or benefit. The recognition and measurement of benefits related to the Company's tax positions requires significant judgment, as uncertainties often exist with respect to new laws, new interpretations of existing laws, and rulings by taxing authorities. Differences between actual results and the Company's assumptions or changes in the Company's assumptions in future periods are recorded in the period they become known.

Net Loss Per Share

Basic loss per share is computed by dividing net loss applicable to common stockholders by the weighted average number of shares of common stock outstanding during each period. The weighted average number of common stock outstanding also includes pre-funded warrants and shares held in abeyance because their exercise requires only nominal consideration for the delivery of the shares. Diluted loss per share includes the effect, if any, from the potential exercise or conversion of securities, such as warrants, stock options and unvested restricted stock that would result in the issuance of incremental shares of common stock. In computing the basic and diluted net loss per share, the weighted average number of shares remains the same for both calculations due to the fact that when a net loss exists, dilutive shares are not included in the calculation as the impact is anti-dilutive.

The following potentially dilutive securities outstanding have been excluded from the computation of diluted weighted average shares outstanding, as their impact would be anti-dilutive (in thousands):

	December 31,	
	2025	2024
Common stock warrants	58,482	55,955
Stock options	2,651	1,837
Restricted stock units	897	472
	62,030	58,264

Recent Accounting Standards Adopted

In December 2023, the FASB issued ASU No. 2023-09, *Improvements to Income Tax Disclosures*, which amends the guidance in ASC 740, Income Taxes. The ASU is intended to improve the transparency of income tax disclosures by prescribing standard categories and greater disaggregation of information in the effective tax rate reconciliation, disclosure of income taxes paid disaggregated by jurisdiction, and modifies other income tax-related disclosures. ASU No. 2023-09 is effective for fiscal years beginning after December 15, 2024 and allows for adoption either prospectively or retrospectively. Early adoption is permitted. The Company adopted ASU 2023-09 for the year ended December 31, 2025, and applied the new disclosure requirement prospectively to the current annual period. Prior period disclosures have not been adjusted to reflect the new disclosure requirements. See Note 11, *Income Taxes*.

Recent Accounting Pronouncements Not Yet Adopted

In November 2024, the FASB issued ASU 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures,* which requires disclosure of disaggregated information about certain income statement expense line items in the notes to the financial statements on an interim and annual basis. ASU 2024-03 will be effective for the annual reporting periods in fiscal years beginning after December 15, 2026, with early adoption permitted. The Company is currently evaluating the impact that the adoption of ASU 2024-03 will have on the consolidated financial statements.

4. Collaboration and In-License Agreements

As part of its business, the Company enters into in-licensing agreements with third parties that often require milestone and royalty payments based on the progress of the licensed asset through development and commercial stages. Milestone payments may be required, for example, upon approval of the product for marketing by a regulatory agency, and the Company may be required to make royalty payments based upon a percentage of net sales of the product. The expenditures required under these arrangements in any period may be material and are likely to fluctuate from period to period. These arrangements may permit the Company to unilaterally terminate development of the product and thereby avoid future contingent payments; however, the Company is unlikely to cease development if the compound successfully achieves clinical testing objectives.

Exclusive License Agreement with GenFleet Therapeutics (Shanghai) Inc.

On March 31, 2022, the Company entered into an exclusive license agreement with GenFleet pursuant to which GenFleet granted to the Company a sublicensable royalty-bearing license under certain of its intellectual property, to develop, manufacture, and commercialize SLS009 for the treatment, diagnosis or prevention of disease in humans and animals in the SLS009 Territory.

In consideration for the exclusive license, the Company agreed to pay to GenFleet (i) an upfront and technology transfer fee of $10.0 million, (ii) potential development and regulatory milestone payments for up to three indications totaling up to $48.0 million in the aggregate, and (iii) potential sales milestone payments totaling up to $92.0 million in the aggregate upon the achievement of certain net sales thresholds in a given calendar year. The Company also agreed to pay GenFleet single-digit tiered royalties based upon a percentage of annual net sales, with the royalty rate escalating based on the level of annual net sales of SLS009 in the SLS009 Territory ranging from the low to high single digits.

There were no payments made to GenFleet pursuant to the exclusive license agreement during the years ended December 31, 2025 and 2024.

Exclusive License Agreement with Memorial Sloan Kettering Cancer Center ("MSK")

On September 4, 2014, the Company entered into a license agreement (the “Original MSK License Agreement”) with MSK under which the Company was granted an exclusive license to develop and commercialize MSK’s WT1 peptide vaccine technology. The Original MSK License Agreement, unless terminated earlier in accordance with the terms of the Original MSK License Agreement, will continue on a country-by-country and licensed product-by-licensed product basis, until the later of: (i) expiration of the last valid claim embracing such licensed product; (ii) expiration of any market exclusivity period granted by law with respect to such licensed product; or (iii) ten (10) years from the first commercial sale in such country.

On May 25, 2017, the Company and MSK entered into an Amended and Restated Exclusive License Agreement (the “MSK A&R License Agreement”). Under the MSK A&R License Agreement, the Company expanded its license under the original MSK License Agreement, as amended, to include a license to commercially develop certain additional WT1 peptides through a program of exploiting certain patents and other rights covering such peptides. The MSK A&R License Agreement, among other changes, added certain milestone payments for each additional patent licensed product as defined in the MSK A&R License Agreement.

On October 11, 2017, the Company and MSK entered into a second Amended and Restated Exclusive License Agreement (the “Second MSK A&R License Agreement”). Under the Second MSK A&R License Agreement, the Company and MSK extended certain milestone dates for the Company in exchange for increased milestone payments.

