UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2025
or
☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the Transition Period from _____ to _____

Commission File Number**: 001-35005**

ASSEMBLY BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware	**20-8729264**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

Two Tower Place, 7th Floor
South San Francisco, California 94080
(Address of Principal Executive Offices)

Registrant's telephone number, including area code: **(833) 509-4583**

Securities Registered Pursuant to Section 12(b) of the Exchange Act:

Title of Each Class	**Trading Symbol(s)**	**Name of Exchange on which Registered**
Common Stock, $0.001 Par Value	ASMB	The Nasdaq Global Select Market

Securities Registered Pursuant to Section 12(g) of the Act: None

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 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 voting stock held by non-affiliates of the registrant, as of June 30, 2025, was $97.8 million. Such aggregate market value was computed by reference to the closing price of the common stock as reported on the Nasdaq Global Select Market on June 30, 2025. For purposes of making this calculation only, the registrant has defined affiliates as including only (1) directors, (2) executive officers and (3) certain stockholders, if any, that hold greater than 10% of the voting stock of the registrant, in each case, as of June 30, 2025. Shares of common stock held by other persons, including certain other holders of more than 10% of the registrant's outstanding common stock, if any, have not been excluded from the above calculation in that such persons are not deemed to be affiliates. The determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 13, 2026, there were 15,862,705 shares of the registrant's common stock, $0.001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Part III of this Annual Report on Form 10-K incorporates information by reference to portions of the definitive proxy statement for the Company's Annual Meeting of Stockholders to be held in 2026, to be filed within 120 days of the registrant's fiscal year ended December 31, 2025.

ASSEMBLY BIOSCIENCES, INC.
TABLE OF CONTENTS

References to Assembly Biosciences, Inc.

Throughout this Annual Report on Form 10-K, the "Company," "Assembly Bio," "Assembly," "we," "us," and "our," except where the context requires otherwise, refer to Assembly Biosciences, Inc. and its consolidated subsidiaries, and "our board of directors" or "the Board" refers to the board of directors of Assembly Biosciences, Inc.

Forward-Looking Statements

This Annual Report on Form 10-K contains "forward-looking statements" that are subject to certain risks and uncertainties, including, without limitation, those set forth in Part I, Item 1A under the heading "Risk Factors," that could cause actual results to materially differ. Such risks and uncertainties include, among other things:

- our ability to realize the potential benefits of our collaboration with Gilead Sciences, Inc. (Gilead), including all financial aspects of the collaboration and equity investments;
- our ability to initiate and complete clinical studies involving our therapeutic product candidates, including studies contemplated by our collaboration with Gilead, in the currently anticipated timeframes or at all;
- safety and efficacy data from clinical or nonclinical studies may not warrant further development of our product candidates;
- clinical and nonclinical data may not differentiate our product candidates from other companies' candidates;
- our ability to maintain financial resources and secure additional funding necessary to continue our research activities, clinical studies and other business operations;
- potential effects of changes in government regulation; and
- results of nonclinical studies may not be representative of disease behavior in a clinical setting and may not be predictive of the outcomes of clinical studies.

You are urged to consider statements that include the words may, will, would, could, should, might, believes, hopes, estimates, projects, potential, enable, expects, plans, anticipates, intends, continues, forecast, designed, goal or the negative of those words or other comparable words to be uncertain and forward-looking. In particular, forward-looking statements include, but are not limited to, statements regarding the timing of commencement of future clinical studies involving our therapeutic product candidates or therapeutic product candidates that Gilead has licensed from us; and our ability to successfully complete, and receive favorable results in, clinical studies for our product candidates. We intend such forward-looking statements to be covered by the safe harbor provisions contained in Section 27A of the Securities Act of 1933, as amended (the Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act). Except as required by law, we assume no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

Risk Factors Summary

The following is a summary of the principal risks that could adversely affect our business, operations and financial results. For more information, see "Item 1A. Risk Factors" in this Annual Report on Form 10-K for the year ended December 31, 2025.

Risks Related to Our Business

- We have no approved products and depend on the future success of the product candidates in our research and development pipeline.
- We are not currently profitable and might never become profitable, and we will need additional financing to complete the development of any product candidates and fund our activities into the future.
- We expect our collaboration with Gilead to be a critical part of the development, manufacture and commercialization of our product candidates.
- Nonclinical and clinical studies required for our product candidates are expensive and time-consuming and may fail to demonstrate the level of safety and efficacy necessary for product approval.
- We rely on contract resource organizations (CROs) to conduct some of our nonclinical and clinical studies due to our lack of suitable facilities and resources. In addition, parts of our business are reliant on CROs, vendors, suppliers and other service providers in locations outside of the United States, including China.
- The ongoing shutdown of the U.S. Department of Homeland Security could prevent the U.S. Customs and Border Protection from performing normal business functions on which the operation of our business relies.
- Top-line, preliminary or interim data may not accurately reflect the final results of a particular study.
- We rely on third parties to formulate and manufacture our product candidates and products that we study in combination with our product candidates. Our use of third parties may increase the risk that we will not have sufficient quantities of our product candidates or other products on time or at an acceptable cost.
- If we lose key management personnel and cannot recruit and retain similarly qualified replacements, our business may materially suffer.
- Our collaboration partners might delay, prevent or undermine the success of our product candidates.
- We may not be successful in establishing and maintaining collaborations, which could adversely affect our ability to develop certain of our product candidates.
- We rely on data provided by third parties that has not been independently.
- Research, development and commercialization goals, including data releases, may not be achieved in the timeframes that we publicly estimate, which could have an adverse impact on our business and could cause our stock price to decline.
- Competitors' developments may render our product candidates or technologies obsolete or non-competitive.
- Other companies with products using the same or similar mechanisms of action as ours may produce negative clinical data, which would adversely affect public and clinical communities' perceptions of our product candidates, and may negatively impact regulatory approval of, or demand for, our potential products.
- Significant disruptions of information technology systems or breaches of data security, including cybersecurity incidents, could materially and adversely affect our business.

- Our ability to use our net operating loss and credit carryforwards and certain other tax attributes may be limited.

Risks Related to Our Regulatory and Legal Environment

- We are and will be subject to extensive and costly government regulation, and the failure to comply with these regulations may have a material adverse effect on our operations and business.
- The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable.
- We and our third-party partners and service providers are subject to stringent privacy laws, information security laws, regulations, policies and contractual obligations related to data privacy and security, and compliance with such laws, regulations, policies and contractual obligations could result in additional costs and liabilities to us and failure to comply could adversely affect our business.
- We and our collaborators may be subject, directly or indirectly, to applicable U.S. federal and state anti-kickback, false claims laws, physician payment transparency laws, other fraud and abuse laws or similar healthcare and security laws and regulations, and health information privacy and security laws, which could expose us or them to criminal sanctions, civil penalties, exclusion or suspension from federal and state healthcare programs, contractual damages, reputational harm and diminished profits and future earnings.
- We face the risk of product liability claims and might not be able to obtain insurance.
- We might be exposed to liability claims associated with the use of hazardous materials and chemicals.
- Our employees, independent contractors, consultants, collaborators and CROs may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements for which we may be held responsible and which could result in significant liability for us and harm our reputation.

Risks Related to Our Intellectual Property

- Our business depends on protecting our intellectual property.
- We may incur substantial costs as a result of litigation or other proceedings relating to our patents and other intellectual property rights.
- We may infringe the intellectual property rights of others, which may prevent or delay our product development efforts and stop us from commercializing or increase the costs of commercializing our product candidates.
- The cost of maintaining our patent protection globally is high and requires continuous review and compliance.
- Intellectual property rights do not address all potential threats to any competitive advantage we may have.

Risks Related to Our Common Stock

- The price of our common stock has in the past and may continue to fluctuate significantly.
- Our bylaws provide that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to bring a claim in a judicial forum they find favorable.

PART I

Item 1. Business

Overview

We are a biotechnology company developing innovative therapeutics targeting serious viral diseases with the potential to improve the lives of patients worldwide. Our pipeline includes multiple clinical-stage investigational therapies, including: (1) two long-acting helicase-primase inhibitors (HPIs) for the treatment of recurrent genital herpes; (2) an orally bioavailable hepatitis delta virus (HDV) entry inhibitor; and (3) a highly potent next-generation capsid assembly modulator (CAM) designed to disrupt the replication cycle of hepatitis B virus (HBV) at several key points. Our pipeline also includes a novel, oral broad-spectrum non-nucleoside polymerase inhibitor (NNPI) for the treatment of transplant-related herpesviruses, which is currently undergoing studies to enable a regulatory filing, and we have additional research programs against multiple antiviral targets. In December 2025, pursuant to our collaboration (Gilead Collaboration) with Gilead Sciences, Inc. (Gilead), Gilead exercised its option to license our HPI program for the treatment of recurrent genital herpes, including our long-acting investigational candidates ABI-1179 (1179) and ABI-5366 (5366). For additional information regarding Gilead's exercise of its option, see "Collaboration and License Agreement—Gilead Sciences, Inc.—Option Exercise."

Our Strategy

Our current business strategy focuses on applying our deep research and development expertise in virology to discover, develop and advance next-generation therapeutics to patients in areas of high unmet medical need with significant market opportunities to market. We continue to rapidly advance our portfolio toward near-term clinical readouts, highlighted by the following on-going and future activities by doing the following:

- **Recurrent Genital Herpes (HSV-1, HSV-2)** – Transitioning our HPI program, including 5366 and 1179 to Gilead and, upon receiving a clinical development plan and budget from Gilead, deciding whether to opt in to the Profit-Share (as defined below under the heading "Collaboration and License Agreement—Gilead Sciences, Inc.—Option Exercise").
- **HDV** – Completing Phase 2 preparation activities and studies of ABI-6250 (6250), with Phase 2 initiation expected in the fourth quarter of 2026.
- **HBV** – Evaluating partnering opportunities for ABI-4334 (4334), for which we have initiated a structured process to find potential partners to further advance the program.
- **Transplant-Associated Herpesviruses** – Advancing ABI-7272 (7272), our oral broad-spectrum NNPI for the treatment of transplant-associated herpesviruses through nonclinical studies to enable a regulatory filing.
- **Research and Discovery** – Continuing to leverage our research team's expertise to identify and nominate new viral targets and novel compounds to address significant unmet medical needs.

We have recruited an accomplished leadership team and research and development organization, with a collective team track record of over 15 approved drugs across multiple viral diseases. In addition, our collaboration with Gilead also brings us an industry-leading partner and brings together the teams' expertise in virology and provides an established partner for late-stage development and commercialization. For additional information regarding the Gilead Collaboration, see "Collaboration and License Agreements—Gilead Sciences, Inc."

Our Clinical Programs and Regulatory Filing-Enabling Program

2025 was a pivotal year for us, as we reported positive data readouts for 5366, 1179, 4334 and 6250 as follows:

- February 2025:
  - 1179 – Positive Phase 1a interim results in the Phase 1a/b study
- June 2025:
  - 4334 – Positive Phase 1b topline results

- August 2025:
  - 5366 – Positive Phase 1b interim results from the weekly dosing cohorts in the Phase 1a/b study
  - 6250 – Positive Phase 1a interim results
- December 2025:
  - 1179 – Positive Phase 1b interim results in the Phase 1a/b study
  - 5366 – Positive Phase 1b interim results from the monthly dosing cohorts in the Phase 1a/b study

In addition, during December 2024, we identified a development candidate, ABI-7423 (7423), in our broad-spectrum NNPI program targeting transplant-associated herpesviruses. 7423 is a prodrug of the parent molecule 7272, and in October 2025, we transitioned our development from 7423 to 7272. 7272 is currently in regulatory filing enabling studies.

Recurrent Genital Herpes/HSV-1 and HSV-2

Genital herpes can be caused by either herpes simplex virus type 1 (HSV-1) or herpes simplex virus type 2 (HSV-2). HSV-1 and HSV-2 are acquired by oral or genital contact either during symptomatic or asymptomatic reactivation of the virus. Both viruses replicate in neurons, where they can remain latent for the rest of the individual's life and periodically reactivate, with the virus spreading, replicating and causing disease in epithelial tissues. Initial infection can be asymptomatic or can be marked by serious symptoms, including painful skin lesions, swelling of lymph nodes and urinary problems that can persist for two to three weeks. While genital herpes can be caused by either HSV-1 or HSV-2, recurrences are more likely to be experienced by individuals infected by HSV-2. Genital herpes recurrence can cause painful genital lesions that can lead to increased transmission and debilitate individuals, and symptoms may become more serious with additional episodes. Additional complications include increased risk of HIV infection, as 30% of HIV infections acquired through sexual transmission are attributable to HSV-2 infection. In addition, people with recurrent genital herpes often experience associated psychosocial impacts, including anxiety, concerns about transmission, depression and social stigma. Immunocompromised individuals may experience more severe and prolonged symptoms due to increased recurrence rates.

HPIs are antiviral agents in development for the treatment of recurrent genital herpes, with a clinically-validated mechanism of action. HPIs inhibit the HSV helicase-primase complex, which is a unique viral enzyme complex without a human homolog, consisting of helicase, primase and cofactor subunits. These subunits have functions that are essential for viral DNA replication and are conserved across HSV-1 and HSV-2. Unlike nucleoside analogs, these compounds do not require phosphorylation by the HSV thymidine kinase (TK) and ongoing viral replication to become active drugs. As a result, HPIs are active immediately upon reactivation of latent HSV-1 and HSV-2. Furthermore, HPIs are active against TK-deficient HSV-1 and HSV-2, which is a major mechanism of resistance to nucleoside analogs.

Most people with initial symptomatic genital herpes who are infected with HSV-2 have frequent recurrences, generally between three and 15 per year, impacting over four million people in the United States and France, Germany, Italy and Spain (collectively, the EU4) and the United Kingdom (UK). Currently, there are three antiviral drugs (all nucleoside analogs) that have been approved in the United States and the EU4/UK for the treatment of genital herpes. However, no new drugs have been approved in these regions to treat genital herpes for more than 25 years. In addition to the approved nucleoside analogs, agents such as local anesthetics or analgesics may be used to alleviate local symptoms of minor pain and discomfort.

Nucleoside analogs can be administered as episodic therapy as individual outbreaks arise or daily as chronic suppressive therapy for those with high post-exposure recurrences. However, these agents are only partially effective at controlling the infection or reducing transmission risk. With current nucleoside analog therapies, only one out of three people with recurrent genital herpes with six or more recurrences per year are able to make it through a year of treatment without a recurrence. There are still high titer (greater than 10^4 HSV-2 DNA copies/mL) shedding episodes under this current standard of care for recurrent genital herpes, which can lead to recurrent episodes and transmission of genital herpes. In addition, nucleoside analogs also carry a high pill burden as a lifelong daily treatment, with doses ranging from one to three times daily. There is also high treatment variability among those taking nucleoside analogs, as many seeking care may not consistently receive suppressive therapy.

Based on the limitations of current therapies, we see a path to advancing the treatment paradigm for people suffering from recurrent genital herpes. To reach that goal, we discovered and began the clinical development of a novel, potent, long-acting HPI for recurrent genital herpes, 5366, which demonstrated low nanomolar potency in vitro against both HSV-1 and HSV-2 clinical isolates and a favorable nonclinical safety profile in the U.S. Food and Drug Administration's (FDA) Good Laboratory Practice (GLP) toxicology studies. In addition, we began development of a second novel, potent, long-acting HPI for genital herpes, 1179, which was in-licensed to us as part of our collaboration with Gilead. As Gilead has exercised its option to exclusively license our HPI program, including 5366 and 1179, development will be in Gilead's sole control following completion of the Phase 1a/b studies of 5366 and 1179, which we are managing until they are complete. For additional information regarding the option exercise, see "Collaboration and License Agreements—Gilead Sciences, Inc.—Option Exercise."

During the first quarter of 2024, we filed a Clinical Trial Application (CTA) to support initiation of a Phase 1a/b clinical study for 5366, which was approved in April 2024, and we dosed our first participant in the Phase 1a portion of this study during the second quarter of 2024.

In September 2024, we announced positive interim data for the Phase 1a portion of the 5366 study and complete data was presented at the STI & HIV 2025 World Congress in July 2025. Results exceeded our objectives for this Phase 1a study and supported 5366's progression into Phase 1b, which we initiated during the third quarter of 2024. Across the Part A (Phase 1a) cohorts evaluated, 5366 had a mean half-life of approximately 20 days when dosed orally, supporting once-weekly oral dosing, the target profile for 5366, as well as showing the potential for once-monthly oral dosing. In the Phase 1a cohorts, 5366 was well-tolerated with a favorable safety profile, with exposures of up to 99 days.

We reported interim data from the Phase 1b portion of the 5366 study in August 2025, focused on two different oral doses of 5366 administered on a once-weekly basis. For the powered antiviral endpoint, HSV-2 shedding rate, highly potent antiviral activity was observed with a 94% reduction compared to placebo ($p<0.01$) over the 29-day evaluation period in the cohort evaluating a 350 mg weekly dose. This reduction exceeded our target for the study of an 80-85% reduction in the rate of HSV-2 shedding. For a secondary clinical endpoint of genital lesion rate, a 94% reduction compared to placebo ($p<0.01$) was observed with the 350 mg weekly dose. The rate of genital swabs with high viral load (i.e., $>10^4$ copies/mL HSV DNA), a potential surrogate for HSV-2 transmission and a secondary endpoint, was reduced by 98% compared to placebo ($p<0.05$) in this cohort.

We reported additional interim data from the Phase 1b portion of the 5366 study in December 2025, which included data from a monthly oral dosing regimen. In the 5366 monthly dose cohort, potent antiviral activity was observed, with a 76% reduction in HSV-2 shedding rate compared to placebo ($p<0.01$) over the 29-day evaluation period. The majority of positive swabs (89%) were collected in the last two weeks of the evaluation period when drug levels were declining. We observed an 88% reduction in virologically confirmed genital lesion rate ($p=0.01$), along with an 81% reduction in the number of samples with high viral load ($p<0.01$) compared to placebo in the monthly dose cohort.

Across the two weekly oral dose cohorts and the monthly oral dose cohort of the Phase 1b study, 5366 demonstrated a pharmacokinetic (PK) profile that continues to support once-weekly and potentially once-monthly dosing.

5366 was observed to be well-tolerated at all dose levels tested in the Phase 1b portion of the study. The two weekly oral cohorts are complete and unblinded safety data has been reported; the oral monthly cohort is ongoing and safety data remains blinded. Across all cohorts, the proportion of participants reporting treatment-emergent adverse events (AEs) was similar between 5366 and placebo recipients, and all were Grade 1 or Grade 2. One Grade 3 AE was reported, hypertriglyceridemia, in a participant with relevant medical history who had Grade 4 elevated triglycerides pre-dose on Day 1. This AE resulted in study discontinuation but was not considered treatment related. The proportion of participants reporting treatment-emergent lab abnormalities was similar in 5366 and placebo recipients with the majority being Grade 1 or Grade 2. In the unblinded weekly oral dose cohorts: there were three participants with treatment-emergent Grade 3 lab abnormalities, all of which are considered unrelated to assigned treatment; one participant with exercise-associated elevation in creatine kinase (150/30 mg QW); one participant with an elevation of cholesterol in the follow up period, which participant had a Grade 2 elevation at baseline (350 gm QW); and one participant, who was dosed with placebo, with decreased neutrophils. There did not appear to be a dose-response relationship in either the frequency or severity of the treatment-emergent AEs or lab abnormalities. No serious AEs have been reported to date.

All participants in the Phase 1b portion of the 5366 study have completed dosing and follow up. The observed PK profile continues to support once-weekly dosing and the potential for once-monthly oral dosing regimens. Additionally, all chronic toxicology studies have been completed. With these data, 5366 is ready to move into a Phase 2 clinical study.

A late-breaking oral presentation of the interim 5366 Phase 1b data reported in August 2025 was presented at the 38th Congress of the International Union Against Sexually Transmitted Infections – Europe, which took place in October 2025 in Athens, Greece. The 5366 data reported in August and December 2025 will be presented at the Congress of the European Society of Clinical Microbiology and Infectious Diseases (ESCMID) taking place in Munich, Germany in April 2026.

In addition to 5366, we have also begun the clinical development of 1179, a structurally-differentiated HPI with single digit nanomolar potency against HSV-1 and HSV-2 and a nonclinical PK and safety profile to date that is supportive of a potential long-acting treatment by once-weekly oral administration. We submitted the CTA for the study in September 2024, which was approved in October 2024. We dosed our first participant in the Phase 1a portion of this study during the fourth quarter of 2024.

In February 2025, we announced positive interim data for the Phase 1a portion of the 1179 study, and in July 2025, we announced additional data for the Phase 1a portion of the study at the STI & HIV 2025 World Congress. Results exceeded our objectives for this Phase 1a study and supported 1179's progression into Phase 1b. We dosed our first participant in the Phase 1b portion of the study in participants with recurrent genital herpes during the second quarter of 2025. We submitted an Investigational New Drug (IND) application in May 2025 to support expansion of the Phase 1b study to sites in the United States, and we received clearance for the IND in June 2025.

In all three single-dose Phase 1a cohorts (50 mg, 100 mg and 300 mg), 1179 was well-tolerated with a favorable safety profile observed. Treatment-emergent AEs were generally Grade 1 in intensity and all were considered not related to study treatment by the study investigators; there were no serious AEs in any dose cohort. A single, self-limited Grade 2 alanine transaminase (ALT) elevation was observed in a subject receiving the highest dose of 300 mg. There were no clinically significant ECG abnormalities, no significant treatment-related laboratory abnormalities and no protocol-defined stopping criteria were met. Plasma concentrations exceeded necessary protein-adjusted EC_{50} for inhibition of HSV replication at all dose levels and the observed half-life of approximately four days supports weekly dosing, the target profile for 1179.

We reported interim data from two oral weekly dose cohorts in the Phase 1b portion of the 1179 study in December 2025. For the powered antiviral endpoint, HSV-2 shedding rate, highly potent antiviral activity was observed with a 98% reduction in HSV-2 shedding rate compared to placebo ($p<0.01$) over the 29-day evaluation period in the 50 mg weekly dose cohort. This reduction exceeded our target for the study of an 80-85% reduction in HSV-2 shedding rate. Further, data revealed a 91% reduction in virologically confirmed lesion rate compared to placebo ($p<0.01$) with the 50 mg weekly dose. There was also a >99% reduction in the number of samples with high viral load, a potential surrogate for HSV-2 transmission and a secondary endpoint.

Across both oral weekly dose cohorts, 1179 demonstrated a PK profile that continues to support once-weekly dosing. 1179 was observed to be well-tolerated at both doses. Overall, the proportion of participants reporting treatment-emergent AEs was similar between 1179 and placebo recipients. Of the treatment-emergent AEs reported, the majority were Grade 1 or Grade 2. The most common AEs were upper respiratory tract infection and headache. There have been no serious AEs reported to date. One Grade 3 AE of migraine was reported in a participant enrolled in the 20 mg/placebo cohort.

All participants in the Phase 1b portion of the 1179 study have completed dosing and follow up. With these data, 1179 is ready to move into Phase 2 enabling studies for a once-weekly treatment regimen, subject to completion of chronic toxicology studies, which are currently underway. The completion of the Phase 1b studies of both 5366 and 1179 constitute an option triggering point under the terms of the Gilead Collaboration Agreement, as defined below under "Collaboration and License Agreement — Gilead Sciences, Inc." The 1179 data reported in December 2025 will be presented at ESCMID in April 2026.

In December 2025, Gilead exercised its option early to license our HPI program for the treatment of recurrent genital herpes, including 5366 and 1179. We expect to receive Gilead's development plan and budget for the HPI program and make our decision regarding the Profit-Share by mid-2026. We anticipate Gilead will initiate a Phase 2 clinical study for the HPI program in 2026. For more information regarding Gilead's exercise of its option, see "Collaboration and License Agreement—Gilead Sciences, Inc.—Option Exercise."

Our HBV and HDV Programs

The World Health Organization (WHO) estimates that 254 million people worldwide are chronically infected with HBV as of 2022, and 1.2 million new infections occur each year. HBV is a leading global cause of chronic liver disease and liver transplants, and the WHO estimates that 1.1 million people died in 2022 from HBV, mostly due to cirrhosis and hepatocellular carcinoma. Of the 254 million people living with chronic HBV infection, only approximately 33 million, or 13%, were aware of their infection, and only approximately 7 million, or 3%, of those diagnosed received treatment. HBV is a highly prevalent disease that infects almost three times the number of people infected with hepatitis C virus and HIV infections combined, according to the WHO.

The current standard of care for chronic HBV infection, nucleos(t)ide analog reverse transcriptase inhibitors (NrtIs), are taken life-long and reduce, but do not eliminate, the virus and result in very low cure rates. No new mechanisms of action (MOA) have been approved for the treatment of chronic HBV infection in over 25 years. The focus of our HBV program is to improve outcomes and increase the number of patients diagnosed and treated through the development of finite and curative therapies targeting an orthogonal MOA.

HDV is a "satellite virus" of HBV because it can only infect people (1) who are already infected with HBV or (2) at the same time as a person is infected with HBV. HDV affects a subset of approximately 12 to 72 million HBV infected people. These individuals infected with HDV, which comprise an estimated 4.5% of hepatitis B surface antigen (HBsAg) positive individuals, experience a substantially increased disease burden, as they account for 18% of cirrhosis and 20% of hepatocellular carcinoma associated with HBV. HDV is considered the most severe form of hepatitis, as 70% of individuals infected with HDV progress to cirrhosis within ten years. While HDV is less prevalent in the United States, it is a significant and serious health problem with inadequate treatment in many parts of Europe, Africa, the Middle East, East Asia and parts of South America. HDV may be significantly underdiagnosed, because there were no HDV-targeted therapies approved until very recently, and the first therapy approved is only approved in the European Union (EU), Australia and Canada. HDV is known to accelerate disease progression and increase the incidence of liver cirrhosis and liver cancer, which results in higher morbidity and mortality rates than HBV alone.