The Company incurred $0.1 million of guaranteed minimum royalty payments under the Second MSK A&R License Agreement during the years ended December 31, 2025 and 2024. Such expenses have been included in research and development costs.

5. Balance Sheet Accounts

Prepaid expenses and other current assets consist of the following (in thousands):

	December 31,	
	2025	2024
Clinical trial costs	$ 2,901	$ 2,172
Professional fees	155	130
Insurance	39	39
Other	223	—
Prepaid expenses and other current assets	$ 3,318	$ 2,341

Accrued expenses and other current liabilities consist of the following (in thousands):

	December 31,	
	2025	2024
Compensation and related benefits	$ 1,753	$ 1,777
Clinical trial costs	1,540	3,339
Professional fees	190	308
Other	42	42
Accrued expenses and other current liabilities	$ 3,525	$ 5,466

6. Legal Proceedings, Commitments and Contingencies

Legal Proceedings

From time to time, the Company may be subject to various pending or threatened legal actions and proceedings, including those that arise in the ordinary course of its business, which may include employment matters, breach of contract disputes and stockholder litigation. Such actions and proceedings are subject to many uncertainties and to outcomes that are not predictable with assurance and that may not be known for extended periods of time. The Company records a liability in its consolidated financial statements for costs related to claims, including future legal costs, settlements and judgments, when the Company has assessed that a loss is probable and an amount can be reasonably estimated. If the reasonable estimate of a probable loss is a range, the Company records the most probable estimate of the loss or the minimum amount when no amount within the range is a better estimate than any other amount. The Company discloses a contingent liability even if the liability is not probable or the amount is not estimable, or both, if there is a reasonable possibility that a material loss may have been incurred.

On December 20, 2023, the Company commenced a binding arbitration proceeding against 3D Medicines, administered by the Hong Kong International Arbitration Centre and governed by New York State law in accordance with the dispute resolution provisions in the 3D Medicines Agreement. The arbitration proceeding involves, among other things, the trigger and payment of the relevant milestone payments due to the Company as well as 3D Medicines' failure to use commercially reasonable best efforts to develop GPS in the 3DMed Territory, and particularly in mainland China. Except for this arbitration proceeding, as of December 31, 2025, there was no other pending or threatened litigation.

Leases

The Company has a non-cancelable operating lease for certain executive, administrative, and general business office space for its headquarters in New York, New York, which commenced on June 5, 2020 and was amended in February 2022 to add additional space. The Company assessed the lease amendment for the additional space and determined it should be accounted for as a separate contract.

On October 1, 2025, the Company agreed to extend the expiration date for its office space by one year through September 30, 2027. The Company assessed the amendment for the lease extension and determined it should be accounted for as a modification of the existing operating leases. Accordingly, on the effective modification date, the Company recognized an increase to its operating lease liabilities and corresponding operating lease right-of-use assets of approximately $0.5 million for the remeasurement at present value of the remaining lease payments using a discount rate of 13.0%.

The weighted average discount rate used to account for the Company's operating lease under ASC 842, *Leases,* as of December 31, 2025 and 2024 was approximately 13.0%. As of December 31, 2025, the lease had a remaining term of 1.75 years.

Rent expense related to the Company's operating lease was approximately $0.6 million for each of the years ended December 31, 2025 and 2024. The Company made cash payments related to operating leases of approximately $0.6 million and $0.5 million during the years ended December 31, 2025 and 2024, respectively.

Future minimum rental payments under the Company's non-cancelable operating lease are as follows as of December 31, 2025 (in thousands):

Total minimum lease payments:	
2026	$ 635
2027	477
Total future minimum lease payments	1,112
Less: imputed interest	(111)
Operating lease liabilities	$ 1,001

7. Stockholders' Equity

Preferred Stock

The Company has authorized up to 5,000,000 shares of preferred stock, $0.0001 par value per share, for issuance. There were no preferred shares outstanding as of December 31, 2025 and 2024.

Common Stock

The Company has authorized up to 350,000,000 shares of common stock, $0.0001 par value per share, for issuance.

Shares of common stock reserved for future issuance are as follows (in thousands):

	December 31, 2025
Warrants outstanding	58,482
Stock options outstanding	2,651
Restricted stock units outstanding	897
Shares reserved for future issuance under the 2023 Amended and Restated Equity Incentive Plan	1,370
Shares reserved for future issuance under the Employee Stock Purchase Plans	764
Total shares of common stock reserved for future issuance	64,164

8. Warrants to Acquire Shares of Common Stock

The following is a summary of the Company's warrants to acquire shares of common stock activity for the year ended December 31, 2025 (in thousands, except per share data):

Warrant Issuance	Outstanding, December 31, 2024	Granted	Exercised	Canceled/Expired	Outstanding, December 31, 2025	Exercise Price Per Share	Expiration
Warrants classified as equity:							
October 2025 Inducement	—	22,364	—	—	22,364	$ 2.0000	October 2030
September 2025 Inducement	—	19,685	—	—	19,685	$ 1.8800	March 2031
January 2025 Registered Direct Offering	—	19,685	(19,685)	—	—	$ 1.2000	January 2030
January 2025 Pre-Funded Warrants	—	11,485	(11,485)	—	—	$ 0.0001	n/a
August 2024 Registered Direct Offering	15,849	—	(15,849)	—	—	$ 1.2000	August 2029
March 2024 Registered Direct Offering	13,029	—	(6,515)	—	6,514	$ 1.4100	September 2029
January 2024 Offering	11,467	—	(4,170)	—	7,297	$ 0.7500	January 2029
Other	15,610	—	(12,654)	(334)	2,622	$ 2.1086	April 2027 - January 2029
	55,955	73,219	(70,358)	(334)	58,482		

Subsequent to December 31, 2025, 26.4 million warrants were exercised at a weighted-average exercise price of approximately $1.61 per share for aggregate proceeds of approximately $42.6 million.