The current standard of care treatment for HDV is off-label pegylated interferon-α (IFN-α) injected weekly or, in the EU, Australia and Canada, a large, complex peptide inhibitor that requires daily injections, bulevirtide. There are no approved HDV treatments in the United States. We believe a safe and effective oral small molecule entry inhibitor would be a significant innovation for people living with HDV, who face a significant and immediate disease burden.

HDV Entry Inhibitor

HDV is a small RNA virus that encodes just two viral proteins and relies on host enzymes as well as the HBsAg from HBV to replicate, which limits the number of HDV-specific antiviral targets. Similar to HBV, HDV utilizes HBsAg to enter hepatocytes by binding the cellular transmembrane protein sodium taurocholate co-transporting peptide (NTCP). NTCP is highly expressed on human hepatocytes, where it serves as one of several proteins involved in the transport of bile acids. The binding of specific small or large molecules to NTCP has been shown to effectively inhibit the interaction of HBsAg with NTCP, which prevents HBV and HDV from infecting hepatocytes.

The inhibition of HBV and HDV infection by molecules that bind NTCP has been demonstrated in vitro, in animal models and clinically. Notably, bulevirtide, a peptide blocker of NTCP, is the only approved therapy for HDV. 6250 has the same clinically-validated MOA as bulevirtide. The binding of NTCP-targeted HBV/HDV entry inhibitors to NTCP has also been shown to inhibit the transport of certain bile acids into cells, which results in plasma elevations of bile acids; this effect has been well-tolerated clinically and may serve as a biomarker of pharmacologically active concentrations of drug in the plasma. In nonclinical studies in non-human primates, clinically-relevant doses of 6250 elevated bile acids to levels similar to those seen in humans with bulevirtide.

We believe a safe and effective oral small molecule entry inhibitor would be a significant innovation for people living with HDV and could significantly improve treatment uptake and diagnosis rates, especially when compared with currently available injectable products.

A Phase 1a clinical study of 6250 was initiated in the fourth quarter of 2024, and in August 2025, we announced interim PK, biomarker and safety data from single-ascending and multiple-ascending doses cohorts in healthy participants. Across the cohorts evaluated to date, a mean half-life of approximately four days was observed for 6250 when dosed orally, supporting the once-daily oral dosing profile target. Given this half-life, accumulation was observed in the multiple-dose cohorts with exposures on the last day of dosing generally reaching six- to seven-fold higher than the exposure seen after the first dose.

Dose-dependent elevations of total serum bile acids (TBAs) were observed for both the 5 mg and 25 mg single-dose cohorts, indicative of NTCP target engagement. In the highest single-dose cohort of 25 mg, coproporphyrin I (CP-1), a biomarker for off-target engagement of the organic anion transporters, OATP1B1 and/or OATP1B3, was also elevated. CP-1 elevation was not noted at the other doses.

Given the predicted 6250 accumulation driven by the long half-life and the observed elevations of TBAs for the single-dose cohorts, doses at and below 1 mg daily were selected for the multiple-dose cohorts to characterize the lower end of the dose-response curve. Elevation of TBAs was observed for both the 0.2 mg and 1 mg daily multiple-dose cohorts, consistent with the respective 6250 exposures. Minimal TBA elevation was observed in the 0.05 mg daily multiple-dose cohort.

Treatment-emergent AEs and laboratory abnormalities were all Grade 1 or 2 in severity with the majority being Grade 1. There were no serious AEs in any dose cohort. No protocol defined stopping criteria were met. There were no clinically significant electrocardiogram (ECG) abnormalities or patterns of AEs noted.

One Grade 2 ALT elevation was observed in the cohort evaluating the highest single-dose level of 25 mg. In this cohort, off-target engagement of other liver transporters was also seen as indicated by elevated CP-1 levels. Grade 1 ALT elevations were observed at a low frequency across the other cohorts. All ALT elevations were self-limited, and none were accompanied with elevations in bilirubin or other markers of liver injury. The elevations resolved in the study period with ongoing drug exposure due to 6250's four-day half-life.

We have completed enrollment and the follow-up period in the Phase 1a study, as well as the chronic toxicology studies to enable longer term dosing and we are preparing for Phase 2 clinical studies, with Phase 2 initiation expected in the fourth quarter of 2026.

6250 Phase 1a data will be presented at the European Association for the Study of the Liver (EASL) Congress taking place in Barcelona, Spain in May 2026.

Capsid Assembly Modulator

HBV is a DNA virus that infects hepatocytes and establishes a reservoir of covalently closed circular DNA (cccDNA), a unique viral DNA moiety that resides in the nucleus of HBV-infected hepatocytes and is associated with viral persistence and chronic infection. No currently approved oral therapies target cccDNA activity directly. As a result, we have worked to discover and develop compounds targeting the core protein, a viral protein involved in numerous aspects of the HBV replication cycle, including the generation of HBV cccDNA.

A benchmark for therapeutic agents aiming to decrease cccDNA levels is the use of several key viral antigens as surrogate biomarkers of active cccDNA. The same biomarkers can be used in both primary human hepatocytes and infected individuals. On this basis, our next-generation CAM, 4334, has shown nonclinical proof of principle. In a variety of cell culture models, 4334 has demonstrated the ability to reduce production of HBV DNA levels as well as the surrogate markers for cccDNA establishment: HBV e antigen (HBeAg), HBV core-related antigen (HBcrAg) and HBV pre-genomic RNA (pgRNA).

As a next-generation CAM, 4334 was optimized to potently disrupt viral replication (MOA #1) and prevent the establishment and replenishment of new cccDNA (MOA #2). In contrast, while active against MOA #1, first-generation CAMs have not demonstrated adequate potency to sufficiently block MOA #2. Further, the current standard

of care, NrtIs, impacts the viral life cycle after establishment of cccDNA and can only inhibit production of new viral particles, and it does so incompletely. The chemical scaffold of 4334 is novel and distinct from all our prior CAM candidates.

We believe that 4334 has a best-in-class nonclinical profile, with single-digit nanomolar potency against MOA #1 and MOA #2, pan-genotypic activity, an improved resistance profile and a favorable safety profile. Through mechanistic studies presented at multiple conferences, we have demonstrated that 4334 promotes the formation of empty capsids by acceleration of capsid assembly, prevents the formation of cccDNA by disrupting incoming capsids, and prematurely disrupts capsids containing duplex linear DNA, the precursor for integrated HBV DNA.

A Phase 1a study demonstrated that 4334 was well-tolerated when administered orally as single or multiple doses. During the second quarter of 2024, we dosed our first participant in a Phase 1b clinical study of 4334. We reported interim clinical results from the initial 150 mg cohort in December 2024, and topline clinical results including a subsequent 400 mg cohort in June 2025. In both the 150 mg and 400 mg cohorts, 4334 continued to show a half-life supportive of once-daily oral dosing. In addition, results for both cohorts indicated that 4334 maintained clinical exposures multiple folds above those anticipated to be required for potent viral activity and inhibition of cccDNA formation. Mean declines in HBV DNA of 2.9 $\log_{10}$ IU/mL and 3.2 $\log_{10}$IU/mL were observed over 28 days in a population of predominately HBeAg negative participants receiving 150 mg and 400 mg, respectively. Among the subset of participants with detectable HBV RNA at baseline, mean declines of 2.5 $\log_{10}$ U/mL and 2.3 $\log_{10}$ U/mL were observed over 28 days in the participants receiving 150 mg and 400 mg, respectively. As anticipated, limited changes in viral antigens were observed for the study population over the 28-day treatment period. These antiviral data are consistent with the high potency seen preclinically for 4334. The safety data also demonstrated that 4334 was well-tolerated with a favorable safety profile observed. The 400 mg cohort was the final cohort for this Phase 1b study and final data was presented at the American Association for the Study of Liver Disease, The Liver Meeting® in November 2025. The completion of the Phase 1b study of 4334 constitutes an option-triggering point under the terms of the Gilead Collaboration Agreement, as defined below under "Collaboration and License Agreement — Gilead Sciences, Inc."

In March 2026, Gilead declined to either exercise its option to license 4334 or defer its option until completion of Phase 2 studies. As a result, the Company retains full control of 4334, including the right to evaluate partnering opportunities for 4334 outside of the Gilead Collaboration. We are actively evaluating partnering opportunities for 4334 and have initiated a structured process to find potential partners. We do not plan to advance 4334 further without a partner.

Transplant-Associated Herpesviruses

In a transplant setting, when patients are experiencing immunosuppression, they are at high risk of uncontrolled viral replication and severe disease brought on by one or more herpesviruses, including cytomegalovirus (CMV), HSV-1, HSV-2, varicella zoster virus (VZV) and Epstein-Barr virus (EBV). Each of these herpesviruses are highly prevalent, as approximately (1) 60% of transplant patients are CMV-positive; (2) 60% of transplant patients are HSV-positive; (3) 80% of transplant patients are VZV-positive and (4) 45% of transplant patients are EBV-positive. These viruses establish lifelong latent infections and frequently reactivate in transplant patients due to the use of immunosuppressive drugs following transplantation. These uncontrolled herpesvirus infections increase the risk of severe disease and serious complications, including organ rejection, graft loss and death, and impacted approximately 95,000 people receiving transplants in 2021 in the United States and Europe.

While there are approved antivirals that are administered in a transplant setting, currently approved antivirals are not active against a broad spectrum of transplant-associated herpesviruses and pose the risk of potentially serious side effects and drug-drug interactions. As a result of these limitations, we identified an opportunity to develop an oral, broad-spectrum NNPI for transplant-associated herpesvirus infections, which could greatly advance treatment.

In December 2024, we nominated 7423, a prodrug, as our development candidate to undergo regulatory filing-enabling studies. In October 2025, we transitioned our discovery and development from 7423 to its parent molecule, 7272, which is currently in regulatory filing-enabling nonclinical studies.

Research Programs

In addition to our investigational therapy programs that have nominated development candidates and have advanced into clinical studies or regulatory filing-enabling studies, our research team continues to actively focus on proprietary research to discover and nominate novel antivirals to treat serious viral diseases.

Collaboration and License Agreement

Gilead Sciences, Inc.

In October 2023, we entered into an Option, License and Collaboration agreement (the Gilead Collaboration Agreement) with Gilead pursuant to which Gilead (1) exclusively licensed to us its HPI program and its NNPI program, while retaining opt-in rights to these programs, and (2) has an option to take an exclusive license, on a program-by-program basis, to all of our other current and future pipeline programs. During the 12-year collaboration term (subject to payment of certain extension fees) and for a specified period thereafter, Gilead may exercise its opt-in rights, on a program-by-program basis, at one of two timepoints—completion of a certain Phase 1 study or, upon payment of a deferral fee and completion of a certain Phase 2 study for the first product within the program—upon payment of an opt-in fee ranging from $45.0 million to $125.0 million per program depending on the type of program and when the option is exercised. Pursuant to the Gilead Collaboration Agreement, Gilead made an $84.8 million upfront cash payment to us. In December 2024, we and Gilead entered into the First Amendment to the Gilead Collaboration Agreement, which restructured the timing of specific options exercisable and the fees payable to us under the terms of the Gilead Collaboration Agreement due to an agreed upon development plan for 6250. To facilitate this development plan, (1) we received a payment of $10.0 million from Gilead and (2) the opt-in fee payable by Gilead in connection with 6250 was restructured, though it remains in the range of opt-in fees detailed above. The $10.0 million payment received in connection with the First Amendment to the Gilead Collaboration Agreement is creditable towards future collaboration-related payments payable by Gilead. This credit was applied toward Gilead's opt-in fee paid for the HPI program in December 2025.

If Gilead exercises its opt-in right to any current or future program under the collaboration, we are eligible to receive up to $330.0 million in potential regulatory and commercial milestones on that program, in addition to royalties ranging from the high single-digits to high teens, depending on the clinical stage of the program at the time of the opt-in. Following Gilead's exercise of its option for each program, we may opt-in to cover 40% of the research and development costs in the United States and share 40% of the profits and operating loss in the United States for products within the program in lieu of receiving milestones and royalties for that program in the United States, unless we later opt out of the cost/profit share for the program. Prior to Gilead's potential exercise of its opt-in, we are primarily responsible for all discovery, research and development on both our programs and the two Gilead-contributed programs. Following Gilead's opt-in, Gilead will control the further discovery, research, development and commercialization on any optioned programs, and is responsible for all related costs unless we opt in to share 40% of all costs and profits in the United States. During the term, Gilead will continue to support the collaboration through extension fees of $75.0 million in each of the third, fifth and seventh anniversaries of the collaboration.

The Gilead Collaboration Agreement is subject to termination by either party for the other party's uncured, material breach or insolvency. Subject to certain limitations, we and Gilead both have certain termination for convenience rights, upon sufficient prior written notice, with respect to programs that one party in-licenses from the other (subject to Gilead's option rights), and with respect to Gilead, for programs it has option rights to (subject to certain time limitations with respect to existing Company programs). Gilead also has a right to terminate the collaborative activities under the Gilead Collaboration Agreement at certain specified points during the collaboration term. Other customary termination rights are further provided in the Gilead Collaboration Agreement.

We and Gilead also entered into a Common Stock Purchase Agreement and an Investor Rights Agreement (together, the Gilead Equity Agreements), which were both amended in June 2024 in connection with a financing transaction, in which a new investor purchased shares of common stock and was issued a warrant (the 2024 Financing Transaction). Pursuant to the Gilead Equity Agreements, Gilead made an upfront equity investment of $15.2 million by purchasing from us 1,089,472 shares of our common stock at a purchase price of $13.92 per share. The terms of the Gilead Equity Agreements provided Gilead the right to elect to purchase additional shares of common stock from us at a premium in an amount that results in Gilead owning 29.9% of our then-outstanding voting common stock. This right was exercised in December 2024, at a purchase price of $21.37 per share, which represents a 35% premium to the

30-trading day volume weighted average price immediately prior to the date of purchase. The Gilead Equity Agreements also include a three-year standstill provision and a two-year lockup provision, each with customary exceptions, and provide Gilead with certain other stock purchase rights and registration rights, as well as the right to designate two directors (or, alternatively, board observers at Gilead's election) to our board of directors. In December 2023, Gilead designated Tomas Cihlar, Ph.D. to serve on our board of directors, and in March 2024, Gilead designated Robert D. Cook II to serve on our board of directors.

Gilead participated in the 2024 Financing Transaction on the same terms as the new investor pursuant to the anti-dilution provision in the Investor Rights Agreement. We and Gilead entered into a Securities Purchase Agreement for the issuance and sale, in a private placement, of 179,500 shares of our common stock and a warrant to purchase up to 179,500 shares of our common stock. The warrant sold to Gilead has an exercise price equal to $17.00 per share, became immediately exercisable on the date of issuance and will expire on June 18, 2029. Subject to certain exceptions, neither Gilead nor its affiliates may exercise any portion of the warrant to the extent that Gilead would own more than 19.9% of the number of our shares of common stock outstanding immediately after giving effect to such exercise.

Gilead also participated in a financing transaction in August 2025 on the same terms as the new investors. We and Gilead entered into a Securities Purchase Agreement for the issuance and sale, in a private placement, of 2,295,920 shares of our common stock at a combined purchase price of $19.60 per shares and accompanying one-half of one Class A Warrant and one-half of one Class B Warrant (collectively, the August 2025 Private Placement). The common stock, the Class A Warrant and the Class B Warrant were sold to Gilead pursuant to the terms of the Investor Rights Agreement. The Class A Warrant and the Class B Warrant each provide for the right to purchase up to 1,147,960 shares of our common stock. The Class A Warrant has an exercise price of $21.60 per share, became immediately exercisable on the date of issuance and will expire on or prior to the earlier of (a) August 11, 2030 (five years from the date of issuance) and (b) the date that is 30 days after the public announcement that we have completed enrollment of at least 200 patients total for our Phase 2 clinical study evaluating 5366 versus valacyclovir. The Class B Warrant has an exercise price of $21.60 per share and is exercisable between November 15, 2026 and December 31, 2026. Notwithstanding the foregoing, if, prior to November 15, 2026, we publicly announce that we have received at least $75.0 million in the aggregate of non-dilutive capital in connection with a collaboration agreement, then the Class B Warrant automatically terminates in full.

In October 2025, as required under the registration rights terms of the Investor Rights Agreement, we filed a registration statement on Form S-3 (the Registration Statement) with the Securities and Exchange Commission (SEC) to register all of the shares of our common stock that have been issued and sold to Gilead, as well as all of the shares of common stock underlying the warrants that have been issued and sold to Gilead. The SEC declared the Registration Statement effective in November 2025.

Option Exercise

In December 2025, Gilead exercised its option to exclusively license our HPI program for the treatment of recurrent genital herpes, including 5366 and 1179. This is the first program that Gilead will advance under the Gilead Collaboration.

Under the terms of the Gilead Collaboration Agreement, we received a $35 million payment in connection with Gilead's exercise of our HPI program. The $35 million payment reflects a $45 million option fee, net of $10 million in accelerated funding that we received under the First Amendment to the Gilead Collaboration Agreement, which was creditable against future payments. Gilead received an exclusive license to 5366 and 1179 and will have the sole right and responsibility for further clinical development and commercialization of the HPI program.

We remain eligible to receive up to $330 million in regulatory and commercial milestones, as well as tiered royalties on net sales ranging from the high single-digits to low teens. We will also have the right to opt in to share 40% of all costs and profits in the United States (the Profit-Share) in lieu of receiving milestones and royalties for that program in the United States after receipt of a development plan and budget from Gilead.

Intellectual Property

We own published and nationalized international Patent Cooperation Treaty (PCT) patent applications relating to compositions of matter and methods of using 5366 and derivatives/analogs thereof to treat HSV. Any patents issuing therefrom are expected to expire in 2043. We also own unpublished, published and nationalized PCT patent applications relating to synthetic processes, crystal forms and pharmaceutical formulations of 5366. Any patents issuing therefrom are expected to expire in 2043 to 2045.

We own a published and nationalized PCT patent application relating to compositions of matter and methods of using compound 6250 and derivatives/analogs thereof to treat HDV and HBV. Any patents issuing therefrom are expected to expire in 2044. We also own a published PCT patent application relating to crystalline forms of 6250. Any patents issuing therefrom are expected to expire in 2045.

We own a published nationalized PCT patent application relating to compositions of matter and methods of using compound 4334 and derivatives/analogs thereof to treat HBV. Any patents issuing therefrom are expected to expire in 2041. We also own published and nationalized PCT patent applications relating to processes for preparing 4334 and crystalline forms of 4334. Any patents issuing therefrom are expected to expire in 2042.

Finally, we own a published PCT patent application relating to compositions of matter and methods of using broad-spectrum NNPIs to treat various herpes viruses.

Government Regulation

Government authorities in the United States, at the federal, state and local level, and in other countries extensively regulate, among other things, the research, development, testing, manufacture, including any manufacturing changes, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, import and export of pharmaceutical products, such as those we are developing.

U.S. drug approval process

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

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

- completion of nonclinical laboratory tests and animal studies in compliance with the FDA's GLP regulations and applicable requirements for the humane use of laboratory animals or other applicable requirements;
- submission to the FDA of an IND application, which must become effective before human clinical studies may begin;
- approval by an independent institutional review board (IRB) or ethics committee at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical studies in accordance with good clinical practices (GCP), and any additional requirements for the protection of human research participants and their health information, to establish the safety and efficacy of the proposed drug for each indication;
- submission to the FDA of a new drug application (NDA);

- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with current good manufacturing practices (cGMP) requirements and to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;

- satisfactory completion of any potential FDA audits of the clinical trial sites that generated the data in support of the NDA to assure compliance with GCP requirements and integrity of the clinical data;

- FDA review and approval of the NDA; and

- compliance with any post-approval requirements, including a risk evaluation and mitigation strategy (REMS), where applicable, and post-approval studies required by the FDA as a condition of approval.

Nonclinical studies and IND

Nonclinical studies include laboratory evaluation of product chemistry and formulation, as well as *in vitro* and animal studies to assess the potential for AEs and in some cases, to establish a rationale for therapeutic use. The conduct of nonclinical studies is subject to federal regulations and requirements, including GLP regulations for safety/toxicology studies. An IND sponsor must submit the results of the nonclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical studies, among other things, to the FDA as part of an IND application. Some long-term nonclinical testing, such as animal tests of reproductive AEs and carcinogenicity, may continue after the IND is submitted. For some products, the FDA may waive the need for certain nonclinical tests. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical studies and places the trial on clinical hold. If an IND or clinical study is placed on clinical hold, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical study can begin. As a result, submission of an IND may not result in the FDA allowing clinical studies to commence.

Clinical studies

Clinical studies involve the administration of the investigational new drug to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include, among other things, the requirement that all research subjects provide their informed consent in writing before their participation in any clinical study. Clinical studies are conducted under written study protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. A protocol for each clinical study and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, an IRB at each institution participating in the clinical study must review and approve the plan for any clinical study before it commences at that institution, and the IRB must conduct continuing review. The IRB must review and approve, among other things, the study protocol and informed consent information to be provided to study subjects. An IRB must operate in compliance with FDA regulations. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether a trial may move forward at designated checkpoints based on access to certain data from the trial. Information about certain clinical studies must be submitted within specific timeframes to the National Institutes of Health for public dissemination at www.clinicaltrials.gov. The Food and Drug Omnibus Reform Act (FDORA), which was signed into law on December 29, 2022, made numerous amendments to the FDCA including provisions intended to, among other things, decentralize and modernize clinical trials and enhance diversity in clinical trial populations.

Human clinical studies are typically conducted in three sequential phases, which may overlap or be combined:

- *Phase 1:* The drug is initially introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness.

- *Phase 2:* The drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to

determine dosage tolerance and optimal dosage. 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 drug is administered to an expanded patient population in adequate and well-controlled clinical studies to generate sufficient data to statistically confirm the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product and to provide adequate information for the labeling of the product.

Progress reports detailing the results of the clinical studies must be submitted at least annually to the FDA. Additionally, IND safety reports must be submitted to the FDA and the investigators within 15 calendar days after determining that the information qualifies for reporting. IND safety reports are required for serious and unexpected adverse reactions, findings from animal or *in vitro* testing or other studies that suggest a significant risk to humans, and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. In addition, a sponsor must notify the FDA within seven calendar days after receiving information concerning any unexpected fatal or life-threatening suspected adverse reaction. Phase 1, Phase 2 and Phase 3 clinical studies may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical study at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical study at its institution if the clinical study is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients.

A manufacturer of an investigational drug for a serious disease or condition is required to make available, such as by posting on its website, its policy regarding evaluating and responding to requests for individual patient access to such investigational drug for use outside a clinical trial. This requirement applies on the earlier of the first initiation of a Phase 2 or Phase 3 trial of the investigational drug or, as applicable, 15 days after the drug receives a designation as a breakthrough therapy, Fast Track product, or regenerative advanced therapy. There also are requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries.

Marketing approval

After the completion of required clinical testing, the results of the nonclinical studies and clinical studies, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the product for one or more indications. Under federal law, the submission of most NDAs is additionally subject to a substantial application user fee, currently $4.682 million, and the sponsor of an approved NDA is also subject to an annual program fee currently set at $0.44 million through September 30, 2026. These fees are typically adjusted on October 1 each year.

The FDA conducts a preliminary review of all NDAs within the first 60 days after submission before accepting them for filing to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA has agreed to specified performance goals in the review of NDAs. Under these goals, the FDA has committed to review most original applications for non-priority products within ten months, and most original applications for priority review products, that is, drugs for a serious or life-threatening condition that the FDA determines represent a significant improvement over existing therapy, within six months. For NDAs for novel products, the ten- and six-month time periods runs from the filing date; for all other original applications, the ten- and six-month time periods run from the submission date. The review process may be extended by the FDA for three additional months to consider certain information or clarification regarding information already provided in the submission. The FDA may also refer applications for novel drugs or products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

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

specifications. In addition, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP and integrity of the clinical data submitted. With passage of the FDORA, Congress clarified the FDA's authority to conduct inspections by expressly permitting inspection of facilities involved in the preparation, conduct, or analysis of clinical and nonclinical studies submitted to FDA as well as other persons holding study records or involved in the study process.

After the FDA's evaluation of the NDA and inspection of the manufacturing facilities, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A complete response letter indicates that the NDA will not be approved in its present form and generally outlines the deficiencies in the submission, which may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval and refuse to approve the NDA. Even if the FDA approves a product, it may limit the approved indications for use for the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical studies, be conducted to further assess a drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution and use restrictions or other risk management mechanisms, including REMS, which can materially affect the potential market and profitability of the product or impose new labeling, testing or distribution and use requirements. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. 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.

Fast Track designation

The FDA is required to facilitate and expedite the development and review of drugs that are intended for the treatment of a serious or life-threatening disease or condition for which there is no effective treatment and which demonstrate the potential to address unmet medical needs for the disease or condition. Under the Fast Track program, the sponsor of a new product candidate may request the FDA to designate the product for a specific indication as a Fast Track product concurrent with or after the filing of the IND for the product candidate. The FDA must determine if the product candidate qualifies for fast track designation within 60 calendar days after receipt of the sponsor's request.

In addition to other benefits, such as the ability to have greater interactions with the FDA, the FDA may initiate review of sections of a Fast Track product's NDA before the application is complete. This rolling review is available if the applicant provides and the FDA approves a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, the FDA's time period goal for reviewing a Fast Track application does not begin until the last section of the NDA is submitted. In addition, the Fast Track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical study process.