The Company's outstanding warrants to acquire shares of common stock consist of equity-classified warrants.

Warrants Classified as Equity

Equity-classified warrants consist of warrants to acquire common stock issued in connection with previous equity financings. During its evaluation of equity classification for warrants to acquire shares of common stock, the Company considered the conditions as prescribed within ASC 815-40, *Derivatives and Hedging, Contracts in an Entity's own Equity* ("ASC 815-40"). The conditions within ASC 815-40 are not subject to a probability assessment. The warrants to acquire shares of common stock do not fall under the liability criteria within ASC 480, *Distinguishing Liabilities from Equity*, as they are not puttable and do not represent an instrument that has a redeemable underlying security. The warrants to acquire shares of common stock do meet the definition of a derivative instrument under ASC 815, but are eligible for the scope exception as they are indexed to the Company's own stock and would be classified in permanent equity if freestanding.

The Company accounted for the September 2025 Inducement as an exercise of the January 2025 Warrants in exchange for the issuance of the September 2025 Warrants, which is a free-standing financial instrument recorded in stockholders' equity. Since the September 2025 Warrants were issued to incentivize the exercise of the January 2025 Warrants, incremental fair value of approximately $14.7 million as a result of the inducement was accounted for as a non-cash equity issuance cost recognized in stockholders' equity. The incremental value was obtained from the revaluation of the January 2025 Warrants pre and post inducement exchange using a Black-Scholes option pricing model. However, there is no net impact to the consolidated statements of stockholders' equity because the warrants are equity classified. The fair value of the September 2025 Warrants was estimated at approximately $30.4 million using a Black-Scholes option pricing model which takes into account the exercise price, the estimated remaining term of the warrants of five and one half years, the historical volatility of the Company's common stock commensurate with the expected term estimated at 114.20%, a risk-free interest rate of 3.67% based on the U.S. Treasury yield commensurate with the expected term, and no future dividends based on the Company's history and expectations.

The Company accounted for the October 2025 Inducement as an exercise of the March 2024 Warrants and August 2024 Warrants in exchange for the issuance of the October 2025 Warrants, which is a free-standing financial instrument recorded in stockholders' equity. Since the October 2025 Warrants were issued to incentivize the exercise of the March 2024 Warrants and August 2024, incremental fair value of approximately $16.1 million as

a result of the inducement was accounted for as a non-cash equity issuance cost recognized in stockholders' equity. The incremental value was obtained from the revaluation of the March 2024 Warrants and August 2024 Warrants pre and post inducement exchange using a Black-Scholes option pricing model. However, there is no net impact to the consolidated statements of stockholders' equity because the warrants are equity classified. The fair value of the October 2025 Warrants was estimated at approximately $37.0 million using a Black-Scholes option pricing model which takes into account the exercise price including the $0.125 per share in additional consideration in accordance with Nasdaq rules, the estimated remaining term of the warrants of five years, the historical volatility of the Company's common stock commensurate with the expected term estimated at 117.24%, a risk-free interest rate of 3.60% based on the U.S. Treasury yield commensurate with the expected term, and no future dividends based on the Company's history and expectations.

9. Licensing Revenue

Exclusive License Agreement with 3D Medicines, Inc.

In December 2020, the Company entered into the 3D Medicines Agreement pursuant to which the Company granted 3D Medicines a sublicensable royalty-bearing license under certain intellectual property owned or controlled by the Company, to develop, manufacture and have manufactured, and commercialize GPS and heptavalent GPS (referred to as GPS Plus) product candidates ("GPS Licensed Products") for all therapeutic and other diagnostic uses in the 3DMed Territory. In partial consideration for the rights granted by the Company, 3D Medicines agreed to pay the Company (i) a one-time upfront cash payment of $7.5 million, and (ii) milestone payments totaling up to $194.5 million in the aggregate upon the achievement of certain technology transfer, development and regulatory milestones, as well as sales milestones based on certain net sales thresholds of GPS Licensed Products in the 3DMed Territory in a given calendar year. 3D Medicines also agreed to pay tiered royalties based upon a percentage of annual net sales of GPS Licensed Products in the 3DMed Territory ranging from the high single digits to the low double digits.

Revenue Recognition

There is $191.5 million in potential future development, regulatory, and sales milestones, not including future royalties, remaining under the 3D Medicines Agreement as of December 31, 2025, which milestones are variable in nature and not under the Company's control. At the end of each reporting period, the Company reevaluates the probability of achievement of the future development, regulatory, and sales milestones subject to constraint and, if necessary, will adjust its estimate of the overall transaction price. Any such adjustments will be recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment. For the sales-based royalties, the Company will recognize revenue when the related sales occur. To date, the Company has not recognized any royalty revenue resulting from any of its licensing arrangements.

In December 2023, the Company commenced a binding arbitration proceeding against 3D Medicines, which involves, among other things, the trigger and payment of certain milestone payments due to the Company. See *Note 6, Legal Proceedings*.

There was no licensing revenue recognized during the years ended December 31, 2025 and 2024, and there was no cost of licensing revenue recognized during the years ended December 31, 2025 and 2024.

10. Stock-Based Compensation

2017 Equity Incentive Plan

On December 29, 2017, the 2017 Equity Incentive Plan was approved by the stockholders of the Company, and currently allows for issuance of up to approximately 17,000 shares of common stock underlying stock options granted prior to September 10, 2019. The 2017 Equity Incentive Plan was terminated upon the approval of the 2019 Incentive Plan subject to outstanding stock options granted under the 2017 Equity Incentive Plan that remain exercisable through maturity for the Company's employees and directors.