Priority review

Under FDA policies, a product candidate may be eligible for priority review, which means the review is generally completed within a six-month time frame from the date a complete application is filed. Products generally are eligible for priority review if they are intended for treatment of a serious or life-threatening disease or condition and provide a significant improvement in safety or effectiveness compared to marketed products in the treatment, diagnosis or prevention of a serious disease or condition.

Accelerated approval

Under the FDA's accelerated approval regulations, the FDA may approve a drug for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients over existing treatments based upon a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality (IMM). In clinical studies, a surrogate endpoint is a measurement of laboratory or clinical signs of a disease or condition that substitutes for a direct measurement of how a participant feels, functions or survives. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. 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 studies to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the drug from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA. With the passage of the FDORA, the FDA is authorized to require a post-approval study to be underway prior to approval or within a specified time period following approval. FDORA also requires the FDA to specify conditions of any required post-approval study and requires sponsors to submit progress reports for required post-approval studies and any conditions required by the FDA until completion or termination of the study. FDORA further enables the FDA to initiate criminal prosecutions for the failure to conduct with due diligence a required post-approval study, including a failure to meet any required conditions specified by the FDA or to submit timely reports.

Breakthrough therapy designation

A sponsor can request designation of a product candidate as a "breakthrough therapy." A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs designated as breakthrough therapies also may be eligible for priority review. The FDA must take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy. Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Orphan drugs

Under the Orphan Drug Act, as amended, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition, which is generally defined as a disease or condition that affects fewer than 200,000 individuals in the United States or that affects more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available the drug for the disease or condition will be recovered from sales of the product in the United States. Orphan drug designation must be requested before submitting an NDA for the application to be eligible to receive orphan drug exclusivity upon approval. After the FDA grants orphan drug designation, the identity of the product and its potential orphan indication are disclosed publicly by the FDA. Orphan drug designation does not shorten the duration of the regulatory review and approval process. If a product that has orphan designation subsequently receives the first FDA approval for a particular active ingredient for the disease or condition for which it has such designation, the product is entitled to Orphan Drug exclusivity, which means that the FDA may not approve other applications to market the same product for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. A drug will be considered clinically superior if it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same orphan disease or condition, or the same drug for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA application user fee.

Pediatric information

Under the Pediatric Research Equity Act of 2003, as amended, an NDA or supplement to an NDA for drug with certain novel features (e.g., new active ingredient, new indication) must contain data that are adequate to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. A sponsor of a new drug subject to the above pediatric testing requirements also is required to submit to the FDA a pediatric study plan generally 60 days after an end-of-Phase 2 meeting with the agency. Generally, the pediatric data requirements do not apply to products with orphan drug designation.

Other regulatory requirements

Any drug manufactured or distributed by us pursuant to FDA approvals will be subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval.

The FDA may impose a number of post-approval requirements, including REMS, as a condition of approval of an NDA. For example, the FDA may require post-marketing testing, including Phase 4 clinical studies, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

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

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including AEs of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, imposition of post-market studies or clinical studies 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 clinical holds on post-approval studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- consent decrees, injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs generally may be promoted only for the approved indications and in accordance with the provisions of the approved labeling. 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.

Physician Drug Samples

As part of the sales and marketing process, pharmaceutical companies frequently provide samples of approved drugs to physicians. The Prescription Drug Marketing Act (PDMA) regulates the distribution of 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. In addition, the PDMA sets forth civil and criminal penalties for violations.

Foreign Regulation

In order to market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical

studies, marketing authorization, commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we would need to obtain the necessary approvals by the comparable regulatory authorities of foreign countries before we can commence clinical studies or marketing of the product in those countries. The approval process varies from country to country and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others.

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any drug products for which we may obtain regulatory approval. Sales of any of our product candidates, if approved, will depend, in part, on the extent to which the costs of the products will be covered by third-party payors, including government health programs such as Medicare and Medicaid, commercial health insurers and managed care organizations. The process for determining whether a payor will provide coverage for a drug product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the drug product once coverage is approved. Third-party payors may limit coverage to specific drug products on an approved list, or formulary, which might not include all of the approved drugs for a particular indication.

The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of drugs have been a focus in this effort. Third-party payors are increasingly challenging the prices charged for medical products and services and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. Accordingly, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our product candidates, in addition to the trials required to obtain FDA or other comparable regulatory approvals. If these third-party payors do not consider our products to be cost-effective compared to other available therapies, they may not cover our products after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to enable us to maintain price levels high enough to realize an appropriate return on our investment in product development. Further, one payor's determination to provide coverage for a product, if approved, does not assure that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement can differ significantly from payor to payor.

Pricing and reimbursement schemes vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies. For example, the EU provides options for its member states to restrict the range of drug products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. EU member states may approve a specific price for a drug product or may instead adopt a system of direct or indirect controls on the profitability of us placing the drug product on the market. Other member states allow companies to fix their own prices for drug products but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert competitive pressure that may reduce pricing within a country. There can be no assurance that any country that has price controls or reimbursement limitations for drug products will allow favorable reimbursement and pricing arrangements for any of our products.

The marketability of any products for which we may receive regulatory approval for commercial sale is dependent on the availability of adequate coverage and reimbursement from government and third-party payors. In addition, the emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on drug pricing. Coverage policies, third-party reimbursement rates and drug pricing regulation may change at any time. For example the Affordable Care Act of 2010, as amended by, the Health Care and Education Reconciliation Act (collectively, ACA), among other things, imposed an annual fee on any entity that manufactures or imports certain branded prescription drugs, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program, and established the Medicare Part D coverage gap discount program. In addition to these provisions, the ACA established a number of bodies whose work may have a future impact on the market for certain pharmaceutical products, including the Patient-Centered Outcomes Research Institute, established to oversee, identify priorities in, and conduct comparative clinical effectiveness research, and the Center for Medicare and Medicaid

Innovation within the Centers for Medicare and Medicaid Services, established to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

Since its enactment, there have been executive, judicial, and Congressional challenges to certain aspects of the ACA. For example, the administration has issued directives designed to delay the implementation of certain ACA provisions or otherwise circumvent requirements for health insurance mandated by the ACA, and Congress has considered legislation that would repeal, or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been signed into law. In addition, the Tax Cuts and Jobs Act, effectively repealed the individual health insurance mandate, which is considered a key component of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. More recently, in June 2025, the U.S. Supreme Court upheld the constitutionality of the ACA's requirement that group health plans and health insurance issuers cover certain preventative services without cost-sharing is unconstitutional.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes included aggregate reductions to certain Medicare payments to providers of up to 2% per fiscal year, which will remain in effect through 2032, unless Congress takes additional action. These and other laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices. Specifically, there have been several recent United States Congressional inquiries and proposed and enacted federal legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. For example, the Inflation Reduction Act of 2022 (IRA) enacted on August 16, 2022, seeks to reduce prescription drug costs by, among other provisions, allowing Medicare to negotiate prices for certain high-cost prescription drugs in Medicare Parts B and D, imposing an excise tax on pharmaceutical manufacturers that refuse to negotiate pricing with Medicare, and requiring inflation rebates to limit annual drug price increases in Medicare. These provisions began taking effect progressively starting in 2023, and, in January 2026, CMS announced the 15 drugs selected for the third cycle of Medicare drug price negotiations. Beginning in 2025, the IRA also eliminated the coverage gap under Medicare Part D by significantly lowering the enrollee maximum out-of-pocket cost and imposing a new manufacturer discount program. However, various industry stakeholders, including certain pharmaceutical companies and industry trade organizations have initiated lawsuits against the federal government asserting that the price negotiation provisions of the IRA are unconstitutional. The impact of these judicial challenges and future government reform measures on us and the pharmaceutical industry as a whole is unclear. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights.

In addition, in September 2020, the FDA issued a final rule that sets up a legal framework for allowing the importation of certain prescription drugs from Canada, and the CMS issued guidance that addresses the treatment of certain imported drugs under the Medicaid Drug Rebate Program. On January 5, 2024, the FDA authorized the state of Florida's Section 804 Importation Program, which is the first major step in allowing the state to import certain prescription drugs from Canada. If the program is ultimately approved, it will be the first such program authorized in the United States.

Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the current administration may reverse or otherwise change measures implemented by the prior administration, both the current administration and Congress have indicated that they will continue to take action to control drug costs.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts,

restrictions on certain product access and marketing cost disclosure and transparency measures. These measures could reduce the ultimate demand for our products, if approved, or put pressure on our product pricing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Other Healthcare Laws

In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to, CMS, other divisions of the U.S. Department of Health and Human Services (e.g., the Office of Inspector General), the U.S. Department of Justice (DOJ), and individual U.S. Attorney offices within the DOJ, and state and local governments. For example, the Company's business practices, including its research and sales, marketing and scientific/ educational grant programs may be required to comply with federal and state fraud and abuse laws, false claims laws, the data privacy, security provisions and breach notification provisions of the Health Insurance Portability and Accountability Act (HIPAA), federal transparency requirements and similar state laws, each as amended. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and patients, prescribers, purchasers, and formulary managers on the other;

- federal civil and criminal false claims laws, including the federal False Claims Act, which can be enforced by private citizens through civil *qui tam* actions, and civil monetary penalty laws that prohibit individuals or entities from, among other things: knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent; making a false statement or record material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. Pharmaceutical manufacturers can be held liable under the False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims;

- HIPAA, among other things, imposes criminal liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it;

- HIPAA, as amended by HITECH, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, 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 attorneys' fees and costs associated with pursuing federal civil actions;

- the federal false statements statute prohibits making a false statement to an agent or agency of the federal government in connection with certain federal matters;

- the federal transparency requirements under the ACA, including the provision commonly referred to as the Physician Payments Sunshine Act, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the U.S. Department of Health and Human Services information related to payments or other transfers of value made to physicians, certain other healthcare professionals (such as nurse practitioners and physicians' assistants, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;

- federal government price reporting laws, which require companies to calculate and report complex pricing metrics in an accurate and timely manner to government programs; and

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

Additionally, we are subject to state and non-U.S. equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope and may apply regardless of the payor. For example, many U.S. states have adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare services reimbursed by any source, not just governmental payors, including private insurers. In addition, some states require pharmaceutical companies to implement compliance programs, comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or to track and report gifts, compensation and other remuneration provided to physicians and other healthcare providers. There also are state laws that require the reporting of marketing expenditures or drug pricing, including information pertaining to and justifying price increases, state and local laws that require the registration of pharmaceutical sales representatives or other state or local licensure, state laws that prohibit various marketing-related activities, such as the provision of certain kinds of gifts or meals, and state laws that require the posting of information relating to clinical trials and their outcomes. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement, we could be subject to penalties.

Privacy and Data Security Laws

There are several privacy and data security laws that may impact our business activities, in the United States and in other jurisdictions where we conduct trials or where we may do business in the future. These laws are evolving and may increase both our obligations and our regulatory risks in the future. As described above, in *Other Healthcare Laws*, in the health care industry generally, under HIPAA, the U.S. Department of Health and Human Services has issued regulations to protect the privacy and security of protected health information, or PHI, used or disclosed by covered entities including certain healthcare providers, health plans and healthcare clearinghouses. HIPAA may apply to us in certain circumstances and may also apply to our business partners in ways that may impact our relationships with them.

In addition to federal privacy regulations under HIPAA, there are a number of state laws in the United States governing confidentiality and security of information that may be applicable to our business. At the state level, California enacted the California Consumer Privacy Act (CCPA), which went into effect on January 1, 2020. The CCPA creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA requires covered companies to provide certain disclosures to consumers about its data collection, use and sharing practices, and to provide affected California residents with ways to opt-out of certain sales or transfers of personal information. Additionally, the California Privacy Rights Act (CPRA), which went into effect on January 1, 2023, significantly expanded the CCPA, imposing additional obligations on companies covered by the legislation and expanding consumers' rights with respect to certain sensitive personal information, among other things. The CPRA also creates a new state agency that will be vested with authority to implement and enforce the CCPA and the CPRA. While there is currently an exception for protected health information that is subject to HIPAA and clinical trial regulations, as currently written, the CCPA may apply to some of our business activities or those of our business partners.

In addition to California, at least twenty other states have passed comprehensive consumer data privacy laws. Like the CCPA and CPRA, these laws create obligations related to the processing of personal information, as well as special obligations for the processing of "sensitive" data (which includes health data in some cases). There are also states that are actively considering comprehensive privacy laws. Additional states may consider such laws in the future, and Congress has also been debating passing a federal privacy law. These laws may impact our business activities or those of our business partners, including identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products.

Privacy laws such as the EU General Data Protection Regulation (EU GDPR) and the UK General Data Protection Regulation (UK GDPR) impose strict obligations on lawful processing, transparency and cross-border transfers of personal data (i.e., information which identifies an individual or from which an individual is identifiable). In respect of our engagement of European contract research organizations (CROs) in the context of clinical trials, the EU GDPR and UK GDPR apply. The EU GDPR applies to any company established in the EU as well as to those outside the EU if they process personal data in connection with the offering of goods or services to EU residents or the monitoring of their behavior within the EU, wherever such processing occurs. The EU GDPR includes operational requirements for companies that receive or process personal data of EU residents. The EU GDPR enhances data protection obligations for processors and controllers of personal data, including, for example, expanded disclosures about how personal information is to be used, limitations on retention of information, mandatory data breach notification requirements and notable obligations on services providers. Noncompliance with the EU GDPR may result in monetary penalties of up to €20 million or 4% of worldwide revenue, whichever is higher. The EU GDPR may increase our responsibility and liability in relation to personal data that we process where such processing is subject to the EU GDPR, and we may be required to implement additional mechanisms to ensure compliance with the EU GDPR, including as implemented by individual countries. In addition to the foregoing, a breach of the EU GDPR could result in regulatory investigations, reputational damage, fines and sanctions, orders to change the processing activities of our personal data, enforcement notices or assessment notices (for a compulsory audit). We may also face civil claims, including representative actions and other class action type litigation (where individuals have suffered harm), potentially amounting to significant compensation or damages liabilities as well as associated costs, diversion of internal resources and reputational harm as the EU GDPR 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.

The European Economic Area (EEA) and UK impose rules with respect to cross-border transfers of personal data outside of the EEA and the UK to third countries including the United States. In July 2020, the EU-US Privacy Shield was invalidated as a valid personal data transfer mechanism between the EU and the U.S., and on June 4, 2021, the European Commission finalized new versions of the Standard Contractual Clauses (New SCCs), which apply to the transfer of personal data outside of the EU to a country not approved by the EU as providing an adequate level of protection for the processing of personal data. The New SCCs must be used for all relevant transfers of personal data outside the EEA (since December 27, 2022). On March 21, 2022, the UK implemented its own UK-specific international data transfer agreement and addendum to the New SCCs (collectively, the SCCs). Effective July 11, 2023, the new EU-US Data Privacy Framework (DPF) has been recognized as adequate under EU law (a new framework to allow transfers of personal data from the EU to certified companies in the United States). The UK has also approved a UK extension to the EU-US Data Privacy Framework, which was laid before Parliament on September 21, 2023, and came into force on October, 12 2023. However, the DPF is subject to further legal challenge just as the EU-US Privacy Shield was, which could cause the legal requirements for personal data transfers from the EU to the U.S. to become uncertain once again. EU data protection authorities have and may again block the use of certain U.S.-based services that involve the transfer of personal data to the U.S. In the EU and other markets, potential new rules and restrictions on the flow of personal data across borders could increase the cost and complexity of doing business in those regions. We currently rely on the New SCCs for both intragroup and third-party data transfers from the EEA, however the cross-border data transfer landscape in the EEA is continually developing, and we are monitoring these developments. We may, in addition to other impacts, experience additional costs associated with increased compliance burdens and be required to engage in new contract negotiations with third parties that aid in processing data on our behalf or localize certain data.

Following the UK's departure from the EU, commonly referred to as "Brexit", the UK GDPR exists alongside the UK Data Protection Act 2018, which implements certain derogations in the UK 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 also be subject to the UK GDPR and will be required to appoint a data protection representative in the UK, provided certain exceptions are not met. While the EU GDPR and the UK GDPR remain substantially similar for the time being, the government of the UK has adopted reforms to its data privacy and cybersecurity legal framework in its Data Use and Access Act 2025, which became law on June 19, 2025 (phasing in between June 2025 and June 2026). Compliance with the EU GDPR and UK 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 developing our products or even prevent us from offering certain products in jurisdictions that we may operate in.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available under such laws, it is possible that some of our current or future business activities or those of our business partners, including certain clinical research, sales and marketing practices and the provision of certain items and services to our customers, could be subject to challenge under one or more privacy and data security laws. The heightening compliance environment and the need to build and maintain robust and secure systems to comply with different privacy compliance and/or reporting requirements in multiple jurisdictions could increase the possibility that a company may fail to comply fully with one or more of these requirements. If our operations are found to be in violation of any of the privacy or data security laws or regulations described above that are applicable to us, or any other laws that apply to us, we may be subject to penalties, including potentially significant criminal, civil and administrative penalties, damages, fines, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and/or oversight if we become subject to a consent decree or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

New Legislation and Regulations

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the testing, approval, manufacturing, marketing, and reimbursement status of products regulated by the FDA. In addition to new legislation, FDA regulations and policies are often revised or interpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether further legislative changes will be enacted or whether FDA regulations, guidance, policies or interpretations will be changed or what the effect of such changes, if any, may be.

We are conscious of the extensive and evolving regulatory frameworks in the jurisdictions in which we operate. There are changes in the regulatory landscape relating to new and emerging technologies such as artificial intelligence (AI), which we use in a limited capacities, including to assist our employees in selecting chemical compounds to evaluate, as well as office-related tasks. The EU has developed a standalone law to govern the offering and use of AI systems in the EU (AI Act), which entered into force on August 1, 2024. The AI Act imposes regulatory requirements onto AI system providers, importers, distributors, and deployers, in accordance with the level of risk involved with the AI system (“unacceptable,” “high,” “limited,” and “minimal” risk). General-purpose AI systems have also been made subject to a number of requirements under the AI Act—mostly akin to the requirements that apply to high-risk AI systems. The AI Act will become enforceable in a gradual manner—depending on the regulatory requirement in question, and ranging anywhere from six to 36 months following adoption and entry into force of the AI Act. Non-compliance with the AI Act may be subject to regulatory fines of up to 7% of annual worldwide turnover or €35 million. We are actively assessing the scope of application, impact, and risk of these developments in the EU and the UK on our business and will continue to assess this moving forward. In November 2025, the European Commission proposed a Digital Omnibus package (Digital Omnibus), which would make targeted amendments to several existing EU digital laws, including the AI Act, the EU GDPR, the NIS 2 Directive, the EU’s Data Act (EU Data Act), and other related frameworks, with the stated aim of simplifying and streamlining aspects of the EU digital regulatory landscape. Although the proposal is intended to reduce administrative burden, any amendments to these frameworks may require us to reassess certain compliance positions and adjust technical or legal practices accordingly, which could affect our operations in the EU. The European Health Data Space (EHDS) Regulation entered into force on March 26, 2025, and introduces stricter requirements for the collection, processing, and sharing of electronic health data across the EU. The phased implementation of the EHDS Regulation runs until March 2034, with requirements that may significantly impact our ability to conduct clinical trials, particularly those relying on real-world data, patient registries, or cross-border research collaborations. The EU Data Act is, at this stage, primarily a forward-looking regulatory consideration rather than a current material risk to our business. The EU Data Act has applied since

September 12, 2025, and establishes new requirements concerning access to, use of and sharing of data generated by connected products and related services, as well as certain business-to-business and business-to-government data sharing arrangements. While our current core business is not the primary focus of the regime, the EU Data Act may become relevant to our operations as our research and development activities evolve, particularly if we decide to develop connected medical or health devices in the future. Any such expansion could require us to adapt our data governance, operational processes and contractual arrangements, which may increase compliance costs and administrative complexity. We are actively assessing the potential application and impact of the EU Data Act on our business but currently view it as a forward-looking consideration. The proposed European Health Data Space (EHDS) Regulation introduces stricter requirements for the collection, processing, and sharing of electronic health data across the EU. If enacted, EHDS may significantly impact our ability to conduct clinical trials, particularly those relying on real-world data, patient registries, or cross-border research collaborations. Additionally, the EU Data Act introduces new obligations regarding the access, sharing, and use of data generated by connected devices, digital platforms, and business-to-business and business-to-government data exchanges. As we conduct clinical trials and utilize digital health technologies and real-world data for research and development, compliance with the EU Data Act may introduce significant regulatory and operational challenges. Non-compliance with any of these regulations may result in fines, operational disruptions or reputational harm, and could impact our financial performance. We are actively assessing the scope of application, impact, and risk of these developments in the EU on our business and will continue to assess this moving forward.

Competition

The pharmaceutical and biotechnology industry is very competitive, and the development and commercialization of new drugs is influenced by rapid technological developments and innovation. We face competition from several companies developing and commercializing products that will be competitive with our drug candidates, including large pharmaceutical and smaller biotechnology companies. Additionally, new entrants may potentially enter the market. Potential competitors include GlaxoSmithKline plc, Enanta Pharmaceuticals, Inc., Arbutus Biopharma Corporation, Vir Bio, Mirum Pharmaceuticals, Huahui Health, Aligos Therapeutics, Innovative Molecules and AiCuris Anti-infective Cures AG (Asahi Kasei, following its pending acquisition of AiCuris), among others. Additionally, we may face competition from currently available HBV treatments. Some of the competitive development programs from these companies may be based on scientific approaches that are similar to our approach, and others may be based on entirely different approaches. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization of products similar to ours or that otherwise target indications that we are pursuing.

Manufacturing

We currently rely on third-party manufacturers to supply the quantities of our investigational product candidates used in our clinical and nonclinical studies. We currently have no plans to establish any manufacturing facilities for our product candidates.

Human Capital Management

As of December 31, 2025, we had 73 total employees and contracts with a number of temporary contractors, consultants and CROs. The majority of our employees work out of our facility in South San Francisco, California. We also have a small number of remote employees spread across the United States and one remote employee in the UK.

We continually evaluate our needs and make strategic choices regarding whether to hire internal teams or outsource certain functions to CROs or contract manufacturing organizations (CMOs), as appropriate. We currently outsource our clinical study management to various CROs and utilize certain CMOs to manufacture both the drug substance and the drug product used in our ongoing and planned clinical studies.

We compete with both large and small companies in our industry for a limited number of qualified applicants to fill highly specialized needs. We generally target our base salaries and annual performance-based cash bonuses at the 50th percentile of our peers and our long-term equity incentive compensation, which all employees receive, between the 50th and 75th percentiles of our peers. In certain circumstances, we offer compensation above these levels, based on a candidate's experience, criticality, amount of responsibility and either individual or Company-wide performance. We routinely review our employees' base salaries to ensure they remain market competitive. Both annual

performance-based cash bonus targets and long-term equity compensation increase based on employees' levels of responsibility. We also offer comprehensive benefits packages to all of our employees, including: 100% Company-covered medical, dental and vision coverage for employees and their families; a 401k program with a Company match; a comprehensive employee assistance program, an employee stock purchase plan; and paid family leave. Our benefits packages also include paid time-off benefits, flexible spending plans, commuter benefits and life and long-term care benefits.

A large majority of our employees have advanced degrees, and we also offer an educational assistance program that reimburses employees up to a maximum amount per year for courses that directly enhance his or her area of professional work or contribute to his or her immediate career growth. This program demonstrates our commitment to analytical growth, enhanced knowledge and professional development.

Reverse Stock Split

On September 27, 2023, we received a letter from the Listing Qualifications Department of the Nasdaq Stock Market notifying us that, because the bid price for our common stock had closed below $1.00 per share for the prior 30 consecutive business days, we were not in compliance with Nasdaq Listing Rule 5450(a)(1), which is the minimum bid price requirement for continued listing on the Nasdaq Global Select Market. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we were provided a 180-calendar day period, or until March 25, 2024, to regain compliance with the minimum bid price requirement. To regain compliance with the Nasdaq Listing Rules, on January 31, 2024, our stockholders approved a reverse stock split of our common stock at a range of ratios between 1-for-7 to 1-for-17, and our board of directors approved the implementation of a reverse stock split at a ratio of 1-for-12 shares of our common stock (the Reverse Stock Split). The Reverse Stock Split was effective as of February 9, 2024, our common stock began trading on the Nasdaq Global Select Market on an as-split basis on February 12, 2024, and the Company regained compliance with the minimum bid price requirement of the Nasdaq Listing Rules on February 27, 2024, by having the closing bid price of our common stock exceed $1.00 for a minimum of ten consecutive trading days during the compliance period.

Corporate History

We were incorporated in Delaware in October 2005 under the name South Island Biosciences, Inc. (which was changed to Ventrus Biosciences, Inc. in April 2007). On July 11, 2014, we acquired Assembly Pharmaceuticals, Inc., a private company, through a merger with our wholly owned subsidiary (the Merger). In connection with the Merger, we changed our name from Ventrus Biosciences, Inc. to Assembly Biosciences, Inc.

Corporate Information

Our principal executive office is at Two Tower Place, 7th Floor, South San Francisco, California 94080. Our telephone number is (833) 509-4583.

Available Information

Our website address is www.assemblybio.com. We routinely post, or have posted, important information for investors on our website in the "Investors" section. We use this website as a means of disclosing material information in compliance with our disclosure obligations under Regulation FD. Accordingly, investors should monitor the "Investors" section of our website, in addition to following our press releases, SEC filings, presentations and webcasts. We make available free of charge through our website our press releases, Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all amendments to those reports as soon as reasonably practicable after electronically filed with or furnished to the SEC.

The information contained on our website is not a part of, and should not be construed as being incorporated by reference, into this report.

The reports filed with the SEC by us and by our officers, directors and significant stockholders are available for review on the SEC's website at www.sec.gov.

Item 1A. Risk Factors

You should carefully consider the following risk factors, together with all other information in this report, including our consolidated financial statements and notes thereto, and in our other filings with the SEC. If any of the following risks, or other risks not presently known to us or that we currently believe to not be material, develop into actual events, then our business, financial condition, results of operations or prospects could be materially adversely affected. If that happens, the market price of our common stock could decline, and stockholders may lose all or part of their investment.

Risks Related to Our Business

We have no approved products and depend on the future success of the product candidates in our research and development pipeline. We cannot be certain that we or our collaborators will be able to obtain regulatory approval for, or successfully commercialize, product candidates from our current pipeline or any other product candidates that we may subsequently identify, license or otherwise acquire.

We and our collaborators are not permitted to market or promote any products in the United States, Europe, China or other countries before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for our current product candidates. We have not submitted an NDA to the FDA or comparable applications to other regulatory authorities and do not expect to be in a position to do so in the near future.

All our product candidates are in clinical development or in varying stages of nonclinical development. Data supporting our clinical development programs are derived from nonclinical data that support our early stage clinical programs, which will determine whether larger, pivotal studies are appropriate. These pivotal studies are necessary to support regulatory approval, and it may be years before these studies are completed, if ever.

In addition to our current product pipeline, we may identify, license or otherwise acquire rights to other technologies or product candidates. Any such transactions would involve numerous risks, and we may be unsuccessful in entering into any such transactions or developing any such technologies or product candidates.

For these reasons, our drug discovery and development may not be successful, and we may be unable to continue clinical development of our product candidates and may not generate product approvals or product revenue, any of which could have a material adverse impact on our business, results of operations and financial condition.

We are not currently profitable and might never become profitable, and we will need additional financing to complete the development of any product candidates and fund our activities into the future.

We do not have any approved products, and we have a history of losses. We expect to continue to incur substantial operating and capital expenditures to advance our current product candidates through clinical development, continue research and discovery efforts to identify potential additional product candidates and seek regulatory approvals for our current and future product candidates. All operations and capital expenditures will be funded from cash on hand, securities offerings, debt financings and payments we may receive from out-licenses, collaborations or other strategic arrangements. Adverse geopolitical and macroeconomic developments, such as potential worsening global economic conditions or economic downturn, ongoing military conflicts, related sanctions, actual and anticipated changes in interest rates, economic inflation and the responses by central banking authorities to control such inflation, and tariffs or the imposition and enforceability of tariffs, trade wars, barriers or restrictions, or threats of such actions and the related uncertainty thereof including uncertainties regarding the ability to obtain refunds for previously paid tariffs that have subsequently been invalidated, could affect our ability to access capital as and when needed.

There is no assurance that we will be successful in raising any necessary additional capital on terms that are acceptable to us, or at all. If we are unable to develop and commercialize any product candidates and generate sufficient revenue or raise capital, we could be forced to reduce staff, delay, scale back or discontinue product development and clinical studies, forego business opportunities, cease operations entirely and sell, or otherwise transfer, all or substantially all of our remaining assets, which would likely have a material adverse impact on our business, results of operations, financial condition and share price.

We expect our collaboration with Gilead to be a critical part of the development, manufacture and commercialization of our product candidates. If this collaboration is unsuccessful, our business could be adversely affected.

In October 2023, we entered into the Gilead Collaboration Agreement with Gilead, whereby Gilead exclusively licensed to us its HPI program and NNPI program, while retaining opt-in rights to these programs, and has an option to take an exclusive license, on a program-by-program basis, to all of our other current and future pipeline programs during the collaboration term. In connection with the entry into the Gilead Collaboration Agreement, we and Gilead also entered into a common stock purchase agreement and an investor rights agreement, which were both amended in June 2024. Also in June 2024, we and Gilead subsequently entered into a securities purchase agreement and warrant agreement. In December 2024, Gilead purchased additional shares of our common stock at a premium pursuant to the terms of the common stock purchase agreement, and we amended the Gilead Collaboration Agreement in connection with an updated development plan for 6250. In August 2025, Gilead purchased additional shares of our common stock and warrants to purchase additional shares of our common stock. In December 2025, Gilead exercised its option and took an exclusive license to our HPI program, and in March 2026, Gilead declined to exercise its option to license 4334 or defer its option until completion of Phase 2 studies. Our agreements and relationship with Gilead pose a number of risks, including, but not limited to, the following:

- Conflicts may arise between us and Gilead, such as conflicts regarding the indications to pursue or concerning the clinical data supporting an opt-in decision, the commercial potential of any optioned investigational products, the interpretation of financial provisions or the ownership of intellectual property developed during the collaboration. Any such conflicts could slow or prevent the development or commercialization of our investigational products.
- If the collaboration with Gilead does not result in the successful development and commercialization of products or if Gilead terminates the Gilead Collaboration Agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, development of our investigational products could be delayed and we may need additional resources to develop our investigational products.
- We will be heavily dependent on Gilead for further development and commercialization of the investigational products from the programs that it opts into, including our HPI program, and transition of these programs to Gilead could delay these programs' clinical and approval timelines.
- We may not be successful in this collaboration due to various other factors, including our ability to demonstrate proof of concept in one or more clinical studies so that Gilead will exercise its option to these programs. In addition, even if we demonstrate clinical proof of concept of a candidate, Gilead may choose not to exercise its option.
- Gilead has the right to designate (and has designated) two directors for appointment to our board of directors pursuant to the terms of the investor rights agreement and owns approximately 28% of our outstanding common stock. Gilead also has the right to acquire additional shares in the open market, up to an amount resulting in Gilead owning a total of 35% of our outstanding common stock. As a result, Gilead may be able to exert significant influence over us.
- Gilead could independently develop, or develop with third parties, products that compete directly or indirectly with our investigational products if Gilead believes that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours.
- Because Gilead has an option to all our current, and future, pipeline programs during the collaboration term, it may be difficult for us to enter into new collaborations.

Nonclinical and clinical studies required for our product candidates are expensive and time-consuming and may fail to demonstrate the level of safety and efficacy necessary for product approval.

Before we or any commercial partners can obtain FDA approval (or other foreign approvals) necessary to sell any of our product candidates, we must show that each potential product is safe and effective. To meet these requirements, we must conduct extensive nonclinical and sufficient, well-controlled clinical studies.

The results of nonclinical studies may not be representative of the product candidates' behavior in a clinical setting and may not be predictive of the outcomes of our clinical studies. In addition, the results of early clinical studies of product candidates may not be predictive of the results of later-stage clinical studies.

Conducting nonclinical and clinical studies is a lengthy, time consuming and expensive process. The length of time

varies substantially according to the type, complexity, novelty, and intended use of the product candidate, and often can be several years or more. In addition, failure or delays can occur at any time during the nonclinical and clinical study process, resulting in additional operating expenses or harm to our business.

The commencement and rate of completion of clinical studies might be delayed by many factors, including, for example:

- delays in reaching agreement with regulatory authorities on study design;
- delays in reaching agreement on acceptable terms with prospective contract research organizations (CROs) and clinical study sites;
- failure to demonstrate efficacy or the emergence of unforeseen safety issues;
- insufficient quantities of qualified materials made using cGMP for use in clinical studies due to manufacturing challenges, delays or interruptions in the supply chain;
- slower than expected rates of participant recruitment or failure to recruit a sufficient number of eligible participants, which may be due to a number of reasons, including the size of the participant population, the proximity of participants to clinical sites, the eligibility criteria for the study, the design of the clinical study, and other potential drug candidates being studied;
- fewer available study sites and academic lab facilities due to changes in government funding of clinical research;
- delays in participants completing participation in a study or return for post-treatment follow-up for any reason, including, product side effects or disease progression;
- modification of clinical study protocols;
- problems with the integrity of data collected in the study;
- delays, suspension, or termination of clinical studies by the institutional review board or ethics committee responsible for overseeing the study at a particular study site; and
- government or other regulatory agency delays or clinical holds requiring suspension or termination of our clinical studies due to safety, tolerability or other issues related to our product candidates.

The failure of nonclinical and clinical studies to demonstrate safety and effectiveness of a product candidate for the desired indications, whether conducted by us or by a CRO, would harm the development of that product candidate and potentially other product candidates. This failure could cause us to abandon a product candidate and could delay development of other product candidates. Any delay in, or failure of, our nonclinical studies or clinical studies could delay, or preclude, the filing of our NDAs and comparable applications with the FDA and foreign regulatory agencies, as applicable, and materially harm our business, prospects, financial condition and results of operations.

We rely on CROs to conduct some of our nonclinical and clinical studies due to our lack of suitable facilities and resources. In addition, parts of our business are reliant on CROs, vendors, suppliers and other service providers in locations outside of the United States, including China.

We do not have sufficient facilities or resources to conduct all our anticipated nonclinical and clinical studies internally. As a result, we contract with CROs to conduct a significant portion of the nonclinical and clinical studies required for regulatory approval for our product candidates. Our reliance on CROs reduces our control over these activities but does not relieve us of our responsibilities. For example, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, including, in the case of clinical studies, CGPs, even if the study is conducted by a CRO. In the event CROs fail to perform their duties in such a fashion or we are unable to retain or continue with CROs on acceptable terms, we may be unable to complete our clinical studies and may fail to obtain regulatory approval for our product candidates.

In addition, these CROs may also have relationships with other entities, some of which may be our competitors. CRO personnel are not our employees, and except for remedies available to us under our agreements with such third parties, we cannot control whether they devote sufficient time and resources to our clinical and nonclinical studies. If these CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to

be replaced 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, including GCPs, or for other reasons, our research, nonclinical or clinical studies may be extended, delayed or terminated and we may not be able to obtain, or may be delayed in obtaining, regulatory approvals for our product candidates, any of which could materially harm our business, prospects, financial condition and results of operations.

Furthermore, we are exposed to a number of risks related to our CROs, vendors, suppliers and other service providers that are located outside of the United States, many of which may be beyond our control. These risks include:

- business interruptions resulting from geopolitical actions such as the war between Russia and Ukraine, the conflicts in the Middle East, including the recent hostilities involving Iran, and in Venezuela, tensions between China and Taiwan, as well as trade tension and/or the imposition and enforceability of tariffs (including tariffs that have been or may be in the future imposed by the United States and other countries and uncertainties regarding the ability to obtain refunds for previously paid tariffs that have subsequently been invalidated), other wars, acts of terrorism, natural disasters or outbreaks of disease;
- increased scrutiny or prohibitions on CROs located in foreign countries, including China;
- different regulatory requirements for drug approvals;
- different standards of care in various countries that could complicate the evaluation of our product candidates;
- different U.S. and foreign drug import and export rules;
- different reimbursement systems and different competitive drugs indicated to treat the indication for which our product candidates are being developed;
- reduced protection for intellectual property rights in certain countries;
- changes in trade, economic or other policies by the U.S. or foreign governments, which may result in new or unexpected changes in tariffs, trade wars, barriers or restrictions, or regulatory requirements;
- compliance with the United States Foreign Corrupt Practices Act (the FCPA) and other anti-corruption and anti-bribery laws;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes; and
- foreign currency fluctuations and compliance with foreign currency exchange rules, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country.

The ongoing shutdown of the U.S. Department of Homeland Security (DHS) could prevent the U.S. Customs and Border Protection (CBP) from performing normal business functions on which the operation of our business relies, which could negatively impact our business.

The ongoing DHS shutdown has resulted in agencies, such as CBP, have been deemed "essential" and are continuing to operate. Disruptions at the CBP and other agencies, including furloughs and reductions in workforce, are subject to the political process, which is inherently unpredictable.

Although we have yet to encounter significant delays at ports of entry due to the shutdown, in past government shutdowns, CBP delays were common in areas requiring manual review or discretionary approvals. If the current shutdown continues, the resulting delays and other disruptions could have a material adverse effect on our business.

Our clinical studies require shipping clinical samples from our clinical study sites around the world to the United States for analysis and processing. CBP delays in import operations and CBP delays in inspecting imports, including difficulties with these samples clearing customs, may delay or otherwise adversely affect our ongoing clinical studies and their timelines, many of which have been communicated publicly.

Top-line, preliminary or interim data may not accurately reflect the final results of a particular study.

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

In addition to top-line, preliminary or interim results, the information that we may publicly disclose regarding a particular nonclinical or clinical study is based on extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure. In addition, any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular drug, drug candidate or our business. If the top-line, preliminary or interim data that we report differ from final results, or if others, including regulatory authorities, disagree with, or do not accept, the data or conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed or delayed, which could harm our business, financial condition, operating results or prospects.

We rely on third parties to formulate and manufacture our product candidates and products that we study in combination with our product candidates. Our use of third parties may increase the risk that we will not have sufficient quantities of our product candidates or other products on time or at an acceptable cost.

We rely on third-party manufacturers to supply the quantities of our investigational product candidates used in our clinical and nonclinical studies. If any product candidate we develop or acquire in the future receives FDA or other regulatory approval, we expect to continue our reliance on one or more third-party contractors to manufacture our products. If, for any reason, we are unable to rely on any third-party sources we have identified to manufacture our product candidates, we would need to identify and contract with additional or replacement third-party manufacturers to manufacture drug substance and drug product for nonclinical, clinical and commercial purposes. We may be unsuccessful in identifying additional or replacement third-party manufacturers, or in negotiating acceptable terms with any that we do identify. If we are unable to establish and maintain manufacturing capacity, the development and sales of our products and our financial performance may be materially and adversely affected.

We are exposed to the following risks with respect to the manufacture of our product candidates:

- We will need to identify manufacturers for commercial supply on acceptable terms, which we may be unable to do because the number of potential manufacturers is limited, and the FDA must evaluate and approve any new or replacement contractor.
- Any third-party manufacturers with whom we contract might be unable to formulate and manufacture our product candidates in the volume and quality required to meet our nonclinical, clinical and, if approved, commercial needs in a timely manner.
- Any third-party manufacturers with whom we contract might be unable to manufacture or obtain from other third parties the active pharmaceutical ingredient needed to manufacture the finished dosage form of our product candidates.
- Any third-party manufacturers with whom we contract might not perform as agreed or might not remain in the contract manufacturing business for the time required to supply our products.
- One or more of any third-party manufacturers with whom we contract could be foreign, which increases the risk of shipping delays and adds the risk of import restrictions.
- We do not have complete control over, and cannot ensure, any third-party manufacturers' compliance with cGMP and other government regulations and corresponding foreign requirements, including periodic FDA and state regulatory inspections.

- We may be required to obtain intellectual property rights from third parties to manufacture our product candidates, and if any third-party manufacturer makes improvements in the manufacturing process for our product candidates, we may not own, or may have to share, the intellectual property rights to the innovation.
- We may be required to share our trade secrets and know-how with third parties, increasing risk of misappropriation or disclosure of our intellectual property by or to third parties.
- When contracting with third-party manufacturers, we might compete with other companies for access to these manufacturers' facilities and might be subject to manufacturing delays if the manufacturers give other clients higher priority than we are given.

Each of these risks could delay our development efforts, nonclinical studies and clinical studies or the approval, if any, of our product candidates by the FDA or applicable non-U.S. regulatory authorities and the commercialization of our product candidates. Furthermore, workforce reductions at the FDA, and any future reductions of staffing or other resources at the FDA, may lead to delays in inspecting facilities and, in turn, delayed FDA approvals for manufacturing changes. This could result in higher costs or deprive us of potential product revenues and materially harm our business, financial condition and results of operations.

If we lose key management personnel and cannot recruit and retain similarly qualified replacements, our business may materially suffer.

We are highly dependent on the services of our executive officers. Our employment agreements with our executive officers do not ensure their retention. We do not currently maintain, nor do we intend to obtain in the future, "key person" life insurance that would compensate us in the event of the death or disability of any of the members of our management team. Our executive officers are critical to our success, and unanticipated loss of any of these key employees could have a material adverse impact on our business, financial condition and results of operations.

Our collaboration partners might delay, prevent or undermine the success of our product candidates.

Our operating and financial strategy for the development, nonclinical and clinical testing, manufacture and commercialization of drug candidates heavily depends on collaborating with corporations, academic institutions, licensors, licensees, and other parties. However, there can be no assurance that we will successfully establish or maintain these collaborations. If a collaboration is terminated, replacement collaborators might not be available on attractive terms, or at all.

The activities of any collaborator, including Gilead, will not be within our control and might not be within our power to influence. There can be no assurance that any collaborator will perform its obligations to our satisfaction or at all, that we will derive any revenue or profits from these collaborations, or that any collaborator will not compete with us. If any collaboration, including the Gilead Collaboration, is unsuccessful, we might require substantially greater capital to undertake development and marketing of our proposed products and might not be able to develop and market these products effectively, if at all. In addition, if Gilead does not opt-in to a program, it might lead to significant delays in introducing proposed products into certain markets and/or reduced sales of proposed products in such markets.

We may not be successful in establishing and maintaining collaborations, which could adversely affect our ability to develop certain of our product candidates.

Developing pharmaceutical products, conducting clinical studies, obtaining regulatory approval and commercializing those products are expensive and lengthy undertakings that require significant resources and expertise. We may seek to enter into collaborations, including licensing or partnering arrangements, with other companies to support the development and commercialization of any or multiple of our programs that Gilead declines to opt into or to obtain financing or share costs on these programs. If we are unable to enter into such collaborations on acceptable terms, if at all, we may be unable to advance certain of our product candidates through further nonclinical or clinical development. We expect to face competition in seeking appropriate partners. Moreover, collaboration arrangements are complex and time consuming to negotiate, document and implement and they may require substantial resources to maintain. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements for the development of our product candidates that Gilead declines to opt into.

If we are unable to reach agreement on favorable terms with a suitable collaboration partner for any of our product candidates that Gilead declines to opt into, we may need to limit the number of our product candidates to advance through further nonclinical or clinical development. Failure to achieve such successful collaborations would limit our

options for support of the development and commercialization of our programs and for financing and would likely have a material adverse impact on our business, results of operations, financial condition and share price.

We rely on data provided by third parties that has not been independently verified and could prove to be false, misleading, or incomplete.

We rely on third-party vendors, scientists, investigators and collaborators to provide us with significant data and other information related to our projects, nonclinical studies and clinical studies, and our business. If these third parties provide inaccurate, misleading, or incomplete data, our business, prospects, and results of operations could be materially and adversely affected.

Research, development and commercialization goals, including data releases, may not be achieved in the timeframes that we publicly estimate, which could have an adverse impact on our business and could cause our stock price to decline.

We set goals and make public statements regarding our expectations on timing of certain accomplishments, developments and milestones under our research and development programs. The actual timing of these events can vary significantly due to a number of factors, including, the amount of time, effort and resources committed to our programs by us and any collaborators and the uncertainties inherent in the clinical development and regulatory approval process. As a result, there can be no assurance that we or any collaborators will initiate or complete clinical development activities, make regulatory submissions or receive regulatory approvals as planned or that we or any collaborators will be able to adhere to our current schedule for the achievement of key milestones under any of our programs. If we or any collaborators fail to achieve one or more of the milestones as planned, or Gilead does not opt-in to any of our programs, our business could be materially and adversely affected, and the price of our common stock could decline.

Developments by competitors might render our product candidates or technologies obsolete or non-competitive.

The pharmaceutical and biotechnology industries are intensely competitive. In addition, the clinical and commercial landscapes for recurrent genital herpes, HDV, HBV and transplant-related herpesviruses are rapidly changing; we expect new data from commercial and clinical-stage products to continue to emerge. We compete with organizations, some with significantly more resources, who are developing competitive product candidates. If our competitors develop effective treatments for recurrent genital herpes, HDV, HBV and transplant-related herpesviruses or any other indication or field we might pursue, and successfully commercialize those treatments, our business and prospects could be materially harmed.

Other companies with products using the same or similar mechanisms of action as ours may produce negative clinical data, which would adversely affect public and clinical communities' perceptions of our product candidates, and may negatively impact regulatory approval of, or demand for, our potential products.

Negative data from clinical studies using a competitor's product candidates with the same or similar mechanisms of action (MOA) as ours could adversely impact the perception of the therapeutic use of our product candidates and our ability to enroll individuals in clinical studies.

The clinical and commercial success of our potential products will depend in part on the public and clinical communities' acceptance of novel classes of product candidates. Moreover, our success depends upon physicians prescribing, and their patients being willing to receive, treatments that involve the use of our product candidates we may develop in lieu of, or in addition to, existing treatments with which they are already familiar and for which more clinical data may be available. Adverse events (AEs) in our nonclinical or clinical studies or those of our competitors or of academic researchers utilizing the same MOA as our product candidates, even if not ultimately attributable to our product candidates, and any resulting publicity could result in increased governmental regulation, larger, more complex, or an increased number of clinical trial requirements, unfavorable public perception, potential regulatory delays in the testing or approval of our product candidates, stricter labeling requirements for our product candidates that are approved, if any, and a decrease in demand for any such products.

Significant disruptions of information technology systems or breaches of data security, including cybersecurity incidents, could materially and adversely affect our business, results of operations and financial condition.

We collect and maintain information in digital form and are increasingly dependent on information technology systems and infrastructure to operate our business. In the ordinary course of our business, we collect, store and transmit large

amounts of confidential information, including trade secrets, other proprietary business information and confidential personal data. We rely on information technology systems that we or our third-party providers operate to process, transmit and store electronic information and otherwise to conduct our day-to-day operations (including confidential business, personal and patient health information in connection with our preclinical and clinical studies and our employees), which information technology systems may become subject to cyberattacks and other security breaches, and system outages. The information technology systems and infrastructure of our current and any future collaborators, contractors and consultants and other third parties on which we rely, are also vulnerable to such incidents.

The risk of a cybersecurity incident or security breach or disruption, particularly through cyberattacks or cyber intrusion, has escalated as the frequency, intensity and sophistication of attempted attacks and intrusions from around the world have increased, become increasingly difficult to detect and could be enhanced or facilitated by artificial intelligence. In addition, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches. A successful cyberattack could cause serious negative consequences for us, including, without limitation, the disruption of operations, the theft, misappropriation, destruction or other compromises of confidential or proprietary information (including financial information, corporate strategic plans, trade secrets and other intellectual property and data), improper access to, use or disclosure of personal and patient health information, other misappropriation of assets, and financial loss. Although we devote resources to protect our information systems, we realize that cyberattacks remain a threat, and there can be no assurance that our efforts (or those of our employees, contractors, consultants and the third-party providers on which we rely) will prevent security breaches that would result in business, legal, financial or reputational harm to us, or would have a material adverse effect on our results of operations and financial condition. In addition, although we carry cyber insurance, in the event of a material security incident, such coverage may not be sufficient to cover all losses. Any failure to prevent or mitigate security breaches or improper access to, use of, or disclosure of our clinical data or patients' personal data could result in significant liability under various U.S. state and federal laws and regulations and laws of foreign jurisdictions regarding data privacy and security (or require notification to governmental agencies, the media or individuals pursuant to such laws) and may cause a material adverse impact to our reputation, affect our ability to use collected data, conduct new studies and potentially disrupt our business.

Our internal computer systems, or those of our third-party CROs or other contractors or consultants, may fail or suffer other disruptions, which could result in a material disruption of our current or future product candidates' development programs. Despite the implementation of security, business continuity and back-up measures, in addition to cyberattacks and security incidents described above, our internal computer systems and those of our third-party CROs and other contractors and consultants are vulnerable to damage from natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such system failure, or accident to date, if such an event were to occur and cause interruptions in our operations (or those of our business partners or other third parties on which we rely), it could result in a material disruption of our programs. For example, any loss of clinical study data from completed or ongoing or planned clinical studies 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 such disruption results in a loss of or damage to our data or applications, other data or applications relating to our technology or current or future product candidates, or inappropriate disclosure of confidential or proprietary information, we could incur liabilities and the further development of our current or future product candidates could be delayed.

Our ability to use our net operating loss and credit carryforwards and certain other tax attributes may be limited.

We have net operating loss carryforwards due to prior period losses generated before January 1, 2024, which if not utilized, will begin to expire in 2029 for net operating loss carryforwards prior to 2018. If we are unable to generate sufficient taxable income to utilize our net operating loss carryforwards, pre-2018 carryforwards could expire unused and be unavailable to offset future income tax liabilities.

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the Code), a corporation that undergoes an "ownership change" (generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period) is subject to annual limitations on its ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post-change income or taxes. We have experienced ownership changes in the past, most recently in August 2025, and future equity issuances may result in additional ownership change. Accordingly, some of our net operating losses or credits could expire unutilized, and our ability to utilize our net operating losses or credits to offset U.S. federal taxable income could be limited, which would result in increased future tax liability to us. We may also be subject to similar limitations at the state level.

Risks Related to Our Regulatory and Legal Environment

We are and will be subject to extensive and costly government regulation, and the failure to comply with these regulations may have a material adverse effect on our operations and business.

Our product candidates are subject to extensive and rigorous domestic government regulation, including regulation by the FDA, the Centers for Medicare and Medicaid Services, other divisions of the U.S. Department of Health and Human Services (HHS), the U.S. Department of Justice, state and local governments, and their respective foreign equivalents. Both before and after approval of any product, we and our collaborators, suppliers, contract manufacturers and clinical investigators are subject to extensive regulation by governmental authorities in the United States and other countries, covering, among other things, testing, manufacturing, quality control, clinical studies, post-marketing studies, labeling, advertising, promotion, distribution, import and export, governmental pricing, price reporting and rebate requirements. Failure to comply with applicable requirements could result in one or more of the following actions: warning or untitled letters; unanticipated expenditures; delays in approval or refusal to approve a product candidate; voluntary or mandatory product recall; product seizure; interruption of manufacturing or clinical studies; operating or marketing restrictions; injunctions; criminal prosecution and civil or criminal penalties, including fines and other monetary penalties; exclusion from federal health care programs such as Medicare and Medicaid; adverse publicity; and disruptions to our business.