2023 Amended and Restated Equity Incentive Plan

On September 10, 2019, the 2019 Equity Incentive Plan ("2019 Equity Plan") was approved by the stockholders of the Company. On June 20, 2023, an amendment to the 2019 Equity Plan was approved by the stockholders of the Company, which amended and restated the 2019 Equity Plan (as amended and restated, the "2023 Amended and Restated Equity Incentive Plan") to increase the number of shares of common stock authorized for issuance under the 2019 Equity Plan by 3,000,000 shares.

The 2023 Amended and Restated Equity Incentive Plan currently allows for issuance of up to approximately 6,036,000 shares of common stock in connection with the grant of stock-based awards, including stock options, restricted stock, restricted stock units, stock appreciation rights and other types of awards as deemed appropriate.

As of December 31, 2025, approximately 1,370,000 shares of common stock were reserved for future grants under the 2023 Amended and Restated Equity Incentive Plan.

The following table summarizes the components of stock-based compensation expense in the consolidated statements of operations for the years ended December 31, 2025 and 2024, respectively (in thousands):

	Years Ended December 31,	
	2025	2024
Research and development	$ 434	$ 346
General and administrative	1,522	1,218
Total stock-based compensation	$ 1,956	$ 1,564

Options to Purchase Shares of Common Stock

The Company uses the Black-Scholes option-pricing model to estimate the fair value of stock-based awards and the following assumptions were used for stock options granted during the years ended December 31, 2025 and 2024, respectively:

	Years Ended December 31,	
	2025	2024
Risk free interest rate	4.25 %	4.01 %
Volatility	122.43 %	130.41 %
Expected term (years)	6.17	6.19
Expected dividend yield	— %	— %

The weighted-average grant date fair value of options granted during the years ended December 31, 2025 and 2024 was $0.85 and $0.48, respectively.

The Company’s expected common stock price volatility assumption is based upon the Company's own implied volatility in combination with the implied volatility of a basket of comparable companies. The expected life assumptions for employee grants were based upon the simplified method, which averages the contractual term of the Company’s options of 10 years with the average vesting term of four years for an average of six years. The expected life assumptions for non-employees were based upon the contractual term of the option. The dividend yield assumption is zero because the Company has never paid cash dividends and presently has no intention to do so. The risk-free interest rate used for each grant was also based upon prevailing short-term interest rates. The Company accounts for forfeitures as they occur, therefore, outstanding stock options equal vested and expected to vest stock options.

As of December 31, 2025, there was approximately $1.0 million of unrecognized compensation cost related to outstanding stock options that is expected to be recognized as a component of the Company’s operating expenses over a weighted-average period of 2.1 years.

The following table summarizes stock option activity of the Company for the years ended December 31, 2025 and 2024, respectively:

	Total Number of Shares (in thousands)	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at January 1, 2024	1,607	$ 5.92		
Granted	671	0.53		
Canceled	(441)	4.97		
Outstanding at December 31, 2024	1,837	4.18		
Granted	817	0.95		
Canceled	(3)	0.72		
Outstanding at December 31, 2025	2,651	$ 3.19	7.43	$ 4,837
Vested and exercisable at December 31, 2025	1,406	$ 5.02	6.42	$ 1,536

The aggregate intrinsic values of outstanding and exercisable stock options at December 31, 2025 were calculated based on the closing price of the Company's common stock as reported on the Nasdaq Capital Market on December 31, 2025 of $3.77 per share. The aggregate intrinsic value equals the positive difference between the closing fair market value of the Company's common stock and the exercise price of the underlying stock options.

Time-Vested RSUs and RSUs with Performance Conditions

The Company granted RSUs pursuant to the Company's 2023 Amended and Restated Equity Incentive Plan that will settle in shares of common stock. As of December 31, 2025, there was approximately $1.0 million of unrecognized compensation cost related to outstanding RSUs that is expected to be recognized as a component of the Company's operating expenses over a weighted-average period of 2.1 years.

The following table summarizes RSU activity of the Company for the years ended December 31, 2025 and 2024, respectively:

	Total Number of Shares (in thousands)	Weighted Average Grant Date Fair Value Per Share
Unvested at January 1, 2024	338	$ 2.99
Granted	429	$ 0.52
Vested	(172)	$ 1.86
Canceled	(123)	$ 1.84
Unvested at December 31, 2024	472	$ 1.46
Granted	1,241	$ 0.96
Vested	(805)	$ 1.10
Canceled	(11)	$ 0.88
Unvested at December 31, 2025	897	$ 1.09

The total fair value of RSUs vested was approximately $1.2 million and $0.2 million during the years ended December 31, 2025 and 2024, respectively.

Amended and Restated 2021 Employee Stock Purchase Plan

On April 22, 2021, the Board of Directors adopted the 2021 Employee Stock Purchase Plan ("2021 ESPP") which was approved by the Company's stockholders on June 8, 2021. The 2021 ESPP allows employees to contribute up to 20% of their cash earnings, subject to a maximum of $25,000 per year under Internal Revenue Service rules, to be used to purchase shares of the Company's common stock on semi-annual purchase dates. The 2021 ESPP allows eligible employees to purchase shares of common stock at a price per share equal to 85% of the lower of the fair market value of the common stock at the beginning or end of each six-month offering period during the term of the 2021 ESPP.

On June 17, 2025, an amendment to the 2021 ESPP was approved by the stockholders of the Company, which amended and restated the 2021 ESPP (as amended and restated, the "Amended and Restated 2021 ESPP") to increase the number of shares of common stock available for sale under the 2021 ESPP by 800,000.