If we or our collaborators obtain regulatory approval for a particular product, the approval might limit the intended medical uses for the product, limit our ability to promote, sell, and distribute the product, require that we conduct costly post-marketing surveillance, and/or require that we conduct ongoing post-marketing studies. Once obtained, any approvals might be withdrawn, including, for example, if there is a later discovery of previously unknown problems with the product, such as a previously unknown safety issue. If we, our collaborators, our contractors or our contract manufacturers fail to comply with applicable regulatory requirements at any stage during the regulatory process, such noncompliance could result in delays in the approval of applications or supplements to approved applications, refusal by a regulatory authority (including the FDA) to review pending marketing authorization applications or supplements to approved applications, untitled letters or warning letters, fines, import and export restrictions, product recalls or seizures, injunctions, total or partial suspension of production, civil penalties, withdrawals of previously approved marketing authorizations, recommendations by the FDA or other regulatory authorities against governmental contracts, and/or criminal prosecutions.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we or our collaborators are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

We, or any current or future collaborators, cannot assure you that we will receive the approvals necessary to commercialize for sale any of our product candidates, or any product candidate we acquire or develop in the future. We will need FDA approval to commercialize our product candidates in the United States and approvals from applicable regulatory authorities in foreign jurisdictions to commercialize our product candidates in those jurisdictions. To obtain FDA approval of any product candidate, we must submit to the FDA an NDA demonstrating that the product candidate is safe and effective for its intended use. This requires significant research, nonclinical studies, and clinical studies. Satisfaction of the FDA’s regulatory requirements typically takes many years, depends upon the type, complexity and novelty of the product candidate and requires substantial resources for research, development and testing. We cannot predict whether our research and clinical approaches will result in drugs that the FDA considers safe and effective for their indicated uses. The FDA has substantial discretion in the approval process and might require us to conduct additional nonclinical and clinical testing, perform post-marketing studies or otherwise limit or impose conditions on any approval we obtain.

The ability of the FDA to review and approve new products has been in the past and may in the future be affected by a variety of factors, including government budget and funding levels, authorization and payment of user fees, the ability to hire and retain key personnel, as well as other statutory, regulatory and policy changes. In addition, funding of other government agencies that support research and development activities that pertain to FDA review, such as research to understand new technologies or establish new standards, can shift in response to changing administrative policies and priorities. Such policy shifts, including, for example, the recent efforts to downsize the federal workforce by restructuring the HHS and eliminating positions at the FDA, including teams critical to the FDA's ability to conduct regular inspections, reviews and other regulatory activities, such as issuing guidance for industry and regulations, and

other federal agencies, may affect the timelines, completeness or duration of the FDA review process. In addition, the HHS may change the user fee reauthorization process or fail to reauthorize user fee programs. As a result, average review times at the FDA may fluctuate, and the outcome of any such review process may be impacted. A prolonged government shutdown or a widespread freeze on federal funding could also significantly impact the ability of the FDA to timely review and process our regulatory submissions and the National Institutes of Health to conduct research or provide grants, or cause other agencies that support the FDA to slow their work. In addition, if future legislation or administrative action or changes in FDA policy prevent the FDA or other regulatory authorities from conducting routine inspections, reviews, or other regulatory activities, 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. Delays in obtaining regulatory approvals might: delay commercialization of, and our ability to derive product revenues from, our product candidates; impose costly procedures on us; and diminish any competitive advantages that we might otherwise enjoy.

Even if we comply with all FDA requests, the FDA might ultimately reject one or more of our NDAs. We cannot be sure that we will ever obtain regulatory approval and commercialize any of our current or future product candidates. In foreign jurisdictions, we are subject to regulatory approval processes and risks similar to those associated with the FDA described above. We cannot assure you that we will receive the approvals necessary to commercialize our product candidates for sale outside the United States.

We and our third-party partners and service providers are subject to stringent privacy laws, information security laws, regulations, policies and contractual obligations related to data privacy and security, and compliance with such laws, regulations, policies and contractual obligations could result in additional costs and liabilities to us and failure to comply could adversely affect our business, financial condition, results of operations and prospects.

We maintain and process certain confidential, sensitive, or personal information in the operation of our business, and rely on certain third-party vendors to process confidential, sensitive or personal information on our behalf, including in the conduct of our clinical trials. We and our third party partners and service providers, including our CROs and other vendors and contractors, are subject to data privacy and security laws and regulations that govern the collection, transmission, storage, use, processing, destruction, retention and security of personal information, including additional laws or regulations relating to health information. The legislative and regulatory landscape for privacy and data protection continues to evolve in jurisdictions worldwide, and these laws may at times be conflicting. It is possible that these laws may be interpreted or applied in a manner that is inconsistent with the practices we or our third party partners maintain, and any of our efforts to comply with the evolving data protection rules may be unsuccessful. Neither we nor our third party partners can guarantee that we or they are and have been in compliance with all applicable data privacy and protection laws, rules regulations, policies and standards. We may need to devote significant resources to seek to understand and comply with this changing landscape, and it is possible that these ongoing compliance efforts may be costly and require modifications to our policies, procedures and systems over time. Failure, or perceived failure, by us or our third-party partners and service providers to comply with laws and regulations regarding privacy and security of personal information could result in penalties under such laws, such as orders requiring a change in business practices, claims for damages or other liabilities, government investigations and enforcement actions, litigation and significant costs for remediation, any of which could adversely affect our business. Even if it is determined that there was no violation of these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity. Any resulting enforcement actions against us or our third party partners could lead to the imposition of fines, criminal prosecution of employees, claims for damages by affected individuals and reputational damage and loss of goodwill. Additionally, if we and any CROs or third parties we use to conduct clinical trials, are unable to properly protect the privacy and security of personal information, including protected health information, we and they could be found to have breached our and their contracts with certain third parties.

There are numerous U.S. federal and state laws and regulations related to the privacy and security of personal information. In particular, the Health Insurance Portability and Accountability Act (HIPAA), as amended by HITECH and their respective implementing regulations, establish privacy and security standards for Covered Entities and Business Associates (as defined by HIPAA) that limit the use and disclosure of individually identifiable health information, or protected health information, and require the implementation of administrative, physical and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity and availability of electronic protected health information. We do not believe that we are currently acting as a covered entity or business associate under HIPAA and thus are not directly subject to its requirements or penalties. However,

we may obtain health information from third parties, including research institutions from which we obtain clinical trial data, that are subject to privacy and security requirements under HIPAA. Determining whether protected health information has been handled in compliance with applicable privacy standards and contractual obligations can be complex and may be subject to changing interpretation. If we or our third party partners fail to comply with applicable privacy laws, including applicable HIPAA privacy and security standards, we could face civil and criminal penalties. HHS enforcement activity can result in financial liability and reputational harm, and responses to such enforcement activity can consume significant internal resources; the HHS also has discretion to impose penalties without attempting to first resolve violations. In addition, state attorneys general are authorized pursuant to certain federal and state laws to bring civil actions seeking either injunctions or damages in response to violations that threaten the privacy of state residents. We cannot be sure how these laws and regulations will be interpreted, enforced or applied to our operations or the operations of our third party partners.

Certain U.S. state laws may be more stringent or broader in scope, or offer greater individual rights, with respect to sensitive and personal information than international, federal, or other state laws, and such laws may differ from each other, which may complicate compliance efforts. For example, in June 2018, California enacted the California Consumer Privacy Act (CCPA), which broadly defines personal information, gives California residents expanded privacy rights and protections, including the right to access and delete certain personal information, as well as the right to opt-out of certain sales of personal information, and provides for civil penalties for violations and a private right of action for data breaches. Additional states have passed privacy laws, such as the Virginia Consumer Data Protection Act and the Colorado Privacy Act, which are similar to the CCPA. Such new privacy laws add further complexity in interpreting and implementing data privacy requirements and restrictions and thus create additional potential legal risk, require additional investment in resources for compliance programs, and could impact business strategies and the availability of previously useful data. This complexity applies to data security as well. Certain other states, including California, Massachusetts and Nevada have adopted laws requiring the implementation of certain security measures to protect personal information, and all 50 states and the District of Columbia, Puerto Rico, the U.S. Virgin Islands and Guam have adopted laws including obligations to provide notification of security breaches of computer databases that contain personal information to affected individuals, state officers and others. We may also be subject to U.S. federal rules, regulations and guidance with respect to data privacy and security practices. According to the Federal Trade Commission (FTC), failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, 15 U.S.C § 45(a). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. These federal and state laws regarding data privacy and security may differ from one another, and the interplay between them may be subject to varying interpretations by courts and government agencies, increasing our costs of compliance and exposing us to potential legal risk.

In the European Union (EU), the processing of personal data, including personal health data, is governed by the provisions of the EU General Data Protection Regulation (EU GDPR), in addition to other applicable laws and regulations. The EU GDPR, together with national legislation, regulations and guidelines of the EU Member States governing the processing of personal data, impose strict obligations with respect to, and restrictions on, the collection, use, retention, protection, disclosure, transfer and processing of personal data. The EU GDPR also imposes strict rules on the transfer of personal data to countries outside the EU that are not deemed to have adequate protections for personal information, including the United States. The EU GDPR authorizes fines for certain violations that are in addition to any civil litigation claims by data subjects. Separately, Brexit has led and could lead to further legislative and regulatory changes and may increase our compliance costs. Data processing in the United Kingdom (UK) is governed by the UK General Data Protection Regulation (UK GDPR), creating two parallel regimes, each of which authorizes similar fines and other potentially divergent enforcement actions for certain violations. Failure to comply with the EU GDPR or the UK GDPR can result in significant fines and other liability, including, under the EU GDPR, fines of up to €20 million (or £17.5 million under the UK GDPR) or four percent (4%) of global revenue, whichever is greater.

Other jurisdictions worldwide are similarly introducing or enhancing privacy and data security laws, rules and regulations, which could increase our compliance costs and the risks associated with noncompliance. Compliance with data protection laws and regulations in the U.S. and internationally could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability

to operate in certain jurisdictions. Although we work to comply with applicable laws, regulations and standards, our contractual obligations and other legal obligations, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another, and may conflict with one another or other legal obligations with which we must comply. Any failure or perceived failure by us or our employees, representatives, contractors, consultants, CROs, collaborators, development partners or other third party partners and service providers to comply with such requirements or adequately address privacy and security concerns, even if unfounded, could have a material adverse effect on our business, financial condition, results of operations and prospects. We cannot guarantee that we and our employees, representatives, contractors, consultants, CROs, collaborators, development partners and other third parties on whom we rely are, and will be, in compliance with all applicable international laws and regulations as they are enforced now or as such laws and regulations evolve or are interpreted.

We and our collaborators may be subject, directly or indirectly, to applicable U.S. federal and state anti-kickback, false claims laws, physician payment transparency laws, other fraud and abuse laws or similar healthcare and security laws and regulations, and health information privacy and security laws, which could expose us or them to criminal sanctions, civil penalties, exclusion or suspension from federal and state healthcare programs, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and others play a primary role in the recommendation and prescription of any products for which we obtain regulatory approval. If we obtain FDA approval for any of our drug candidates and begin commercializing those drugs in the United States, our operations may be subject to various federal and state fraud and abuse laws, including the federal Anti-Kickback Statute, the federal False Claims Act, and physician payment sunshine laws and regulations. Additionally, we are subject to state and non-U.S. equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope and may apply regardless of the payor. These laws may impact, among other things, our proposed sales, marketing and education programs. For example, there are federal and state healthcare laws and regulations that govern prescription drug marketing practices, including off-label promotion, and increased scrutiny of direct-to-consumer advertisements. In addition, we may be subject to patient privacy regulation by both the federal government and the states and foreign jurisdictions in which we conduct our business. If we fail to comply with any applicable federal, state or foreign legal requirement, we could be subject to penalties.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

Violations of these laws may be punishable by criminal and/or civil sanctions, including penalties, fines and/or exclusion or suspension from federal and state healthcare programs such as Medicare and Medicaid and debarment from contracting with the U.S. government. In addition, private individuals have the ability to bring actions on behalf of the U.S. government under the federal False Claims Act as well as under the false claims laws of several states.

If any of the physicians or other providers or entities with whom we expect to do business with are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs, which may also adversely affect our business.

We face the risk of product liability claims and might not be able to obtain insurance.

Our business exposes us to the risk of product liability claims that are inherent in drug development. If the use of one or more of our product candidates or approved drugs, if any, harms people, we might be subject to costly and damaging product liability claims brought against us by clinical study participants, consumers, health care providers, pharmaceutical companies or others selling our products. Our inability to obtain sufficient product liability/clinical study insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of pharmaceutical products we develop. We cannot predict all of the possible harms or side effects that might result and, therefore, the amount of insurance coverage we maintain might not be adequate to cover all liabilities we might incur. If we are unable to obtain insurance at an acceptable cost or otherwise protect against potential product liability claims, we will be exposed to significant liabilities, which might materially and adversely affect our business and financial position. If we are sued for any injury allegedly caused by our products, our liability could exceed our total assets and our ability to pay. Any successful product liability claims brought against us would decrease our cash and may adversely affect our business, stock price and financial condition.

We might be exposed to liability claims associated with the use of hazardous materials and chemicals.

Our research, development and manufacturing activities and/or those of our third-party contractors might involve the controlled use of hazardous materials and chemicals. Although we will strive to have our safety procedures, and those of our contractors, comply with federal, state and local laws and regulations for using, storing, handling and disposing of these materials, we cannot completely eliminate the risk of accidental injury or contamination from these materials. In the event of such an accident, we could be held liable for any resulting damages, and any liability could materially and adversely affect our business, financial condition and results of operations. In addition, the federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous or radioactive materials and waste products might require us to incur substantial compliance costs that could materially and adversely affect our business, financial condition and results of operations.

Our employees, independent contractors, consultants, collaborators and CROs may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements for which we may be held responsible and which could result in significant liability for us and harm our reputation.

We are exposed to the risk of fraud or other misconduct, including failure to:

- comply with applicable regulations of, and provide accurate information to, the FDA or comparable foreign regulatory authorities;
- comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities;
- comply with the FCPA, the U.K. Bribery Act 2010, the PRC Criminal Law, the PRC Anti-unfair Competition Law and other anti-bribery and trade laws;
- report financial information and data accurately; or
- disclose unauthorized activities.

Misconduct could also involve the improper use or misrepresentation of information obtained during clinical studies, creating fraudulent data in our nonclinical studies or clinical studies or illegal misappropriation of product materials, which could result in regulatory sanctions, delays in clinical studies, or serious harm to our reputation.

It is not always possible to identify and deter misconduct. 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 comply with such laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could harm our business, results of operations, financial condition and cash flows, including through the imposition of significant fines or other sanctions.

Risks Related to Our Intellectual Property

Our business depends on protecting our intellectual property.

If we, our licensors and our collaborators do not obtain protection for our respective intellectual property rights, our competitors might be able to take advantage of our research and development efforts to develop competing drugs. Our success, competitive position and future revenues, if any, depend in part on our ability and the abilities of our licensors to obtain and maintain patent protection for our products, methods, processes and other technologies, to preserve our trade secrets, to prevent third parties from infringing on our proprietary rights and to operate without infringing the proprietary rights of third parties.

We rely upon a combination of patents, trade secret protection and contractual arrangements to protect the intellectual property related to our technologies. We will only be able to protect our products and proprietary information and technology by preventing unauthorized use by third parties to the extent that our patents, trade secrets, and contractual positions allow us to do so. We cannot be certain that we will secure any rights to any issued patents with claims that cover any of our proprietary product candidates and technologies. The patent prosecution process is expensive and time-consuming, and we may be unable to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. We could fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection or before our competitors secure patents covering such discoveries. The patent process also is subject to numerous risks and uncertainties, and there can be no assurance that we will be successful in protecting our products by obtaining and defending patents.

Composition-of-matter patents relating to the active pharmaceutical ingredient are generally considered to be the strongest form of intellectual property protection for pharmaceutical products. Such patents provide protection not limited to any one method of use. Method-of-use patents protect the use of a product for the specified method(s) and do not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Formulation patents protect the formulation of a product and do not prevent a competitor from making and marketing a product that has an identical active pharmaceutical ingredient to our product if the product is formulated differently than the patented formulation. We rely on a combination of these and other types of patents to protect our product candidates, and there can be no assurance that our intellectual property will create and sustain the competitive position of our product candidates.

Biotechnology and pharmaceutical product patents involve highly complex legal and scientific questions. Any patent applications that we own or license may fail to result in issued patents. In addition, the U.S. Patent and Trademark Office (USPTO) and patent offices in other jurisdictions often require that patent applications concerning pharmaceutical and/or biotechnology-related inventions are limited or narrowed substantially to cover only the specific innovations exemplified in the patent application, thereby limiting the scope of protection against competitive challenges. As a result, even if we or our licensors obtain patents, the patents might be substantially narrower than anticipated.

If patents successfully issue from our applications, third parties may challenge their validity or enforceability, which may result in such patents being narrowed, invalidated, or held unenforceable. Even if our patents and patent applications are not challenged by third parties, those patents and patent applications may not prevent others from designing around our claims and may not otherwise adequately protect our product candidates.

Patent and other intellectual property protection is crucial to the success of our business and prospects, and there is a substantial risk that such protections, if obtained, will prove inadequate. The legal systems of certain countries, including China, do not always favor the enforcement of patents, trade secrets, and other intellectual property rights, particularly those relating to pharmaceutical and biotechnology products, which could make it difficult for us to stop infringement of our patents, misappropriation of our trade secrets, or marketing of competing products in violation of our proprietary rights.

Beyond the protection afforded by patents, we seek to rely on trade secret protection and confidentiality agreements to protect proprietary know-how, information, or technology that is not covered by our patents. Although our agreements require all of our employees to assign their inventions to us, and we require all of our employees, consultants, advisors, collaborators, contractors and any third parties who have access to our trade secrets, proprietary know-how and other confidential information and technology to enter into appropriate confidentiality agreements, we cannot be certain that our trade secrets, proprietary know-how and other confidential information and technology will not be subject to unauthorized disclosure or that our competitors will not otherwise gain access to or independently develop substantially equivalent trade secrets, proprietary know-how and other information and technology. If we are unable to prevent unauthorized disclosure of our intellectual property related to our product candidates and technology to third parties, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business and operations.

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

We may in the future be involved in legal or administrative proceedings involving our intellectual property, including infringement of our intellectual property by third parties. These lawsuits or proceedings likely would be expensive, consume time and resources and divert the attention of managerial and scientific personnel, even if we were successful in stopping the infringement of such patents. There is a risk that these proceedings will decide that such patents or other intellectual property rights are not valid and that we do not have the right to stop the other party from using our inventions. There is also the risk that, even if the validity of such patents is upheld, the court or administrative agency will refuse to stop the other party on the ground that such other party's activities do not infringe our rights to such patents. If we were not successful in defending our intellectual property, our competitors could develop and market products based on our discoveries, which may reduce demand for our products.

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

Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. Our competitors may have filed, and may in the future file, patent applications covering products and technologies similar to ours. Any such patent application may have priority over our patent applications, which could further require us to

obtain rights from third parties to issued patents covering such products and technologies. We cannot guarantee that the manufacture, use or marketing of any product candidates that we develop will not infringe third-party patents.

If a patent infringement suit were brought against us, we may be forced to stop or delay developing, manufacturing, or selling potential products that are claimed to infringe a third party's intellectual property, unless that third party grants us rights to use its intellectual property. In such cases, we may be required to obtain licenses to patents or proprietary rights of others to continue development, manufacture or sale of our products. If we are unable to obtain a license or develop or obtain non-infringing technology, or if we fail to defend an infringement action successfully, or if we are found to have infringed a valid patent, we may incur substantial costs and monetary damages, encounter significant delays in bringing our product candidates to market and be precluded from manufacturing or selling our product candidates, any of which could harm our business significantly.

The cost of maintaining our patent protection globally is high and requires continuous review and compliance. We may not be able to effectively maintain our intellectual property position throughout the major markets of the world.

The USPTO and foreign patent authorities require maintenance fees, payments and continued compliance with a number of procedural and documentary requirements. Noncompliance may result in abandonment or lapse of patents or patent applications and a partial or complete loss of patent rights in the relevant jurisdiction. Such a loss could reduce royalty payments for lack of patent coverage from our collaboration partners or may result in competition, either of which could have a material adverse effect on our business.

We have made, and will continue to make, certain strategic decisions in balancing the costs and the potential protections afforded by the patent laws of certain countries. As a result, we may not be able to prevent third parties from practicing our inventions in all countries, or from selling or importing products made using our inventions in and into the United States or other countries. Third parties may use our technologies in territories in which we have not obtained patent protection to develop their own products and may infringe our patents in territories which provide inadequate enforcement mechanisms. Such third-party products may compete with our product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Such competition could materially and adversely affect our business and financial condition.

Intellectual property rights do not address all potential threats to any competitive advantage we may have.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and intellectual property rights may not adequately protect our business or permit us to maintain our competitive advantage. The following examples are illustrative:

- Others may be able to make compounds that are the same as, or similar to, our current or future product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed.
- We or any of our licensors or strategic partners might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or have exclusively licensed.
- We or any of our licensors or strategic partners might not have been the first to file patent applications covering certain of our inventions.
- Others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights.
- The prosecution of our pending patent applications may not result in granted patents.
- Granted patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable, because of legal challenges by our competitors.
- Patent protection on our product candidates may expire before we are able to develop and commercialize the product, or before we are able to recover our investment in the product.
- Our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for such activities, as well as in countries in which we do not have patent rights and may then use the information learned from such activities to develop competitive products for sale in markets where we intend to market our product candidates.

Risks Related to Our Common Stock

The price of our common stock has in the past and may continue to fluctuate significantly, and you could lose all or part of your investment.

The price of our common stock fluctuates widely. Continued volatility in the market price of our common stock might prevent a stockholder from being able to sell shares of our common stock at or above the price paid for such shares. The trading price of our common stock has in the past and may continue to be volatile and subject to wide price fluctuations in response to various factors, many of which are beyond our control, such as the progress, results and timing of our clinical and nonclinical studies and other studies involving our product candidates, the success or failure of our product candidates, the receipt or loss of required regulatory approvals for our product candidates, the availability of capital or the other risks discussed in this "Risk Factors" section.

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to bring a claim in a judicial forum they find favorable for disputes with us or our directors, officers or other employees.

Our amended and restated bylaws provide that, with certain limited exceptions, unless we consent to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a claim of breach of fiduciary duty owed by any of our current or former directors, officers or other employees to us or to our stockholders; (3) any action asserting a claim arising pursuant to the Delaware General Corporation Law, or our certificate of incorporation or bylaws (as each may be amended from time to time); or (4) any action asserting a claim governed by the internal affairs doctrine. Alternatively, if such court does not have jurisdiction, the Superior Court of Delaware, or, if such other court does not have jurisdiction, the United States District Court for the District of Delaware, will be the sole and exclusive forum for such actions and proceedings. The choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage such lawsuits against us and our directors, officers, and other employees. Alternatively, if a court were to find the choice of forum provision contained in our amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could have a material adverse impact on our business. The choice of forum provision in our amended and restated bylaws will not preclude or contract the scope of exclusive federal or concurrent jurisdiction for actions brought under the federal securities laws, including the Exchange Act or the Securities Act, or the respective rules and regulations promulgated thereunder.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Risk Management and Strategy

We recognize the critical importance of developing, implementing, and maintaining robust cybersecurity measures to help maintain the security, confidentiality, integrity, and availability of our business systems and confidential information, including personal information and intellectual property. Our cybersecurity program includes systems and processes that are designed to assess, identify and manage material risks from cybersecurity threats and includes: maintenance and monitoring of information security policies aligned with global regulatory controls; user and employee awareness of cyber policies and practices; simulated phishing exercises; information systems configuration management; identity and information asset protection; infrastructure security systems; and cyber threat operations with regular monitoring and threat hunting, including system penetration tests through a third-party service provider. This program includes processes to oversee and identify material risks from cybersecurity threats associated with our use of third-party service providers. We also maintain a cyber incident response plan designed to assist us in identifying, responding to and recovering from cybersecurity incidents. We use the findings from these and other processes to help us improve our information security practices, procedures and technologies. We also collaborate with third parties to assess the effectiveness of our cybersecurity program. These include cybersecurity assessors, consultants, and other external cybersecurity experts to assist in the identification, verification, and validation of material risks from cybersecurity threats, as well as to support associated mitigation plans when necessary.

Cybersecurity is integrated into our overall risk management systems, including our annual enterprise risk management, internal controls, business continuity and crisis management, third-party risk management, insurance risk management, and employee compliance processes. Our Cyber Incident Response Team, comprised of our Vice President, General Counsel and Corporate Secretary, our Vice President, Finance, and our Executive Director, Information Technology, consults with, or provides input to each of these programs to ensure that material risks from cybersecurity threats are appropriately assessed, identified, and managed.

As of the date of this report, there have been no cybersecurity threats, including as a result of any previous cybersecurity incidents, that have materially affected or are reasonably likely to materially affect us, including our business, strategy, results of operations, or financial condition. For additional description of cybersecurity risks and potential related impacts on the Company, refer to the risk factor captioned "Significant disruptions of information technology systems or breaches of data security, including cybersecurity incidents, could materially and adversely affect our business, results of operations and financial condition" in "Item 1A. Risk Factors."

Governance

While our board of directors has oversight responsibility for risk management generally, the Audit Committee is specifically responsible for overseeing our cybersecurity risk management program to ensure cybersecurity risks are identified, assessed, managed, and monitored. Our Executive Director, Information Technology, who has over 15 years of experience in the cybersecurity field and regularly attends cybersecurity conferences and actively implements new technologies to keep our systems up to date and secure, provides periodic updates to the Audit Committee in this regard, and details our cybersecurity program supported by key performance indicators across the range of cybersecurity functions related to risk management and governance, identity and information asset protection, core security and endpoint security, and cyber threat operations. These updates include descriptions of cybersecurity incidents, including those associated with our third-party service providers. The Audit Committee is responsible for updating our full board of directors on material risks from cybersecurity incidents or threats.

Item 2. Properties

We lease office space for corporate and administrative functions and laboratory space in South San Francisco, California under a sublease that expires in September 2029.

We believe these leased facilities are adequate for our current needs and that additional space will be available in the future on commercially reasonable terms as needed.

Item 3. Legal Proceedings

We are not a party to any material legal proceedings at this time. From time to time, we may be subject to various legal proceedings and claims that arise in the ordinary course of our business activities. Although the results of litigation and claims cannot be predicted with certainty, we do not believe we are party to any claim or litigation the outcome of which, if determined adversely to us, would individually or in the aggregate be reasonably expected to have a material adverse effect on our business. Regardless of the outcome, litigation can have an adverse effect on us because of defense and settlement costs, diversion of management resources and other factors.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information for Common Stock

Our common stock is traded under the symbol "ASMB" and is quoted on The Nasdaq Global Select Market.

Holders of Record

As of March 13, 2026, there were 56 stockholders of record, which excludes stockholders whose shares were held in nominee or street name by brokers.

Dividend Policy

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

Recent Sales of Unregistered Securities

There were no unregistered sales of equity securities in 2025.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

We did not purchase any of our registered equity securities during the period covered by this Annual Report on Form 10-K.

Item 6. [Reserved]

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and the related notes thereto and other financial information appearing elsewhere in this Annual Report on Form 10-K. The following discussion contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those expressed or implied in any forward-looking statements as a result of various factors, including those set forth in this Form 10-K under "Item 1A. Risk Factors."

Overview

We are a biotechnology company developing innovative therapeutics targeting serious viral diseases with the potential to improve the lives of patients worldwide. Our pipeline includes multiple clinical-stage investigational therapies, including: (1) two long-acting helicase-primase inhibitors (HPI) for the treatment of recurrent genital herpes; (2) an orally bioavailable hepatitis delta virus (HDV) entry inhibitor; and (3) a highly potent next-generation capsid assembly modulator (CAM) designed to disrupt the replication cycle of hepatitis B virus (HBV) at several key points. Our pipeline also includes a novel, oral broad-spectrum non-nucleoside polymerase inhibitor (NNPI) for the treatment of transplant-related herpesviruses, which is currently undergoing studies to enable a regulatory filing, and we have additional research programs against multiple antiviral targets. In December 2025, pursuant to our collaboration with Gilead Sciences, Inc. (Gilead and the Gilead Collaboration), Gilead exercised its option to license our HPI program for the treatment of recurrent genital herpes, including our long-acting investigational candidates ABI-1179 (1179) and ABI-5366 (5366). For additional information regarding Gilead's exercise of its option, see "Collaboration and License Agreement—Gilead Sciences, Inc.—Option Exercise."

Our Clinical Programs and Regulatory Filing-Enabling Program

2025 was a pivotal year for us, as we reported data readouts for 5366, 1179, 4334 and 6250 as follows:

- February 2025:
  - 1179 – Positive Phase 1a interim results in the Phase 1a/b study
- June 2025:
  - 4334 – Positive Phase 1b topline results
- August 2025:
  - 5366 – Positive Phase 1b interim results from the weekly dosing cohorts in the Phase 1a/b study
  - 6250 – Positive Phase 1a interim results
- December 2025:
  - 1179 – Positive Phase 1b interim results in the Phase 1a/b study
  - 5366 – Positive Phase 1b interim results from the monthly dosing cohorts in the Phase 1a/b study

In addition, during December 2024, we identified a development candidate, ABI-7423 (7423), in our broad-spectrum NNPI program targeting transplant-associated herpesviruses. 7423 is a prodrug, and in October 2025, we transitioned our development from 7423 to 7272, its parent molecule. 7272 is currently in regulatory filing enabling studies.

Recurrent Genital Herpes/HSV-1 and HSV-2

Genital herpes can be caused by either herpes simplex virus type 1 (HSV-1) or herpes simplex virus type 2 (HSV-2). HSV-1 and HSV-2 are acquired by oral or genital contact either during symptomatic or asymptomatic reactivation of the virus. Both viruses replicate in neurons, where they can remain latent for the rest of the individual's life and periodically reactivate, with the virus spreading, replicating and causing disease in epithelial tissues. Initial infection can be asymptomatic or can be marked by serious symptoms, including painful skin lesions, swelling of lymph nodes and urinary problems that can persist for two to three weeks. While genital herpes can be caused by either HSV-1 or

HSV-2, recurrences are more likely to be experienced by individuals infected by HSV-2. Genital herpes recurrence can cause painful genital lesions that can lead to increased transmission and debilitate individuals, and symptoms may become more serious with additional episodes. Additional complications include increased risk of HIV infection, as 30% of HIV infections acquired through sexual transmission are attributable to HSV-2 infection. In addition, people with recurrent genital herpes often experience associated psychosocial impacts, including anxiety, concerns about transmission, depression and social stigma. Immunocompromised individuals may experience more severe and prolonged symptoms due to increased recurrence rates.

HPIs are antiviral agents in development for the treatment of recurrent genital herpes, with a clinically-validated mechanism of action. HPIs inhibit the HSV helicase-primase complex, which is a unique viral enzyme complex without a human homolog, consisting of helicase, primase and cofactor subunits. These subunits have functions that are essential for viral DNA replication and are conserved across HSV-1 and HSV-2. Unlike nucleoside analogs, these compounds do not require phosphorylation by the HSV thymidine kinase (TK) and ongoing viral replication to become active drugs. As a result, HPIs are active immediately upon reactivation of latent HSV-1 and HSV-2. Furthermore, HPIs are active against TK-deficient HSV-1 and HSV-2, which is a major mechanism of resistance to nucleoside analogs.

Most people with initial symptomatic genital herpes who are infected with HSV-2 have frequent recurrences, generally between three and 15 per year, impacting over four million people in the United States and France, Germany, Italy and Spain (collectively, the EU4) and the United Kingdom (UK). Currently, there are three antiviral drugs (all nucleoside analogs) that have been approved in the United States and the EU4/UK for the treatment of genital herpes. However, no new drugs have been approved in these regions to treat genital herpes for more than 25 years. In addition to the approved nucleoside analogs, agents such as local anesthetics or analgesics may be used to alleviate local symptoms of minor pain and discomfort.

Nucleoside analogs can be administered as episodic therapy as individual outbreaks arise or daily as chronic suppressive therapy for those with high post-exposure recurrences. However, these agents are only partially effective at controlling the infection or reducing transmission risk. With current nucleoside analog therapies, only one out of three people with recurrent genital herpes with six or more recurrences per year are able to make it through a year of treatment without a recurrence. There are still high titer (greater than 10^4 HSV-2 DNA copies/mL) shedding episodes under this current standard of care for recurrent genital herpes, which can lead to recurrent episodes and transmission of genital herpes. In addition, nucleoside analogs also carry a high pill burden as a lifelong daily treatment, with doses ranging from one to three times daily. There is also high treatment variability among those taking nucleoside analogs, as many seeking care may not consistently receive suppressive therapy.

Based on the limitations of current therapies, we see a path to advancing the treatment paradigm for people suffering from recurrent genital herpes. To reach that goal, we discovered and began the clinical development of a novel, potent, long-acting HPI for recurrent genital herpes, 5366, which demonstrated low nanomolar potency in vitro against both HSV-1 and HSV-2 clinical isolates and a favorable nonclinical safety profile in the U.S. Food and Drug Administration's (FDA) Good Laboratory Practice (GLP) toxicology studies. In addition, we began development of a second novel, potent, long-acting HPI for genital herpes, 1179, which was in-licensed to us as part of our collaboration with Gilead. As Gilead has exercised its option to exclusively license our HPI program, including 5366 and 1179, development will be in Gilead’s sole control following completion of the Phase 1a/b studies of 5366 and 1179, which we are managing until they are complete. For additional information regarding the option exercise, see “Collaboration and License Agreements—Gilead Sciences, Inc.—Option Exercise.”

During the first quarter of 2024, we filed a Clinical Trial Application (CTA) to support initiation of a Phase 1a/b clinical study for 5366, which was approved in April 2024.

We reported interim data from the Phase 1b portion of the 5366 study in August 2025, focused on two different oral doses of 5366 administered on a once-weekly basis. For the powered antiviral endpoint, HSV-2 shedding rate, highly potent antiviral activity was observed with a 94% reduction compared to placebo ($p<0.01$) over the 29-day evaluation period in the cohort evaluating a 350 mg weekly dose. This reduction exceeded our target for the study of an 80-85% reduction in the rate of HSV-2 shedding. For a secondary clinical endpoint of genital lesion rate, a 94% reduction compared to placebo ($p<0.01$) was observed with the 350 mg weekly dose. The rate of genital swabs with high viral load (i.e., $>10^4$copies/mL HSV DNA), a potential surrogate for HSV-2 transmission and a secondary endpoint, was reduced by 98% compared to placebo ($p<0.05$) in this cohort.

We reported additional interim data from the Phase 1b portion of the 5366 study in December 2025, which included data from a monthly oral dosing regimen. In the 5366 monthly dose cohort, potent antiviral activity was observed, with a 76% reduction in HSV-2 shedding rate compared to placebo ($p<0.01$) over the 29-day evaluation period. The majority of positive swabs (89%) were collected in the last two weeks of the evaluation period when drug levels were declining. We observed an 88% reduction in virologically confirmed genital lesion rate ($p=0.01$), along with an 81% reduction in the number of samples with high viral load ($p<0.01$) compared to placebo in the monthly dose cohort.

Across the two weekly oral dose cohorts and the monthly oral dose cohort of the Phase 1b study, 5366 demonstrated a pharmacokinetic (PK) profile that continues to support once-weekly and potentially once-monthly dosing.

5366 was observed to be well-tolerated at all dose levels tested in the Phase 1b portion of the study. The two weekly oral cohorts are complete and unblinded safety data has been reported; the oral monthly cohort is ongoing and safety data remains blinded. Across all cohorts, the proportion of participants reporting treatment-emergent AEs was similar between 5366 and placebo recipients, and all were Grade 1 or Grade 2. One Grade 3 AE was reported, hypertriglyceridemia, in a participant with relevant medical history who had Grade 4 elevated triglycerides pre-dose on Day 1. This AE resulted in study discontinuation but was not considered treatment related. The proportion of participants reporting treatment-emergent lab abnormalities was similar in 5366 and placebo recipients with the majority being Grade 1 or Grade 2. In the unblinded weekly oral dose cohorts: there were three participants with treatment-emergent Grade 3 lab abnormalities, all of which are considered unrelated to assigned treatment; one participant with exercise-associated elevation in creatine kinase (150/30 mg QW); one participant with an elevation of cholesterol in the follow up period, which participant had a Grade 2 elevation at baseline (350 gm QW); and one participant, who was dosed with placebo, with decreased neutrophils. There did not appear to be a dose-response relationship in either the frequency or severity of the treatment-emergent AEs or lab abnormalities. No serious AEs have been reported to date.

All participants in the Phase 1b portion of the 5366 study have completed dosing and follow up. The observed PK profile continues to support once-weekly dosing and the potential for once-monthly oral dosing regimens. Additionally, all chronic toxicology studies have been completed. With these data, 5366 is ready to move into a Phase 2 clinical study.

A late-breaking oral presentation of the interim 5366 Phase 1b data reported in August 2025 was presented at the 38th Congress of the International Union Against Sexually Transmitted Infections – Europe, which took place in October 2025 in Athens, Greece. The 5366 data reported in August and December 2025 will be presented at the Congress of the European Society of Clinical Microbiology and Infectious Diseases (ESCMID) taking place in Munich, Germany in April 2026.

In addition to 5366, we have also begun the clinical development of 1179, a structurally-differentiated HPI with single digit nanomolar potency against HSV-1 and HSV-2 and a nonclinical PK and safety profile to date that is supportive of a potential long-acting treatment by once-weekly oral administration. We submitted the CTA for the study in September 2024, which was approved in October 2024.

We reported interim data from two oral weekly dose cohorts in the Phase 1b portion of the 1179 study in December 2025. For the powered antiviral endpoint, HSV-2 shedding rate, highly potent antiviral activity was observed with a 98% reduction in HSV-2 shedding rate compared to placebo ($p<0.01$) over the 29-day evaluation period in the 50 mg weekly dose cohort. This reduction exceeded our target for the study of an 80-85% reduction in HSV-2 shedding rate. Further, data revealed a 91% reduction in virologically confirmed lesion rate compared to placebo ($p<0.01$) with the 50 mg weekly dose. There was also a >99% reduction in the number of samples with high viral load, a potential surrogate for HSV-2 transmission and a secondary endpoint.

Across both oral weekly dose cohorts, 1179 demonstrated a PK profile that continues to support once-weekly dosing. 1179 was observed to be well-tolerated at both doses. Overall, the proportion of participants reporting treatment-emergent AEs was similar between 1179 and placebo recipients. Of the treatment-emergent AEs reported, the majority were Grade 1 or Grade 2. The most common AEs were upper respiratory tract infection and headache. There have been no serious AEs reported to date. One Grade 3 AE of migraine was reported in a participant enrolled in the 20 mg/placebo cohort.

All participants in the Phase 1b portion of the 1179 study have completed dosing and follow up. With these data, 1179 can move directly into Phase 2 enabling studies for a once-weekly treatment regimen, subject to the completion of chronic toxicology studies, which are underway. The completion of the Phase 1b studies of both 5366 and 1179 constitute an option triggering point under the terms of the Gilead Collaboration Agreement, as defined below under "Collaboration and License Agreement — Gilead Sciences, Inc." The 1179 data reported in December 2025 will be presented at ESCMID in April 2026.

In December 2025, Gilead exercised its option early to license our HPI program for the treatment of recurrent genital herpes, including 5366 and 1179. We expect to receive Gilead's development plan and budget for the HPI program and make our decision regarding the Profit-Share (as defined below) by mid-2026. We anticipate Gilead will initiate a Phase 2 clinical study for the HPI program in 2026. For more information regarding Gilead's exercise of its option, see "Collaboration and License Agreement—Gilead Sciences, Inc.—Option Exercise."

Our HBV and HDV Programs

The World Health Organization (WHO) estimates that 254 million people worldwide are chronically infected with HBV as of 2022, and 1.2 million new infections occur each year. HBV is a leading global cause of chronic liver disease and liver transplants, and the WHO estimates that 1.1 million people died in 2022 from HBV, mostly due to cirrhosis and hepatocellular carcinoma. Of the 254 million people living with chronic HBV infection, only approximately 33 million, or 13%, were aware of their infection, and only approximately 7 million, or 3%, of those diagnosed received treatment. HBV is a highly prevalent disease that infects almost three times the number of people infected with hepatitis C virus and HIV infections combined, according to the WHO.

The current standard of care for chronic HBV infection, nucleos(t)ide analog reverse transcriptase inhibitors (NrtIs), are taken life-long and reduce, but do not eliminate, the virus and result in very low cure rates. No new mechanisms of action (MOA) have been approved for the treatment of chronic HBV infection in over 25 years. The focus of our HBV program is to improve outcomes and increase the number of patients diagnosed and treated through the development of finite and curative therapies targeting an orthogonal MOA.

HDV is a "satellite virus" of HBV because it can only infect people (1) who are already infected with HBV or (2) at the same time as a person is infected with HBV. HDV affects a subset of approximately 12 to 72 million HBV infected people. These individuals infected with HDV, which comprise an estimated 4.5% of hepatitis B surface antigen (HBsAg) positive individuals, experience a substantially increased disease burden, as they account for 18% of cirrhosis and 20% of hepatocellular carcinoma associated with HBV. HDV is considered the most severe form of hepatitis, as 70% of individuals infected with HDV progress to cirrhosis within ten years. While HDV is less prevalent in the United States, it is a significant and serious health problem with inadequate treatment in many parts of Europe, Africa, the Middle East, East Asia and parts of South America. HDV may be significantly underdiagnosed, because there were no HDV-targeted therapies approved until very recently, and the first therapy approved is only approved in European Union (EU), Australia and Canada. HDV is known to accelerate disease progression and increase the incidence of liver cirrhosis and liver cancer, which results in higher morbidity and mortality rates than HBV alone.

The current standard of care treatment for HDV is off-label pegylated interferon-α (IFN-α) injected weekly or, in the EU, Australia and Canada, a large, complex peptide inhibitor that requires daily injections, bulevirtide. There are no approved HDV treatments in the United States. We believe a safe and effective oral small molecule entry inhibitor would be a significant innovation for people living with HDV, who face a significant and immediate disease burden.

HDV Entry Inhibitor

HDV is a small RNA virus that encodes just two viral proteins and relies on host enzymes as well as the HBsAg from HBV to replicate, which limits the number of HDV-specific antiviral targets. Similar to HBV, HDV utilizes HBsAg to enter hepatocytes by binding the cellular transmembrane protein sodium taurocholate co-transporting peptide (NTCP). NTCP is highly expressed on human hepatocytes, where it serves as one of several proteins involved in the transport of bile acids. The binding of specific small or large molecules to NTCP has been shown to effectively inhibit the interaction of HBsAg with NTCP, which prevents HBV and HDV from infecting hepatocytes.

The inhibition of HBV and HDV infection by molecules that bind NTCP has been demonstrated in vitro, in animal models and clinically. Notably, bulevirtide, a peptide blocker of NTCP, is the only approved therapy for HDV. 6250

has the same clinically-validated MOA as bulevirtide. The binding of NTCP-targeted HBV/HDV entry inhibitors to NTCP has also been shown to inhibit the transport of certain bile acids into cells, which results in plasma elevations of bile acids; this effect has been well-tolerated clinically and may serve as a biomarker of pharmacologically active concentrations of drug in the plasma. In nonclinical studies in non-human primates, clinically-relevant doses of 6250 elevated bile acids to levels similar to those seen in humans with bulevirtide.

We believe a safe and effective oral small molecule entry inhibitor would be a significant innovation for people living with HDV and could significantly improve treatment uptake and diagnosis rates, especially when compared with currently available injectable products.

A Phase 1a clinical study of 6250 was initiated in the fourth quarter of 2024, and in August 2025, we announced interim PK, biomarker and safety data from single-ascending and multiple-ascending doses cohorts in healthy participants. Across the cohorts evaluated to date, a mean half-life of approximately four days was observed for 6250 when dosed orally, supporting the once-daily oral dosing profile target. Given this half-life, accumulation was observed in the multiple-dose cohorts with exposures on the last day of dosing generally reaching six- to seven-fold higher than the exposure seen after the first dose.

Dose-dependent elevations of total serum bile acids (TBAs) were observed for both the 5 mg and 25 mg single-dose cohorts, indicative of NTCP target engagement. In the highest single-dose cohort of 25 mg, coproporphyrin I (CP-1), a biomarker for off-target engagement of the organic anion transporters, OATP1B1 and/or OATP1B3, was also elevated. CP-1 elevation was not noted at the other doses.

Given the predicted 6250 accumulation driven by the long half-life and the observed elevations of TBAs for the single-dose cohorts, doses at and below 1 mg daily were selected for the multiple-dose cohorts to characterize the lower end of the dose-response curve. Elevation of TBAs was observed for both the 0.2 mg and 1 mg daily multiple-dose cohorts, consistent with the respective 6250 exposures. Minimal TBA elevation was observed in the 0.05 mg daily multiple-dose cohort.

Treatment-emergent AEs and laboratory abnormalities were all Grade 1 or 2 in severity with the majority being Grade 1. There were no serious AEs in any dose cohort. No protocol defined stopping criteria were met. There were no clinically significant electrocardiogram abnormalities or patterns of AEs noted.

One Grade 2 ALT elevation was observed in the cohort evaluating the highest single-dose level of 25 mg. In this cohort, off-target engagement of other liver transporters was also seen as indicated by elevated CP-1 levels. Grade 1 ALT elevations were observed at a low frequency across the other cohorts. All ALT elevations were self-limited, and none were accompanied with elevations in bilirubin or other markers of liver injury. The elevations resolved in the study period with ongoing drug exposure due to 6250's four-day half-life.

We have completed enrollment and the follow-up period in the Phase 1a study, as well as the chronic toxicology studies to enable longer term dosing and we are preparing for Phase 2 clinical studies, with Phase 2 initiation expected in the fourth quarter of 2026.

6250 Phase 1a data will be presented at the European Association for the Study of the Liver (EASL) Congress taking place in Barcelona, Spain in May 2026.

Capsid Assembly Modulator

HBV is a DNA virus that infects hepatocytes and establishes a reservoir of covalently closed circular DNA (cccDNA), a unique viral DNA moiety that resides in the nucleus of HBV-infected hepatocytes and is associated with viral persistence and chronic infection. No currently approved oral therapies target cccDNA activity directly. As a result, we have worked to discover and develop compounds targeting the core protein, a viral protein involved in numerous aspects of the HBV replication cycle, including the generation of HBV cccDNA.

A benchmark for therapeutic agents aiming to decrease cccDNA levels is the use of several key viral antigens as surrogate biomarkers of active cccDNA. The same biomarkers can be used in both primary human hepatocytes and infected individuals. On this basis, our next-generation CAM, 4334, has shown nonclinical proof of principle. In a variety of cell culture models, 4334 has demonstrated the ability to reduce production of HBV DNA levels as well as

the surrogate markers for cccDNA establishment: HBV e antigen (HBeAg), HBV core-related antigen (HBcrAg) and HBV pre-genomic RNA (pgRNA).

As a next-generation CAM, 4334 was optimized to potently disrupt viral replication (MOA #1) and prevent the establishment and replenishment of new cccDNA (MOA #2). In contrast, while active against MOA #1, first-generation CAMs have not demonstrated adequate potency to sufficiently block MOA #2. Further, the current standard of care, NrtIs, impacts the viral life cycle after establishment of cccDNA and can only inhibit production of new viral particles, and it does so incompletely. The chemical scaffold of 4334 is novel and distinct from all our prior CAM candidates.

We believe that 4334 has a best-in-class nonclinical profile, with single-digit nanomolar potency against MOA #1 and MOA #2, pan-genotypic activity, an improved resistance profile and a favorable safety profile. Through mechanistic studies presented at multiple conferences, we have demonstrated that 4334 promotes the formation of empty capsids by acceleration of capsid assembly, prevents the formation of cccDNA by disrupting incoming capsids, and prematurely disrupts capsids containing duplex linear DNA, the precursor for integrated HBV DNA.

A Phase 1a study demonstrated that 4334 was well-tolerated when administered orally as single or multiple doses. During the second quarter of 2024, we dosed our first participant in a Phase 1b clinical study of 4334. We reported interim clinical results from the initial 150 mg cohort in December 2024, and topline clinical results including a subsequent 400 mg cohort in June 2025. In both the 150 mg and 400 mg cohorts, 4334 continued to show a half-life supportive of once-daily oral dosing. In addition, results for both cohorts indicated that 4334 maintained clinical exposures multiple folds above those anticipated to be required for potent viral activity and inhibition of cccDNA formation. Mean declines in HBV DNA of 2.9 $\log_{10}$ IU/mL and 3.2 $\log_{10}$ IU/mL were observed over 28 days in a population of predominately HBeAg negative participants receiving 150 mg and 400 mg, respectively. Among the subset of participants with detectable HBV RNA at baseline, mean declines of 2.5 $\log_{10}$ U/mL and 2.3 $\log_{10}$ U/mL were observed over 28 days in the participants receiving 150 mg and 400 mg, respectively. As anticipated, limited changes in viral antigens were observed for the study population over the 28-day treatment period. These antiviral data are consistent with the high potency seen preclinically for 4334. The safety data also demonstrated that 4334 was well-tolerated with a favorable safety profile observed. The 400 mg cohort was the final cohort for this Phase 1b study and final data was presented at the American Association for the Study of Liver Disease, The Liver Meeting® in November 2025. The completion of the Phase 1b study of 4334 constitutes an option triggering point under the terms of the Gilead Collaboration Agreement, as defined below under "Collaboration and License Agreement — Gilead Sciences, Inc."

In March 2026, Gilead declined to either exercise its option to license 4334 or defer its option until completion of Phase 2 studies. As a result, the Company retains full control of 4334, including the right to evaluate partnering opportunities for 4334 outside of the Gilead Collaboration. We are actively evaluating partnering opportunities for 4334 and have initiated a structured process to find potential partners. We do not plan to advance 4334 further without a partner.

Transplant-Associated Herpesviruses

In a transplant setting, when patients are experiencing immunosuppression, they are at high risk of uncontrolled viral replication and severe disease brought on by one or more herpesviruses, including cytomegalovirus (CMV), HSV-1, HSV-2, varicella zoster virus (VZV) and Epstein-Barr virus (EBV). Each of these herpesviruses are highly prevalent, as approximately (1) 60% of transplant patients are CMV-positive; (2) 60% of transplant patients are HSV-positive; (3) 80% of transplant patients are VZV-positive and (4) 45% of transplant patients are EBV-positive. These viruses establish lifelong latent infections and frequently reactivate in transplant patients due to the use of immunosuppressive drugs following transplantation. These uncontrolled herpesvirus infections increase the risk of severe disease and serious complications, including organ rejection, graft loss and death, and impacted approximately 95,000 people receiving transplants in 2021 in the United States and Europe.