During the years ended December 31, 2025 and 2024, 115,449 and 103,853 shares of common stock, respectively, were purchased by employees under the 2021 ESPP for proceeds of approximately $0.1 million. There are approximately 764,000 shares of common stock reserved for issuance under the 2021 ESPP as of December 31, 2025.

11. Income Taxes

The components of the Company's loss before income taxes are as follows (in thousands):

	As of December 31,	
	2025	2024
U.S.	$ (9,569)	$ (9,535)
Non - U.S.	(17,294)	(21,346)
	$ (26,863)	$ (30,881)

The components of the Company's net deferred tax assets (liabilities) are as follows (in thousands):

	As of December 31,	
	2025	2024
Deferred tax assets:		
Net operating loss carryforwards	$ 16,730	$ 14,116
Licensing deduction deferral	2,763	3,286
Capitalized Section 174 research and development	2,185	2,502
Stock-based compensation	797	622
Lease liability	216	216
Other	355	324
Gross deferred tax assets	23,046	21,066
Valuation allowance	(22,838)	(20,866)
Net deferred tax assets	$ 208	$ 200
Deferred tax liabilities:		
Right of use asset	(208)	(200)
Gross deferred tax liabilities	(208)	(200)
Net deferred tax liabilities	$ —	$ —

A reconciliation of the provision for income taxes to the amount computed by applying the 21% statutory U.S. federal income tax rate to income before taxes after the adoption of ASU 2023-09 is as follows:

	Year Ended December 31, 2025	
	$	%
U.S. federal statutory income tax rate	(5,641)	21.0 %
Valuation allowance	1,917	(7.1)%
Nontaxable or nondeductible items	140	(0.5)%
Other	(47)	0.2 %
Foreign rate differential - Bermuda	3,631	(13.5)%
Effective income tax rate	—	—

A reconciliation of the provision for income taxes to the amount computed by applying the 21% statutory U.S. federal income tax rate to income before taxes for years prior to the adoption of ASU 2023-09 is as follows:

	Year Ended December 31, 2024
	%
U.S. federal statutory income tax rate	21.0 %
State and local taxes, net of federal benefit	0.4 %
Foreign rate differential	(14.5)%
Valuation allowance	(6.6)%
Permanent differences	(0.5)%
Other	0.2 %
Effective income tax rate	— %

There was no income taxes paid, or refunds received, during the years ended December 31, 2025 and 2024. There was no income tax benefit or expense for the years ended December 31, 2025 and 2024.

In assessing the realizability of deferred tax assets, management considers whether it is more-likely-than-not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. The valuation allowance increased by approximately $2.0 million for the year ended December 31, 2025, which was primarily driven by increases in net operating loss ("NOL") carryforwards and partially offset by decreases related to licensing deduction deferrals and capitalized research and development.

At December 31, 2025, the Company had domestic federal and state net operating loss carryforwards of approximately $77.7 million and $5.0 million, respectively, available to reduce future taxable income, which expire beginning in 2027.

Under the provisions of the Internal Revenue Code, the NOL and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. NOL and tax credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant shareholders over a three-year period in excess of 50%, as defined under Sections 382 and 383 of the Internal Revenue Code of 1986, respectively, as well as similar state tax provisions. This could limit the amount of tax attributes that the Company can utilize annually to offset future taxable income or tax liabilities. The amount of the annual limitation, if any, will be determined based on the value of the Company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. The Company has completed several financings since its inception, which may have resulted in a

change in control as defined by Sections 382 and 383 of the Internal Revenue Code, or could result in a change in control in the future. Utilization of the net operating loss and tax credits carryforwards may be limited by “ownership change” rules, as defined in Section 382 of the Internal Revenue Code of 1986, as amended, and similar state provisions. This annual limitation may result in the expiration of the net operating losses and credits before utilization.

The Company files income tax returns in the United States and various state jurisdictions. As of December 31, 2025, all of the Company's federal and state tax returns are open to examination due to net operating loss and research and development credit carryforwards.

The Company does not recognize tax benefits that are not more-likely-than-not to be supported based upon the technical merits of the tax position taken. In assessing its unrecognized tax benefits, the Company has analyzed its tax return filing positions in all of the federal, state and foreign filing jurisdictions where it is required to file income tax returns, as well as all open years in those jurisdictions.

As of December 31, 2025, the Company has no unrecognized tax benefits or accrued interest or penalties associated with uncertain tax positions. The Company does not believe that it is reasonably possible that its unrecognized tax benefits would significantly change in the following 12 months.

12. Employee Benefit Plan

The Company sponsors a 401(k) Plan. Employees become eligible for participation upon the start of employment. Participants may elect to have a portion of their salary deferred and contributed to the 401(k) Plan up to the limit allowed under the Internal Revenue Code. The Company makes a matching contribution to the plan for each participant who has elected to make tax-deferred contributions for the plan year. The Company made matching contributions which amounted to approximately $117,000 and $124,000 for the years ended December 31, 2025 and 2024, respectively. These amounts were charged to the consolidated statements of operations. The employer contributions vest immediately.

13. Subsequent Events

The Company evaluated all events or transactions that occurred after December 31, 2025 up through the date these consolidated financial statements were issued. Other than as disclosed elsewhere in the notes to the consolidated financial statements, the Company did not have any material subsequent events.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

The term "disclosure controls and procedures" means our controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934, as amended, or the Exchange Act, is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

We carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a – 15(e) and 15d – 15(e)). Based upon that evaluation, our principal executive officer and principal financial officer concluded that, as of the end of the period covered in this report, our disclosure controls and procedures were effective to ensure that information required to be disclosed in reports filed under the Exchange Act is recorded, processed, summarized and reported within the required time periods and is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Our principal executive officer and principal financial officer do not expect that our disclosure controls or internal controls will prevent all error and all fraud. Although our disclosure controls and procedures were designed to provide reasonable assurance of achieving their objectives, a control system, no matter how well conceived and operated, can provide only reasonable, but not absolute assurance that the objectives of the system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented if there exists in an individual a desire to do so. There can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, our management conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control—Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on that evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2025.

Attestation Report of the Independent Registered Public Accounting Firm

This report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our independent registered public accounting firm pursuant to Section 989G of the Dodd-Frank Wall Street Reform and Consumer Protection Act, which exempts smaller reporting companies from the auditor attestation requirement.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting (as defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the year ended December 31, 2025 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

Rule 10b5-1 Trading Plans

None of our directors or officers have adopted, modified, or terminated any trading plans under Rule10b5-1 of the Exchange Act or any similar arrangements during the fourth quarter of 2025.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by item 10 is incorporated herein by reference from the Company's Proxy Statement, which will be filed with the SEC within 120 days after the end of the Company's 2025 fiscal year pursuant to Regulation 14A for its 2026 Annual Meeting of Stockholders.

ITEM 11. EXECUTIVE COMPENSATION

The information required by item 11 is incorporated herein by reference from the Company's Proxy Statement, which will be filed with the SEC within 120 days after the end of the Company's 2025 fiscal year pursuant to Regulation 14A for its 2026 Annual Meeting of Stockholders.

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

The information required by item 12 is incorporated herein by reference from the Company's Proxy Statement, which will be filed with the SEC within 120 days after the end of the Company's 2025 fiscal year pursuant to Regulation 14A for its 2026 Annual Meeting of Stockholders.

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

The information required by item 13 is incorporated herein by reference from the Company's Proxy Statement, which will be filed with the SEC within 120 days after the end of the Company's 2025 fiscal year pursuant to Regulation 14A for its 2026 Annual Meeting of Stockholders.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by item 14 is incorporated herein by reference from the Company's Proxy Statement, which will be filed with the SEC within 120 days after the end of the Company's 2025 fiscal year pursuant to Regulation 14A for its 2026 Annual Meeting of Stockholders.

PART IV

ITEM 15. EXHIBITS

Exhibit Number	Description	Form	Exhibit	Filing Date
3.1	Composite Amended and Restated Certificate of Incorporation of the Registrant (formerly, Galena Biopharma, Inc.), amended as of December 27, 2017.	10-K	3.1	April 13, 2018
3.2	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock.	8-K	3.1	March 12, 2018
3.3	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Registrant.	8-K	3.1	November 6, 2019
3.4	Amended and Restated By-Laws of the Registrant.	8-K	3.3	January 5, 2018
4.1	Form of Common Stock Certificate.	10-K	4.1	April 13, 2018
4.2	Form of Contingent Value Rights Agreement among the Registrant (formerly RXi Pharmaceuticals Corporation), Computershare Trust Company, N.A., Computershare Inc., and Robert E Kennedy, dated April 13, 2011.	8-K	10.1	April 14, 2011
4.3	First Amendment to Contingent Value Rights Agreement among the Registrant (formerly RXi Pharmaceuticals Corporation), Computershare Trust Company, N.A., Computershare Inc., and Robert E Kennedy, dated February 15, 2012.	10-K	10.2	March 28, 2012
4.4	Form of Warrant.	8-K	4.1	April 1, 2022
4.5	Description of Securities.	10-K	4.41	March 13, 2020
4.6	Form of Warrant.	8-K	4.1	February 24, 2023
4.7	Form of Common Warrant issued in connection with January 2024 Offering.	8-K	4.2	January 8, 2024
4.8	Form of Pre-Funded Warrant issued in connection with January 2024 Offering.	8-K	4.1	January 8, 2024
4.9	Form of Common Warrant issued in connection with March 2024 Registered Direct Offering.	8-K	4.2	March 15, 2024
4.10	Form of Pre-Funded Warrant issued in connection with March 2024 Registered Direct Offering.	8-K	4.1	March 15, 2024
4.11	Form of Pre-Funded Warrant.	8-K	4.1	August 1, 2024
4.12	Form of Common Warrant.	8-K	4.2	August 1, 2024
4.13	Form of Pre-Funded Warrant.	8-K	4.1	January 29, 2025
4.14	Form of Warrant.	8-K	4.2	January 29, 2025
4.15	Form of Inducement Warrant	8-K	4.1	September 11, 2025
4.16	Form of Inducement Warrant	8-K	4.1	October 27, 2025
9.1	Securities Purchase Agreement dated March 7, 2018 by and between the Registrant and certain investors.	8-K	10.1	March 12, 2018
10.1*	SELLAS Life Sciences Group, Ltd Stock Incentive Plan #1.	S-4/A	10.61	October 30, 2017
10.2*	Form of Restricted Stock Unit Grant and Agreement under SELLAS Life Sciences Group Ltd Stock Incentive Plan #1.	S-4/A	10.63	October 30, 2017
10.3*	2017 Equity Incentive Plan of the Registrant.	8-K	10.10	January 5, 2018