While there are approved antivirals that are administered in a transplant setting, currently approved antivirals are not active against a broad spectrum of transplant-associated herpesviruses and pose the risk of potentially serious side effects and drug-drug interactions. As a result of these limitations, we identified an opportunity to develop an oral, broad-spectrum NNPI for transplant-associated herpesvirus infections, which could greatly advance treatment.

In December 2024, we nominated 7423, a prodrug, as our development candidate to undergo regulatory filing-enabling studies. In October 2025, we transitioned our discovery and development from 7423 to its parent molecule, 7272, which is currently in regulatory filing-enabling nonclinical studies.

Research Programs

In addition to our investigational therapy programs that have nominated development candidates and have advanced into clinical studies or regulatory-filing enabling studies, our research team continues to actively focus on proprietary research to discover and nominate novel antivirals to treat serious viral diseases.

Collaboration and License Agreement

Gilead Sciences, Inc.

In October 2023, we entered into an Option, License and Collaboration agreement (the Gilead Collaboration Agreement) with Gilead pursuant to which Gilead (1) exclusively licensed to us its HPI program and its NNPI program, while retaining opt-in rights to these programs, and (2) has an option to take an exclusive license, on a program-by-program basis, to all of our other current and future pipeline programs. During the 12-year collaboration term (subject to payment of certain extension fees) and for a specified period thereafter, Gilead may exercise its opt-in rights, on a program-by-program basis, at one of two timepoints—completion of a certain Phase 1 study or, upon payment of a deferral fee and completion of a certain Phase 2 study for the first product within the program—upon payment of an opt-in fee ranging from $45.0 million to $125.0 million per program depending on the type of program and when the option is exercised. Pursuant to the Gilead Collaboration Agreement, Gilead made an $84.8 million upfront cash payment to us. In December 2024, we and Gilead entered into the First Amendment to the Gilead Collaboration Agreement, which restructured the timing of specific options exercisable and the fees payable to us under the terms of the Gilead Collaboration Agreement due to an agreed upon development plan for 6250. To facilitate this development plan, (1) we received a payment of $10.0 million from Gilead and (2) the opt-in fee payable by Gilead in connection with 6250 was restructured, though it remains in the range of opt-in fees detailed above. The $10.0 million payment received in connection with the First Amendment to the Gilead Collaboration Agreement is creditable towards future collaboration-related payments payable by Gilead. This credit was applied toward Gilead's opt-in fee paid for the HPI program in December 2025.

If Gilead exercises its opt-in right to any current or future program under the collaboration, we are eligible to receive up to $330.0 million in potential regulatory and commercial milestones on that program, in addition to royalties ranging from the high single-digits to high teens, depending on the clinical stage of the program at the time of the opt-in. Following Gilead's exercise of its option for each program, we may opt-in to cover 40% of the research and development costs in the United States and share 40% of the profits and operating loss in the United States for products within the program in lieu of receiving milestones and royalties for that program in the United States, unless we later opt out of the cost/profit share for the program. Prior to Gilead's potential exercise of its opt-in, we are primarily responsible for all discovery, research and development on both our programs and the two Gilead-contributed programs. Following Gilead's opt-in, Gilead will control the further discovery, research, development and commercialization on any optioned programs, and is responsible for all related costs unless we opt in to share 40% of all costs and profits in the United States. During the term, Gilead will continue to support the collaboration through extension fees of $75.0 million in each of the third, fifth and seventh anniversaries of the collaboration.

The Gilead Collaboration Agreement is subject to termination by either party for the other party's uncured, material breach or insolvency. Subject to certain limitations, we and Gilead both have certain termination for convenience rights, upon sufficient prior written notice, with respect to programs that one party in-licenses from the other (subject to Gilead's option rights), and with respect to Gilead, for programs it has option rights to (subject to certain time limitations with respect to existing Company programs). Gilead also has a right to terminate the collaborative activities under the Gilead Collaboration Agreement at certain specified points during the collaboration term. Other customary termination rights are further provided in the Gilead Collaboration Agreement.

We and Gilead also entered into a Common Stock Purchase Agreement and an Investor Rights Agreement (together, the Gilead Equity Agreements), which were both amended in June 2024 in connection with a financing transaction, in which a new investor purchased shares of common stock and was issued a warrant (the 2024 Financing Transaction). Pursuant to the Gilead Equity Agreements, Gilead made an upfront equity investment of $15.2 million by purchasing

from us 1,089,472 shares of our common stock at a purchase price of $13.92 per share. The terms of the Gilead Equity Agreements provided Gilead the right to elect to purchase additional shares of common stock from us at a premium in an amount that results in Gilead owning 29.9% of our then-outstanding voting common stock. This right was exercised in December 2024, at a purchase price of $21.37 per share, which represents a 35% premium to the 30-trading day volume weighted average price immediately prior to the date of purchase. The Gilead Equity Agreements also include a three-year standstill provision and a two-year lockup provision, each with customary exceptions, and provide Gilead with certain other stock purchase rights and registration rights, as well as the right to designate two directors (or, alternatively, board observers at Gilead's election) to our board of directors. In December 2023, Gilead designated Tomas Cihlar, Ph.D. to serve on our board of directors, and in March 2024, Gilead designated Robert D. Cook II to serve on our board of directors.

Gilead participated in the 2024 Financing Transaction on the same terms as the new investor pursuant to the anti-dilution provision in the Investor Rights Agreement. We and Gilead entered into a Securities Purchase Agreement for the issuance and sale, in a private placement, of 179,500 shares of our common stock and a warrant to purchase up to 179,500 shares of our common stock. The warrant sold to Gilead has an exercise price equal to $17.00 per share, became immediately exercisable on the date of issuance and will expire on June 18, 2029. Subject to certain exceptions, neither Gilead nor its affiliates may exercise any portion of the warrant to the extent that Gilead would own more than 19.9% of the number of our shares of common stock outstanding immediately after giving effect to such exercise.

Gilead also participated in a financing transaction in August 2025 on the same terms as the new investors. We and Gilead entered into a Securities Purchase Agreement for the issuance and sale, in a private placement, of 2,295,920 shares of our common stock at a combined purchase price of $19.60 per shares and accompanying one-half of one Class A Warrant and one-half of one Class B Warrant (collectively, the August 2025 Private Placement). The common stock, the Class A Warrant and the Class B Warrant were sold to Gilead pursuant to the terms of the Investor Rights Agreement. The Class A Warrant and the Class B Warrant each provide for the right to purchase up to 1,147,960 shares of our common stock. The Class A Warrant has an exercise price of $21.60 per share, became immediately exercisable on the date of issuance and will expire on or prior to the earlier of (a) August 11, 2030 (five years from the date of issuance) and (b) the date that is 30 days after the public announcement that we have completed enrollment of at least 200 patients total for our Phase 2 clinical study evaluating 5366 versus valacyclovir. The Class B Warrant has an exercise price of $21.60 per share and is exercisable between November 15, 2026 and December 31, 2026. Notwithstanding the foregoing, if, prior to November 15, 2026, we publicly announce that we have received at least $75.0 million in the aggregate of non-dilutive capital in connection with a collaboration agreement, then the Class B Warrant automatically terminates in full.

In October 2025, as required under the registration rights terms of the Investor Rights Agreement, we filed a registration statement on Form S-3 (the Registration Statement) with the Securities and Exchange Commission (SEC) to register all of the shares of our common stock that have been issued and sold to Gilead, as well as all of the shares of common stock underlying the warrants that have been issued and sold to Gilead. The SEC declared the Registration Statement effective in November 2025.

Option Exercise

In December 2025, Gilead exercised its option to exclusively license our HPI program for the treatment of recurrent genital herpes, including 5366 and 1179. This is the first program that Gilead will advance under the Gilead Collaboration.

Under the terms of the Gilead Collaboration Agreement, we received a $35 million payment in connection with Gilead's exercise of our HPI program. The $35 million payment reflects a $45 million option fee, net of $10 million in accelerated funding that we received under the First Amendment to the Gilead Collaboration Agreement, which was creditable against future payments. Gilead received an exclusive license to 5366 and 1179 and will have the sole right and responsibility for further clinical development and commercialization of the HPI program.

We remain eligible to receive up to $330 million in regulatory and commercial milestones, as well as tiered royalties on net sales ranging from the high single-digits to low teens. We will also have the right to opt in to share 40% of all costs and profits in the United States (the Profit-Share) in lieu of receiving milestones and royalties for that program in the United States after receipt of a development plan and budget from Gilead.

Operations

Since our inception, we have had no revenue from product sales and have funded our operations principally through debt financings prior to our initial public offering in 2010 and through equity financings and collaborations since then. Our operations to date have been primarily limited to organizing and staffing our company, discovering and developing our product candidates, licensing our product candidates, maintaining and improving our patent portfolio and raising capital.

We have generated significant losses to date, and we expect to continue to generate losses as we develop our product candidates. As of December 31, 2025, we had an accumulated deficit of $832.0 million. Because we do not generate revenue from any of our product candidates, our losses will continue as we further develop and seek regulatory approval for, and commercialize, our product candidates. Additionally, we expect our research and development expenses to increase over the coming years as we continue the development of our product candidates. As a result, our operating losses are likely to be substantial over the next several years and thereafter if none of our product candidates are approved or successfully launched. We are unable to predict the extent of any future losses or when we will become profitable, if at all.

Critical Accounting Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which we have prepared in accordance with accounting principles generally accepted in the United States. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported amounts of revenues and expenses during the reporting periods. Note 2 to the Consolidated Financial Statements describes the significant accounting policies and methods used in the preparation of our consolidated financial statements.

We evaluate our estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Revenue Recognition from Collaboration

We analyze our collaboration arrangements to assess whether such arrangements, or transactions between arrangement participants, involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities or are more akin to a vendor-customer relationship. In making this evaluation, we consider whether the activities of the collaboration are considered to be distinct and deemed to be within the scope of the collaborative arrangement accounting standard and those that are more reflective of a vendor-customer relationship and, therefore, within the scope of the revenue with contracts with customers accounting standard. This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement.

For arrangements or transactions between arrangement participants determined to be within the scope of the contracts with customers accounting standard, we evaluate the term of the arrangement and recognize revenue when the customer obtains control of promised goods or services in a contract for an amount that reflects the consideration we expect to receive in exchange for those goods or services. For contracts with customers, we apply the following five-step model, each of which requires judgment, in order to determine this amount: (1) identification of the contract(s) with a customer; (2) identification of the performance obligations in the contract, including whether they are distinct in the context of the contract; (3) measurement of the transaction price, including the constraint on variable consideration; (4) allocation of the transaction price to the performance obligations; and (5) recognition of revenue when (or as) we satisfy each performance obligation.

We only apply the five-step model to contracts when it is probable we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer. As part of the accounting for contracts with customers, we must develop assumptions that require judgment to determine the estimated relative standalone selling price (SSP) of each performance obligation identified in the contract. We then allocate the total transaction price to each performance obligation based on its SSP and recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when or as the performance obligation is satisfied.

We account for contract modifications, defined as changes in the scope or price (or both) of a contract that are approved by the parties to the contract, such as a contract amendment, when the parties to a contract approve a modification that

either creates new, or changes existing, enforceable rights and obligations of the parties to the contract. We use one of the following methods depending on facts and circumstances: (i) as a separate contract if the modification adds distinct goods or services and the price reflects the SSP of those additional goods or services; (ii) as a termination of the existing contract and creation of a new contract if the remaining goods or services are distinct from those transferred before the modification; or (iii) as a cumulative catch-up adjustment to the original contract if the remaining goods or services are not distinct from those transferred before the modification.

We entered into the First Amendment to the Gilead Collaboration Agreement in December 2024 and a letter agreement in July 2025. We determined each of these amendments to the Gilead Collaboration Agreement represent a contract modification within the scope of the revenue from contracts with customers guidance. For both contract modifications, we concluded there continues to be a single combined performance obligation consisting of a series of distinct research and development services (R&D Services), and therefore, the remaining services under the modified agreement are distinct from the R&D Services already provided. Accordingly, we accounted for each modification as a termination of the existing contract and the creation of a new contract and are recognizing the revenue prospectively by reassessing the transaction price and allocating it to the remaining R&D Services. We estimated the SSP of extension fees and opt-in rights pursuant to the modified Gilead Collaboration Agreement using significant estimates, including forecasted revenues and costs, development timelines, discount rates, and probabilities of technical and regulatory success. For both modifications, we concluded none of the options in the contract were performance obligations as they were contingent upon option exercise, were capable of being distinct from the R&D Services and were not offered at a discount to their SSP.

In December 2025, Gilead exercised its option to exclusively license our HPI program, which we determined was a new contract under the contracts with customers accounting standard as it was deemed an exercise of a marketing offer made pursuant to the original terms of the Gilead Collaboration Agreement and First Amendment. We determined the exclusive license granted to Gilead for the HPI program represents a distinct performance obligation because Gilead can benefit from the license together with readily available resources and its ability to sublicense the rights. The $35.0 million opt-in fee is included in the fixed transaction price. Variable consideration related to regulatory and commercial milestone payments, royalties and cost reimbursements are constrained because such amounts are highly susceptible to factors outside our influence.

We recognize revenue from R&D Services under the Gilead Collaboration Agreement over time using a cost-based input method, which continues to be appropriate following subsequent contract modifications of the Gilead Collaboration Agreement. We recognize revenue from exclusive licenses to our programs under the Gilead Collaboration Agreement at a point in time upon transfer of the license, when Gilead obtains the ability to use and benefit from the license.

Revenue related to certain performance obligations that are satisfied over time could be materially impacted as a result of changes in the estimated total research effort required to satisfy those obligations. In addition, amounts of variable consideration (including regulatory and commercial milestones) are included in the transaction price to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur and when the uncertainty associated with the variable consideration is subsequently resolved. The effect of any change made to an estimated input component or variable consideration and, therefore revenue recognized, would be recorded as a change in estimate. Such changes in estimate could have a material impact on the revenue recognized in a future period. We regularly review our expectations of the extent of progress, including whether any variable consideration was no longer constrained, and, if any changes in estimates were made, we recognized revenue using the cumulative catch-up method.

Research and Development Contract Costs and Accruals

As part of the process of preparing our consolidated financial statements, we are required to estimate certain research and development expenses. This process involves reviewing quotations and contracts, reviewing the terms of our license agreements, communicating with our vendors and 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 the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. Payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods or services are received. Such payments are evaluated for current or long-term classification based on when they will be realized or consumed. Examples of estimated amortized or accrued research and development expenses include fees to:

- contract research organizations (CROs) and other service providers in connection with clinical studies;

- contract manufacturing organizations (CMOs) in connection with the production of clinical trial materials; and
- vendors in connection with nonclinical development activities.

We base our expenses related to clinical studies on our estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that conduct and manage clinical studies 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 and expense recognition. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In either amortizing or accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the related prepayment or accrual accordingly. 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 our reporting changes in estimates in any particular period. Adjustments to prior period estimates have not been material for the years ended December 31, 2025 and 2024.

Results of Operations

Comparison of the Years Ended December 31, 2025 and 2024

Collaboration Revenue

The following table summarizes the period-over-period changes in our collaboration revenue (in thousands, except for percentages):

	Year Ended December 31,		$ Change	% Change
	2025	2024	2025 vs. 2024	2025 vs. 2024
Collaboration revenue from a related party	$ 72,303	$ 28,520	$ 43,783	154%

Collaboration revenue was $72.3 million for the year ended December 31, 2025 compared to $28.5 million for the year ended December 31, 2024. The $43.8 million increase was primarily driven by the recognition of $35.0 million of revenue associated with the exclusive license granted and transferred to Gilead for the HPI program in December 2025. The increase also reflects the additional $10.0 million payment we received in December 2024 under the First Amendment to the Gilead Collaboration Agreement, which was largely recognized in 2025.

Research and Development Expenses

Research and development expenses consist primarily of employee-related expenses, fees paid to CROs and CMOs, lab supplies and other third-party expenses that support our research and discovery, nonclinical and clinical activities. External program costs represent a significant portion of our research and development expenses, which we track by product candidate once it has been nominated. We use our employee and infrastructure resources, as well as certain third-party costs, across multiple research and development programs, and we do not specifically allocate these costs to our programs.

The following table summarizes the period-over-period changes in our research and development expenses (in thousands, except for percentages):

	Year Ended December 31,		$ Change	% Change
	2025	2024	2025 vs. 2024	2025 vs. 2024
External program expenses:				
5366	$ 9,353	$ 6,215	$ 3,138	50%
1179	8,119	4,239	3,880	92%
6250	5,780	6,396	(616)	(10%)
4334	890	2,646	(1,756)	(66%)
7272 [1]	2,300	—	2,300	100%
Research and discovery	8,161	8,985	(824)	(9%)
VBR	—	(43) [2]	43	(100%)
Total external program expenses	34,603	28,438	6,165	22%
Employee and contractor-related expenses	26,729	23,819	2,910	12%
Facility and other expenses	3,481	3,676	(195)	(5%)
Total research and development expenses	$ 64,813	$ 55,933	$ 8,880	16%

(1) In October 2025, we transitioned our discovery and development from 7423 to its parent molecule, 7272, which is currently in regulatory filing-enabling preclinical studies.

(2) Reflects net amounts refundable to us after final reconciliation of costs for the clinical trial conducted pursuant to the Clinical Trial Collaboration Agreement with Arbutus Biopharma Corporation, which was terminated in February 2023. We received the refund in 2025.

Research and development expenses were $64.8 million for the year ended December 31, 2025, compared to $55.9 million for the year ended December 31, 2024. The $8.9 million increase was primarily driven by higher external program expenses as we advanced our pipeline. Most notably, our HPI program incurred additional costs as both the 1179 and 5366 Phase 1a/b studies were underway during 2025, with more participants enrolled than in 2024. Employee and contractor-related expenses also increased, reflecting $2.1 million in increased compensation costs driven by annual salary increases and larger bonuses due to strong performance against our 2025 corporate objectives. The increase additionally reflects $1.1 million of higher stock-based compensation expense associated with performance stock units (PSUs) granted in 2025. These increases were partially offset by decreases in external program expenses from the completion of our 4334 Phase 1b study in mid-2025.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other related costs for personnel in executive, finance, accounting, business development, information technology, legal and human resources functions. Other significant costs include facility costs not otherwise included in research and development expenses, insurance costs, legal fees relating to patents and corporate matters and fees for accounting and consulting services.

The following table summarizes the period-over-period change in our general and administrative expenses (in thousands, except for percentages):

	Year Ended December 31,		$ Change	% Change
	2025	2024	2025 vs. 2024	2025 vs. 2024
General and administrative expenses	$ 19,608	$ 18,007	$ 1,601	9%

General and administrative expenses were $19.6 million for the year ended December 31, 2025, compared to $18.0 million for the year ended December 31, 2024. The $1.6 million increase was primarily driven by $1.2 million of higher professional fees related to patent filings as well as an increase of $0.5 million in stock-based compensation expense associated with PSUs granted in 2025.

Interest and Other Income, Net

Interest income consists of interest earned on our cash and cash equivalents and available-for-sale marketable securities.

The following table summarizes the period-over-period changes in our interest and other income, net (in thousands, except for percentages):

	Year Ended December 31,		$ Change	% Change
	2025	2024	2025 vs. 2024	2025 vs. 2024
Interest and other income, net	$ 5,996	$ 5,573	$ 423	8%

Interest and other income, net was $6.0 million for the year ended December 31, 2025, compared to $5.6 million for the year ended December 31, 2024. The $0.4 million increase was primarily driven by a larger investment portfolio balance following our financing transaction in August 2025.

Income Tax Expense

The following table summarizes the period-over-period changes in our income tax expense (in thousands, except for percentages):

	Year Ended December 31,		$ Change	% Change
	2025	2024	2025 vs. 2024	2025 vs. 2024
Income tax expense	$ —	$ 330	$ (330)	(100%)

There was no income tax expense for the year ended December 31, 2025. Income tax expense was $0.3 million for the year ended December 31, 2024 due to taxable income incurred from the upfront payments received under the Gilead Collaboration in 2023.

Liquidity and Capital Resources

Sources of Liquidity

As a result of our significant research and development expenditures and the lack of any FDA-approved products to generate product sales revenue, we have not been profitable and have generated operating losses since we were incorporated in October 2005. We have funded our operations through December 31, 2025 principally through equity financings, raising an aggregate of $821.8 million in net proceeds, and strategic collaborations, raising an aggregate of $236.2 million.

Funding Requirements

We expect our future operating expenses to increase over the coming years as we continue to expand our pipeline and advance our candidates. We monitor our cash needs and the status of the capital markets on a continuous basis. From time to time, we opportunistically raise capital and have done so numerous times since our initial public offering by issuing equity securities. We expect to continue to raise capital when and as needed and at the time and in the manner most advantageous to us.

As of December 31, 2025, we held cash, cash equivalents and marketable securities of $248.1 million. Based on our current operating plan, we believe we have sufficient funds to meet our operating requirements into 2028. We have based our estimate on assumptions that may prove to be wrong, and we may utilize our available capital resources sooner than we currently expect.

Our contractual obligations include operating lease obligations totaling $3.2 million as of December 31, 2025, of which $0.8 million are short-term. We also enter into contracts in the normal course of business with CROs for clinical trials and CMOs for clinical supply manufacturing and with vendors for nonclinical research studies and other services and products for operating purposes, which generally provide for termination within 30 days of notice.

Our future capital requirements will depend on many factors, including:

- our ability to realize future potential benefits pursuant to the Gilead Collaboration and maintain the collaboration;
- the future development costs we would incur if we elect to participate in the Profit-Share for programs advanced by Gilead under the Gilead Collaboration;
- the scope, progress, results and costs of our ongoing drug discovery, nonclinical development, laboratory testing and clinical studies of our product candidates and any additional clinical studies we may conduct in the future;
- our ability to manufacture, and to contract with third parties to manufacture, adequate supplies of our product candidates for our clinical studies and any eventual commercialization;
- the costs, timing and outcome of regulatory review of our product candidates; and
- the costs of preparing, filing and prosecuting patent applications in the United States and abroad, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims.

Cash Flows

The following table summarizes our cash flows for the periods presented (in thousands):

	Year Ended December 31,	
	2025	2024
Net cash used in operating activities	$ (41,093)	$ (51,117)
Net cash (used in) provided by investing activities	(113,468)	40,171
Net cash provided by financing activities	174,667	29,449
Net increase in cash and cash equivalents	$ 20,106	$ 18,503

Operating Activities

Net cash used in operating activities was $41.1 million for the year ended December 31, 2025, compared to $51.1 million for the same period in 2024. The decrease was primarily due to $25.2 million more cash received under the Gilead Collaboration Agreement in 2025 compared to 2024, partially offset by higher operating expenses in 2025 from the advancement of our clinical pipeline, most notably due to costs incurred for our HPI program.

Investing Activities

Net cash used in investing activities was $113.5 million for the year ended December 31, 2025, compared to net cash provided by investing activities of $40.2 million for the same period in 2024. The change was primarily due to our purchases of marketable securities following our financing in August 2025, as we invested the proceeds from those offerings.

Financing Activities

Net cash provided by financing activities was $174.7 million for the year ended December 31, 2025, compared to $29.4 million for the same period in 2024. The increase was due to larger net proceeds of $166.4 million from our financing in August 2025 and the subsequent exercise of warrants issued in that transaction, totaling $5.5 million, compared to the $27.3 million net proceeds received from our June and December 2024 financings.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Not applicable.

Item 8. Financial Statements and Supplementary Data

(a) Financial Statements

The financial statements required to be filed pursuant to this Item 8 are appended to this report. An index of those financial statements is found on page F-1.

(b) Supplementary Data

Not applicable.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain a system of disclosure controls and procedures, as defined in Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934, as amended (the Exchange Act), that is designed to provide reasonable assurance that information, which is required to be disclosed in our reports filed pursuant to the Exchange Act, is accumulated and communicated to management in a timely manner. At the end of fiscal year ending December 31, 2025, we carried out an evaluation, under the supervision, and with the participation of, our management, including our Chief Executive Officer and President, who serves as our principal executive officer, and our VP, Finance, who serves as our principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Exchange Act Rule 13a-15(b). Based upon that evaluation, our Chief Executive Officer and President and our VP, Finance concluded that our disclosure controls and procedures for the fiscal year ending as of December 31, 2025 were effective at reasonable assurance levels.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Our internal control over financial reporting is designed to provide reasonable assurance to our management and board of directors regarding the preparation and fair presentation of published financial statements. A control system, no matter how well designed and operated, can only provide reasonable, not absolute, assurance that the objectives of the control system are met. Because of these inherent limitations, management does not expect that our internal controls over financial reporting will prevent all error and all fraud. Under the supervision and with the participation of our management, including our Chief Executive Officer and President, who serves as our principal executive officer, and our VP, Finance, who serves as our principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control-Integrated Framework issued in 2013 by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework in Internal Control-Integrated Framework, our management concluded that our internal control over financial reporting was effective as of December 31, 2025.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting in the fourth quarter of 2025 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

Not applicable.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Except as set forth below, the information required by this item will be contained in our definitive proxy statement to be filed with the SEC in connection with the Annual Meeting of Stockholders (Proxy Statement) within 120 days after the conclusion of our fiscal year ended December 31, 2025 and is incorporated in this Annual Report on Form 10-K by reference.

Code of Ethics

Our Board has adopted a Code of Ethics for our principal executive officer and all senior financial officers and a Code of Conduct applicable to all of our employees and our directors. Both Codes are available under the "Investors—Corporate Governance" section of our website at www.assemblybio.com. If we make any substantive amendments to, or grant any waivers from, the Code of Ethics for our principal executive officer, principal financial officer, principal accounting officer, controller or persons performing similar functions, or any officer or director, we will disclose the nature of such amendment or waiver on our website or in a Current Report on Form 8-K.