Exhibit Number	Description	Form	Exhibit	Filing Date
10.4*	Form of Stock Option Grant Notice and Option Agreement under the 2017 Equity Incentive Plan.	8-K	10.2	March 19, 2018
10.5*	Form of Restricted Stock Unit Grant and Agreement under the 2017 Equity Incentive Plan.	10-K	10.9	April 13, 2018
10.6*	Employment Agreement, effective July 1, 2019, by and between the Registrant and Angelos Stergiou.	10-Q	10.3	May 14, 2020
10.7*	Employment Agreement, effective as of January 11, 2018, by and between the Registrant and John Burns.	8-K	10.1	January 18, 2018
10.8*	Letter Employment Agreement, effective as of January 2, 2020, by and between the Registrant and Dragan Cicic.	10-K	10.9	March 20, 2025
10.9*	Change in Control Severance Agreement, dated December 14, 2021, between SELLAS Life Sciences Group, Inc and Dragan Cicic, M.D.		10.1	December 16, 2021
10.10*	Amendment to Change in Control Severance Agreement, effective as of January 22, 2024, by and between the Registrant and Dragan Cicic.	10-K	10.11	March 20, 2025
10.11*	Amendment to Change in Control Severance Agreement, effective as of March 4, 2025, by and between the Registrant and Dragan Cicic.	10-K	10.12	March 20, 2025
10.12*	Amendment to Change in Control Severance Agreement, effective as of March 4, 2025, by and between the Registrant and John Burns.	10-K	10.13	March 20, 2025
10.14+	Amended and Restated Exclusive License Agreement by and between SELLAS Life Sciences Group Ltd and Memorial Sloan Kettering Cancer Center, effective October 11, 2017.	S-4/A	10.65	October 30, 2017
10.15	Form of Indemnity Agreement between the Registrant and each of its directors and executive officers.	8-K	10.8	January 5, 2018
10.16*	2023 Amended and Restated Equity Incentive Plan.	10-Q	10.1	August 10, 2023
10.17*	Form of Stock Option Grant Notice and Option Agreement under the 2023 Amended and Restated Equity Incentive Plan.	10-K	10.48	March 13, 2020
10.18*	Form of Restricted Stock Unit Grant and Agreement under the 2023 Amended and Restated Equity Incentive Plan.	10-K	10.49	March 13, 2020
10.19	Amendment to Warrant to Purchase Common Stock, dated January 2, 2020, between the Registrant and the holders.	8-K	10.1	January 7, 2020
10.20	Form of Placement Agent Agreement.	8-K	1.1	January 10, 2020
10.21	Sublease, dated June 5, 2020, between the Registrant and Riemer & Braunstein LLP.	8-K	10.1	June 11, 2020
10.22	First Amendment to Sublease, dated December 6, 2021, by and between the Registrant and Riemer & Braunstein LLP.	10-K	10.36	March 31, 2022
10.23*	2021 Employee Stock Purchase Plan.	S-8	99.4	August 13, 2021
10.24	Form of Registration Rights Agreement.	8-K	10.2	August 4, 2020
10.25+	Exclusive License Agreement, dated December 7, 2020, among the Registrant, SLSG Limited, LLC and 3D Medicines Inc.	8-K	10.1	January 28, 2021
10.26+	Side Letter Agreement, dated December 5, 2022, by and between the Registrant and 3D Medicines Inc.	10-K	10.39	March 16, 2023
10.27	Sales Agreement, dated as of April 16, 2021, by and between SELLAS Life Sciences Group, Inc. and Cantor Fitzgerald & Co.	S-3	1.2	April 16, 2021
10.28+	License Agreement, dated March 31, 2022, by and between SELLAS Life Sciences Group, Inc. and GenFleet Therapeutics (Shanghai) Inc.	10-Q	10.1	May 12, 2022
10.29	Form of Amendment to Common Stock Purchase Warrant.	8-K	10.1	March 1, 2023

Exhibit Number	Description	Form	Exhibit	Filing Date
10.30*	2023 Amended and Restated Equity Incentive Plan.	10-Q	10.1	August 10, 2023
10.31	Addendum to the Side Letter Agreement dated May 24, 2023 by and between the Registrant and 3D Medicines Inc.	10-Q	10.2	August 10, 2023
10.32	Second Amendment to Sublease, dated December 11, 2023, by and between SELLAS Life Sciences Group, Inc. and Times Square Tower Associates LLC.	8-K	10.1	December 11, 2023
10.33	Form of Securities Purchase Agreement, dated as of October 30, 2023, by and among SELLAS Life Sciences Group, Inc. and the purchaser party thereto.	8-K	10.1	October 31, 2023
10.34	Form of Placement Agency Agreement.	8-K	1.1	October 31, 2023
10.35	Separation Agreement, effective as of March 26, 2024, by and between the Registrant and Robert Francomano.	10-K	10.50	March 28, 2024
10.36	Separation Agreement, effective as of March 27, 2024, by and between the Registrant and Barbara Wood.	10-K	10.51	March 28, 2024
10.37	Form of Placement Agency Agreement entered into in connection with January 2024 Offering.	8-K	1.1	January 8, 2024
10.38	Form of Securities Purchase Agreement, dated as of January 8, 2024, by and among SELLAS Life Sciences Group, Inc. and the purchasers party hereto.	8-K	10.1	January 8, 2024
10.39	Form of Placement Agency Agreement entered into in connection with March 2024 Registered Direct Offering.	8-K	1.1	March 15, 2024
10.40	Form of Securities Purchase Agreement, dated as of March 15, 2024, by and among SELLAS Life Sciences Group, Inc. and the purchasers party hereto.	8-K	10.1	March 15, 2024
10.41	Form of Placement Agent Agreement.	8-K	1.1	August 1, 2024
10.42	Form of Securities Purchase Agreement, dated as of July 30, 2024, by and among SELLAS Life Sciences Group, Inc. and the purchaser party thereto.	8-K	10.1	August 1, 2024
10.43	Letter Agreement, effective October 3, 2024, by and between SELLAS Life Sciences Group, Inc. and Times Square Tower Associates LLC.	8-K	10.1	October 4, 2024
10.44	Placement Agent Agreement, dated as of January 28, 2025, by and among SELLAS Life Sciences Group, Inc., A.G.P./Alliance Global Partners and Maxim Group LLC.	8-K	1.1	January 29, 2025
10.45	Form of Securities Purchase Agreement, dated as of January 28, 2025, by and among SELLAS Life Sciences Group, Inc. and the purchasers party thereto.	8-K	10.1	January 29, 2025
10.46	Amended and Restated 2021 Employee Stock Purchase Plan	10-Q	10.1	August 12, 2025
10.47	Form of Inducement Agreement	8-K	10.1	September 11, 2025
10.48	Letter Agreement by and between SELLAS Life Sciences Group, Inc. and Times Square Tower Associates LLC	8-K	10.1	October 3, 2025
10.49	Form of Inducement Agreement	8-K	10.1	October 27, 2025
14.1	Code of Business Conduct and Ethics.	10-K	14.1	March 20, 2025
19.1	Insider Trading Policy.	10-K	19.1	March 20, 2025
21.1	Subsidiaries of the Registrant.			
23.1	Consent of Baker Tilly US, LLP, Independent Registered Public Accounting Firm.			
24.1	Powers of Attorney (included on signature page hereto).			
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities and Exchange Act, as amended.			

Exhibit Number	Description	Form	Exhibit	Filing Date
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities and Exchange Act, as amended.			
32.1**	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.			
97.1	SELLAS Life Sciences Group, Inc. Clawback Policy.	10-K	97	March 28, 2024
101.INS***	XBRL Instance Document.			
101.SCH***	XBRL Taxonomy Extension Schema.			
101.CAL***	XBRL Taxonomy Extension Calculation Linkbase.			
101.DEF***	XBRL Taxonomy Extension Definition Linkbase.			
101.LAB***	XBRL Taxonomy Extension Label Linkbase.			
101.PRE***	XBRL Taxonomy Extension Presentation Linkbase.			

* Indicates management contract or compensatory plans or arrangements.

** The certification attached as Exhibit 32.1 pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed “filed” by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing of the registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

^ The schedules and exhibits to this exhibit have been omitted pursuant to Item 601(b)(2) or 601(b)(10)(iv), as applicable, of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the SEC upon request.

\+ Confidential treatment has been granted with respect to certain portions of this exhibit. Omitted portions have been filed separately with the SEC.

*** In accordance with Rule 406T of Regulation S-T, the Interactive Data Files in Exhibit 101 are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Exchange Act of 1934, as amended, and otherwise are not subject to liability under these sections.

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements 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.

SELLAS Life Sciences Group, Inc.

Date: March 19, 2026 By: */s/ Angelos M. Stergiou*

Angelos M. Stergiou, MD, ScD h.c.
President and Chief Executive Officer

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Angelos Stergiou and John Burns, 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 (including post-effective amendments) to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said 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, his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

In accordance with the Securities Exchange Act of 1934, 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/ Angelos M. Stergiou Angelos M. Stergiou, M.D., ScD h.c.	President, Chief Executive Officer and Director (Principal Executive Officer)	March 19, 2026
/s/ John T. Burns John T. Burns, CPA	Senior Vice President, Chief Financial Officer (Principal Financial and Accounting Officer)	March 19, 2026
/s/ John Varian John Varian	Chair of the Board of Directors	March 19, 2026
/s/ David Scheinberg David Scheinberg, M.D., PhD.	Director	March 19, 2026
/s/ Robert Van Nostrand Robert Van Nostrand	Director	March 19, 2026
/s/ Jane Wasman Jane Wasman	Director	March 19, 2026
/s/ Katherine Kalin Katherine Kalin	Director	March 19, 2026

Exhibit 21.1

SELLAS Life Sciences Group, Inc.

The following is a list of subsidiaries of the Company as of December 31, 2025.

SUBSIDIARY (Name under which subsidiary does business)	**STATE OF INCORPORATION OR OTHER JURISDICTION OF ORGANIZATION**
Sellas Life Sciences Limited	Ireland
Sellas Life Sciences Group Ltd.	Bermuda
SLSG Limited LLC	Delaware

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-1 (Nos. 333-225140, 333-231723, and 333-238799), Form S-3 (Nos. 333-213908, 333-224845, 333-226251, 333-233869, 333-246333, 333-255318, 333-278334, 333-278337 and 333-290829) and Form S-8 (Nos. 333-174819, 333-182578, 333-210833, 333-213248, 333-230741, 333-237168, 333-258799, 333-264899, 333-270608, 333-276615, and 333-289534) of SELLAS Life Sciences Group, Inc. (the "Company"), of our report dated March 19, 2026, relating to the consolidated financial statements of the Company appearing in this Annual Report on Form 10-K of the Company for the year ended December 31, 2025.

/s/ Baker Tilly US, LLP

San Jose, California
March 19, 2026

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Angelos M. Stergiou, certify that:

1. I have reviewed this Annual Report on Form 10-K of SELLAS Life Sciences Group, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Dated: March 19, 2026

/s/ Angelos M. Stergiou

Angelos M. Stergious, MD, ScD h.c.
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, John T. Burns, certify that:

1. I have reviewed this Annual Report on Form 10-K of SELLAS Life Sciences Group, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Dated: March 19, 2026

/s/ John T. Burns

John T. Burns
Senior Vice President, Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the accompanying Annual Report of SELLAS Life Sciences Group, Inc., (the "Company") on Form 10-K for the year ended December 31, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer of the Company certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to his knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the Company's financial condition and results of operations.

By: */s/ Angelos M. Stergiou*

Angelos M. Stergiou, MD, ScD h.c.
President and Chief Executive Officer
(Principal Executive Officer)

Date: March 19, 2026

By: */s/ John T. Burns*

John T. Burns
Senior Vice President, Chief Financial Officer
(Principal Financial Officer)

Date: March 19, 2026

A signed original of this written statement required by Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350 has been provided to the Registrant and will be retained by the Registrant and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.