Item 11. Executive Compensation

The information required by this item will be contained in the Proxy Statement and is incorporated into this Annual Report on Form 10-K by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

Except for the table regarding equity compensation plans, the information required by this item will be contained in the Proxy Statement and is incorporated into this Annual Report on Form 10-K by reference.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table sets forth the indicated information as of December 31, 2025 with respect to our equity compensation plans.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)		Weighted average exercise price of outstanding options, warrants and rights[1] (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)	
Equity compensation plans approved by security holders	1,368,993	[2]	$ 23.71	479,093	[3]
Equity compensation plans not approved by security holders	10,679,161	[4]	$ 20.66	14,594	[5]
Total	12,048,154			493,687	

(1) The weighted average exercise price is calculated solely based on the exercise prices of the outstanding stock options and warrants and does not reflect the shares that will be issued upon the vesting of outstanding awards of restricted stock units (RSUs) or performance stock units (PSUs), which have no exercise price.

(2) This number includes the following: 15,196 shares subject to stock options granted under the 2010 Equity Incentive Plan (2010 Plan); 205,462 shares subject to outstanding awards granted under the Assembly Biosciences, Inc. Amended and Restated 2014 Stock Incentive Plan (2014 Plan), of which 204,692 were subject to outstanding stock options and 770 were subject to outstanding RSUs; and 1,148,335 shares subject to outstanding awards granted under the Assembly Biosciences, Inc. Amended and Restated 2018 Stock Incentive Plan, as amended (2018 Plan), of which 822,690 were subject to outstanding stock options, 84,813 were subject to outstanding RSUs and 240,832 were subject to outstanding PSUs. This number excludes purchase rights currently accruing under the Assembly Biosciences, Inc. Second Amended and Restated 2018 Employee Stock Purchase Plan (ESPP).

(3) This number includes: no shares under the 2010 Plan, which has been frozen; 9,606 shares available for issuance under the 2014 Plan; 383,390 shares available for issuance under the 2018 Plan; and 86,097 shares reserved for issuance under the ESPP.

(4) This number includes 50,452 shares subject to stock options granted under the 2017 Inducement Award Plan (2017 Inducement Plan); 41,666 shares subject to stock options granted under the 2019 Inducement Award Plan (2019 Inducement Plan); 58,746 shares subject to stock options granted under the 2020 Inducement Award Plan (2020 Inducement Plan); and 10,528,297 warrants granted in offerings in June 2024 and August 2025.

(5) This number includes: 14,589 shares available for issuance under the 2017 Inducement Plan, no shares under the 2019 Inducement Plan and 5 shares available for issuance under the 2020 Inducement Plan.

Our stockholder-approved equity compensation plans consist of the 2018 Plan, the 2014 Plan, the 2010 Plan and the ESPP. Effective on June 2, 2016, the 2010 Plan was frozen, and no further grants will be made under the 2010 Plan. Shares that are forfeited under the 2010 Plan on or after June 2, 2016 will become available for issuance under the 2014 Plan. An “Award” under the 2018 Plan, 2014 Plan or 2010 Plan is any right to receive our common stock consisting of non-statutory stock options, incentive stock options, stock appreciation rights, RSUs, PSUs, or any other stock award.

In May 2018, our stockholders approved the ESPP, which was amended and restated in May 2021, May 2024 and June 2025. The ESPP provides for the purchase by employees of up to an aggregate of 225,000 shares of the Company’s common stock at the end of predetermined offering periods at 85% of the lower of the fair market value at the beginning or end of each offering period. Eligible employees may participate in the ESPP at a minimum of 1% and up to a maximum of 15% of such employee’s compensation for each pay period, subject to annual statutory limits.

Our outstanding equity compensation arrangements that have not been approved by our stockholders consist of the 2017 Inducement Plan, the 2019 Inducement Plan, the 2020 Inducement Plan and warrants granted in a registered direct offering and a private placement in June 2024. In April 2017, our board of directors adopted the 2017 Inducement Plan and reserved 66,666 shares of our common stock for issuance under the 2017 Inducement Plan. In August 2019, our board of directors adopted the 2019 Inducement Plan and reserved 41,666 shares of our common stock for issuance under the 2019 Inducement Plan. In March 2020, our board of directors adopted the 2020 Inducement Plan and reserved 66,666 shares of our common stock for issuance under the 2020 Inducement Plan. The only persons eligible to receive grants of awards under the 2017 Inducement Plan, the 2019 Inducement Plan or the 2020 Inducement Plan are individuals who satisfy the standards for inducement grants under Nasdaq Marketplace Rule 5635(c)(4) and the related guidance under Nasdaq IM 5635-1-that is, generally, a person not previously an employee or director of ours, or following a bona fide period of non-employment, as an inducement material to the individual's entering into employment with us. An “Award” is any right to receive our common stock pursuant to the Inducement Plan, consisting of non-statutory stock options, stock appreciation rights, restricted stock awards, RSUs, PSUs, or any other stock award.

Item 13. Certain Relationships and Related Party Transactions, and Director Independence

The information required by this item will be contained in the Proxy Statement and is incorporated into this Annual Report on Form 10-K by reference.

Item 14. Principal Accountant Fees and Services

The information required by this item will be contained in the Proxy Statement and is incorporated into this Annual Report on Form 10-K by reference.

Item 15. Exhibits, Financial Statement Schedules

(a) *Exhibits.* The following exhibits are filed as part of this Annual Report on Form 10-K:

Exhibit Number	Description of Document	Registrant's Form	Dated	Exhibit No.	Filed Herewith
3.1	Sixth Amended and Restated Certificate of Incorporation dated May 25, 2022.	10-K	03/28/2024	3.1	
3.2	Certificate of Amendment to Sixth Amended and Restated Certificate of Incorporation of Assembly Biosciences, Inc., dated February 9, 2024.	8-K	02/13/2024	3.1	
3.3	Amended and Restated Bylaws as amended through December 12, 2024.	8-K	12/13/2024	3.1	
4.1	Specimen of Common Stock Certificate.	10-K	03/20/2025	4.1	
4.2	Description of Securities.	10-K	03/28/2024	4.2	
4.3	Registered Warrant.	8-K	06/18/2024	4.1	
4.4	Private Placement Warrant.	8-K	06/18/2024	4.2	
4.5	Form of Class A Warrant.	10-Q	11/10/2025	4.1	
4.6	Form of Class B Warrant.	10-Q	11/10/2025	4.2	
4.7	Form of Pre-Funded Warrant.	10-Q	11/10/2025	4.3	
4.8	Private Placement Class A Warrant.	10-Q	11/10/2025	4.4	
4.9	Private Placement Class B Warrant.	10-Q	11/10/2025	4.5	
10.1	Sublease, dated July 26, 2023, by and between Arsenal Biosciences, Inc., as Sublandlord, and Assembly Biosciences, Inc., as Subtenant.	10-Q	11/08/2023	10.1	
10.2	First Amendment to Sublease, dated December 30, 2024, by and between Arsenal Biosciences, Inc. and Assembly Biosciences, Inc.	8-K	01/03/2025	10.1	
10.3‡	Option, License and Collaboration Agreement, dated October 15, 2023, by and between Assembly Biosciences, Inc. and Gilead Sciences, Inc.	8-K	10/17/2023	10.1	
10.4‡	First Amendment to Option, License and Collaboration Agreement, dated December 19, 2024, by and between Assembly Biosciences, Inc. and Gilead Sciences, Inc.	8-K	12/19/2024	10.1	
10.5‡	Common Stock Purchase Agreement, dated October 15, 2023, by and between Assembly Biosciences, Inc. and Gilead Sciences, Inc.	8-K	10/17/2023	10.2	
10.6	Amendment No. 1 to Common Stock Purchase Agreement, dated June 17, 2024, by and between Assembly Biosciences, Inc. and Gilead Sciences, Inc.	8-K	06/18/2024	10.3	
10.7‡	Investor Rights Agreement, dated October 15, 2023, by and between Assembly Biosciences, Inc. and Gilead Sciences, Inc.	8-K	10/17/2023	10.3	
10.8	Amendment No. 1 to Investor Rights Agreement, dated June 17, 2024, by and between Assembly Biosciences, Inc. and Gilead Sciences, Inc.	8-K	06/18/2024	10.4	
10.9#	Amended and Restated Employment Agreement, dated December 12, 2022, between Assembly Biosciences, Inc. and Jason A. Okazaki.	10-K	03/22/2023	10.7	
10.10#	Employment Agreement, dated May 1, 2020, between Assembly Biosciences, Inc. and William E. Delaney IV, Ph.D., effective as of May 27, 2020.	10-K	02/25/2021	10.12	
10.11#	Employment Agreement, dated November 8, 2023, between Assembly Biosciences, Inc. and Anuj Gaggar, M.D., Ph.D.	10-K	03/28/2024	10.11	

Exhibit Number	Description of Document	Registrant's Form	Dated	Exhibit No.	Filed Herewith
10.12#	Employment Agreement, dated February 10, 2022, between Assembly Biosciences, Inc. and Nicole S. White, Ph.D., effective as of February 16, 2022.	10-K	03/28/2024	10.12	
10.13#	2010 Equity Incentive Plan.	S-1/A	10/4/2010	10.14	
10.14#	Assembly Biosciences, Inc. Amended and Restated 2014 Stock Incentive Plan.	8-K	06/06/2016	10.1	
10.15#	Omnibus Amendment to Assembly Biosciences, Inc. Stock Incentive Plans.	10-Q	05/08/2020	10.2	
10.16#	Form of Notice of Stock Option Grant and Stock Option Agreement under the Amended and Restated 2014 Stock Incentive Plan.	10-K	03/22/2023	10.12	
10.17#	Form of Restricted Stock Unit Award Notice and Restricted Stock Unit Award Agreement under the Amended and Restated 2014 Stock Incentive Plan.	10-Q	11/01/2017	10.1	
10.18#	Assembly Biosciences, Inc. 2017 Inducement Award Plan.	10-Q	08/09/2017	10.1	
10.19#	Form of Notice of Stock Option Grant and Stock Option Agreement under the 2017 Inducement Award Plan.	10-Q	08/09/2017	10.2	
10.20#	Form of Restricted Stock Unit Award Notice and Restricted Stock Unit Award Agreement under the 2017 Inducement Award Plan.	10-Q	08/09/2017	10.3	
10.21#	Assembly Biosciences, Inc. Amended and Restated 2018 Stock Incentive Plan.	8-K	06/03/2024	10.1	
10.22#	Amendment No. 1 to Assembly Biosciences, Inc. Amended and Restated 2018 Stock Incentive Plan.	8-K	06/09/2025	10.1	
10.23#	Amendment No. 2 to Assembly Biosciences, Inc. Amended and Restated 2018 Stock Incentive Plan.	8-K	06/09/2025	10.2	
10.24#	Form of Notice of Stock Option Grant and Stock Option Agreement under the 2018 Stock Incentive Plan.	10-K	03/22/2023	10.22	
10.25#	Form of Restricted Stock Unit Award Notice and Restricted Stock Unit Award Agreement under the 2018 Stock Incentive Plan.	8-K	06/01/2018	10.3	
10.26#	Form of Stock Appreciation Right Award Agreement for Non-U.S. Grantees under the Assembly Biosciences, Inc. 2018 Stock Incentive Plan.	8-K	10/12/2018	10.4	
10.27#	Form of Performance-Based Stock Appreciation Right Award Agreement for Non-U.S. Grantees under the Assembly Biosciences, Inc. 2018 Stock Incentive Plan.	10-K	03/11/2022	10.27	
10.28#	Assembly Biosciences, Inc. Second Amended and Restated 2018 Employee Stock Purchase Plan.	8-K	06/03/2024	10.2	
10.29#	Amendment No. 1 to Assembly Biosciences, Inc. Second Amended and Restated 2018 Employee Stock Purchase Plan.	8-K	06/09/2025	10.3	
10.30#	Assembly Biosciences, Inc. 2019 Inducement Award Plan.	10-Q	11/07/2019	10.4	
10.31#	Form of Notice of Stock Option Grant and Stock Option Agreement under the 2019 Inducement Award Plan.	10-Q	11/07/2019	10.5	
10.32#	Assembly Biosciences, Inc. 2020 Inducement Award Plan.	10-Q	05/08/2020	10.3	
10.33#	Form of Notice of Stock Option Grant and Stock Option Agreement under the 2020 Inducement Award Plan.	10-Q	05/08/2020	10.4	
10.34#	Form of Restricted Stock Unit Award Notice and Restricted Stock Unit Award Agreement under the 2020 Inducement Award Plan.	10-Q	05/08/2020	10.5	

Exhibit Number	Description of Document	Registrant's Form	Dated	Exhibit No.	Filed Herewith
10.35	Securities Purchase Agreement, dated June 16, 2024, by and between Assembly Biosciences, Inc. and the Purchaser.	8-K	06/18/2024	10.1	
10.36	Securities Purchase Agreement, dated June 17, 2024, by and between Assembly Biosciences, Inc. and Gilead Sciences, Inc.	8-K	06/18/2024	10.2	
10.37	Securities Purchase Agreement, dated August 8, 2025, by and between Assembly Biosciences, Inc. and Gilead Sciences, Inc.	8-K	08/11/2025	10.1	
10.38#	Assembly Biosciences, Inc. 2024 Corporate Bonus Plan.	8-K	03/15/2024	10.1	
19.1	Assembly Biosciences, Inc. Insider Trading Policy.	10-K	03/20/2025	19.1	
21.1	List of Subsidiaries of Assembly Biosciences, Inc.	10-K	03/20/2025	21.1	
23.1	Consent of Independent Registered Public Accounting Firm.				X
24.1	Power of Attorney (included on signature page).				X
31.1	Certification of the Principal Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Certification of the Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1**	Certification of the Principal Executive Officer Pursuant to 18 U.S.C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
32.2**	Certification of the Principal Financial Officer Pursuant to 18 U.S.C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
97.1#	Clawback Policy.	10-K	03/28/2024	97.1	
101.INS	Inline XBRL Instance Document-the instance document does not appear in the Interactive Data File as its XBRL tags are embedded within the Inline XBRL document.				
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Document.				
104	Cover Page Interactive Data File, formatted in Inline XBRL (included as Exhibit 101)				

† The schedules to this exhibit have been omitted pursuant to Item 601(a)(5) of Regulation S-K.

‡ Portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

Represents management contracts or compensatory plans or arrangements.

** The certification attached as Exhibit 32.1 that accompanies this Annual Report on Form 10-K is to be deemed furnished and shall not be deemed "filed" with the SEC and is not to be incorporated by reference into any filing of Assembly Biosciences, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Annual Report on Form 10-K, irrespective of any general incorporation language contained in such filing.

Item 16. Form 10-K Summary

None.

SIGNATURES

In accordance with Section 13 or 15(d) of the Securities Exchange Act, the Registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ASSEMBLY BIOSCIENCES, INC.

Date: March 19, 2026

By: /s/ Jason A. Okazaki
Name: Jason A. Okazaki
Title: Chief Executive Officer and President

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Jason A. Okazaki and John O. Gunderson, jointly and severally, his or her attorneys-in-fact, each with the power of substitution, for him or her in any and all capacities, to sign any amendments to this report, and to file the same, with exhibits thereto and other documents in connection therewith with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact, or his or her substitute or substitutes may do or cause to be done by virtue hereof.

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

Signature	Title	Date
/s/ Jason A. Okazaki Jason A. Okazaki	Chief Executive Officer, President and Director (Principal Executive Officer)	March 19, 2026
/s/ Jeanette M. Bjorkquist Jeanette M. Bjorkquist	VP, Finance (Principal Financial Officer and Principal Accounting Officer)	March 19, 2026
/s/ William R. Ringo, Jr. William R. Ringo, Jr.	Chairman of the Board	March 19, 2026
/s/ Anthony E. Altig Anthony E. Altig	Director	March 19, 2026
/s/ Tomas Cihlar, Ph.D. Tomas Cihlar, Ph.D.	Director	March 19, 2026
/s/ Gina Consylman Gina Consylman	Director	March 19, 2026
/s/ Robert D. Cook II Robert D. Cook II	Director	March 19, 2026
/s/ Sir Michael Houghton, Ph.D. Sir Michael Houghton, Ph.D.	Director	March 19, 2026
/s/ Lisa R. Johnson-Pratt, M.D. Lisa R. Johnson-Pratt, M.D.	Director	March 19, 2026
/s/ Susan Mahony, Ph.D. Susan Mahony, Ph.D.	Director	March 19, 2026
/s/ John G. McHutchison, A.O., M.D. John G. McHutchison, A.O., M.D.	Director	March 19, 2026

ASSEMBLY BIOSCIENCES, INC.
FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Assembly Biosciences, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Assembly Biosciences, Inc. (the Company) as of December 31, 2025 and 2024, the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity and cash flows for each of the two years in the period ended December 31, 2025, 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 financial position of the Company at December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2025, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

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

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

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

Critical Audit Matter

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

Collaboration Agreement with Gilead Sciences, Inc.

Description of the Matter

As described in Note 8 to the consolidated financial statements, in July 2025, the Company entered into a letter agreement related to its 2023 Gilead Collaboration Agreement, which provided reimbursement to the Company for certain nonclinical study activities. The Company determined the letter agreement represents a contract modification within the scope of the revenue from contracts with customers guidance. The Company concluded there is a single combined performance obligation for research and development services during the remaining collaboration term and will recognize revenue over time using a cost-based input method. Additionally, in December 2025, Gilead exercised its option to exclusively license the Company's helicase-primase inhibitor (HPI) program. The Company determined that Gilead's exercise of the option represents a distinct performance obligation within the scope of the revenue from contracts with customers guidance. The Company recognized the revenue at a point in time upon the transfer of the license to Gilead.

Auditing the Company's accounting for the contract modification and option exercise required increased audit effort due to the complex and judgmental nature of evaluating the terms and assumptions under the agreements and determining the appropriate accounting under the revenue recognition guidance.

How We Addressed the Matter in Our Audit

To test the conclusions that the July 2025 modification and the December 2025 option exercise were accounted for appropriately, our audit procedures included, among others, reviewing the letter agreement and reviewing the option exercise notice and related communications, and evaluating whether management's accounting positions considered all relevant facts and terms. We further evaluated management's technical accounting analyses, including the identification of performance obligation, determination of the transaction price, and assessment of the timing of revenue recognition, and assessed whether management appropriately considered and applied the relevant accounting guidance and interpretations.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2015.

San Jose, California
March 19, 2026

ASSEMBLY BIOSCIENCES, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands except for share amounts and par value)

	As of December 31,	
	2025	**2024**
ASSETS		
Current assets		
Cash and cash equivalents	$ 58,450	$ 38,344
Marketable securities	189,656	73,735
Accounts receivable from collaboration with a related party	974	—
Prepaid expenses and other current assets	5,469	3,424
Total current assets	254,549	115,503
Property and equipment, net	221	284
Operating lease right-of-use (ROU) assets	2,508	3,069
Other assets	312	312
Total assets	**$ 257,590**	**$ 119,168**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 1,171	$ 585
Accrued research and development expenses	2,387	2,273
Other accrued expenses	7,749	6,862
Deferred revenue from a related party - short-term	36,904	37,622
Operating lease liabilities - short-term	569	461
Total current liabilities	48,780	47,803
Deferred revenue from a related party - long-term	—	35,378
Operating lease liabilities - long-term	2,059	2,628
Total liabilities	**50,839**	**85,809**
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; no shares issued or outstanding	—	—
Common stock, $0.001 par value; 150,000,000 shares authorized as of December 31, 2025 and December 31, 2024; 15,855,329 and 7,457,240 shares issued and outstanding as of December 31, 2025 and December 31, 2024, respectively	16	7
Additional paid-in capital	1,038,823	859,488
Accumulated other comprehensive loss	(41)	(211)
Accumulated deficit	(832,047)	(825,925)
Total stockholders' equity	206,751	33,359
Total liabilities and stockholders' equity	**$ 257,590**	**$ 119,168**

See Accompanying Notes to the Consolidated Financial Statements

ASSEMBLY BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands except for share and per share amounts)

	Year Ended December 31,	
	2025	**2024**
Collaboration revenue from a related party	$ 72,303	$ 28,520
Operating expenses		
Research and development	64,813	55,933
General and administrative	19,608	18,007
Total operating expenses	84,421	73,940
Loss from operations	**(12,118)**	**(45,420)**
Other income		
Interest and other income, net	5,996	5,573
Total other income	5,996	5,573
Loss before income taxes	**(6,122)**	**(39,847)**
Income tax expense	—	330
Net loss	**$ (6,122)**	**$ (40,177)**
Other comprehensive loss		
Unrealized gain (loss) on marketable securities	170	(130)
Comprehensive loss	**$ (5,952)**	**$ (40,307)**
Net loss per share, basic and diluted	$ (0.55)	$ (6.69)
Weighted average common shares outstanding, basic and diluted	11,210,934	6,004,560

See Accompanying Notes to the Consolidated Financial Statements

ASSEMBLY BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(In thousands except for share amounts)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of December 31, 2023	**5,482,752**	**$ 5**	**$ 826,921**	**$ (81)**	**$ (785,748)**	**$ 41,097**
Issuance of common stock under at-the-market (ATM) equity offering program, net of issuance costs	152,666	—	2,030	—	—	2,030
Issuance of common stock and warrants in a registered direct offering, net of issuance costs	634,500	1	9,661	—	—	9,662
Issuance of common stock and warrants in a private placement to a related party, net of issuance costs	1,119,999	1	17,601	—	—	17,602
Issuance of common stock upon exercise of stock options	514	—	5	—	—	5
Issuance of common stock under Employee Stock Purchase Plan (ESPP)	14,937	—	150	—	—	150
Issuance of common stock for settlement of restricted stock units (RSUs)	51,872	—	—	—	—	—
Unrealized loss on marketable debt securities	—	—	—	(130)	—	(130)
Stock-based compensation	—	—	3,120	—	—	3,120
Net loss	—	—	—	—	(40,177)	(40,177)
Balance as of December 31, 2024	**7,457,240**	**$ 7**	**$ 859,488**	**$ (211)**	**$ (825,925)**	**$ 33,359**
Issuance of common stock under ATM equity offering program, net of issuance costs	161,645	1	1,921	—	—	1,922
Issuance of common stock, pre-funded warrants and warrants in an underwritten offering, net of issuance costs	5,591,840	6	123,594	—	—	123,600
Issuance of common stock and warrants in a private placement to a related party, net of issuance costs	2,295,920	2	42,783	—	—	42,785
Issuance of common stock upon exercise of warrants	255,103	—	5,510	—	—	5,510
Issuance of common stock under ESPP	69,320	—	725	—	—	725
Issuance of common stock upon exercise of stock options	5,406	—	125	—	—	125
Issuance of common stock for settlement of RSUs	18,855	—	—	—	—	—
Unrealized gain on marketable debt securities	—	—	—	170	—	170
Stock-based compensation	—	—	4,677	—	—	4,677
Net loss	—	—	—	—	(6,122)	(6,122)
Balance as of December 31, 2025	**15,855,329**	**$ 16**	**$ 1,038,823**	**$ (41)**	**$ (832,047)**	**$ 206,751**

See Accompanying Notes to the Consolidated Financial Statements

ASSEMBLY BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31,	
	2025	**2024**
Cash flows from operating activities		
Net loss	$ (6,122)	$ (40,177)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	129	129
Stock-based compensation	4,677	3,120
Net accretion of investments in marketable debt securities	(2,346)	(3,658)
Non-cash rent expense	851	1,417
Realized gain on investments in marketable debt securities	(3)	—
Changes in operating assets and liabilities:		
Accounts receivable from collaboration	(974)	43
Prepaid expenses and other current assets	(2,045)	73
Accounts payable	586	124
Accrued research and development expenses	114	1,388
Other accrued expenses	887	1,118
Deferred revenue from a related party	(36,096)	(13,294)
Operating lease liabilities	(751)	(1,400)
Net cash used in operating activities	(41,093)	(51,117)
Cash flows from investing activities		
Proceeds from maturities of marketable securities	116,432	130,700
Purchases of marketable securities	(229,834)	(90,501)
Purchases of property and equipment	(66)	(28)
Net cash (used in) provided by investing activities	(113,468)	40,171
Cash flows from financing activities		
Proceeds from the issuance of common stock, pre-funded warrants and warrants in an underwritten offering, net of issuance costs	123,600	—
Proceeds from the issuance of common stock and warrants in private placements to a related party, net of issuance costs	42,785	17,602
Proceeds from the exercise of warrants	5,510	—
Proceeds from the issuance of common stock under ATM equity offering program, net of issuance costs	1,922	2,030
Proceeds from the issuance of common stock under ESPP	725	150
Proceeds from the exercise of stock options	125	5
Proceeds from the issuance of common stock and warrants in a registered direct offering, net of issuance costs	—	9,662
Net cash provided by financing activities	174,667	29,449
Net increase in cash and cash equivalents	20,106	18,503
Cash and cash equivalents at the beginning of the year	38,344	19,841
Cash and cash equivalents at the end of the year	**$ 58,450**	**$ 38,344**
Supplemental non-cash investing and financing activities		
Operating lease liabilities arising from obtaining ROU assets	$ —	$ 1,966

See Accompanying Notes to the Consolidated Financial Statements

Note 1 - Nature of Business

Overview

Assembly Biosciences, Inc. (together with its subsidiaries, Assembly or the Company), incorporated in Delaware in October 2005, is a biotechnology company developing innovative therapeutics targeting serious viral diseases with the potential to improve the lives of patients worldwide. The Company's pipeline includes multiple clinical-stage investigational therapies, including: (1) two long-acting helicase-primase inhibitors (HPI) for the treatment of recurrent genital herpes; (2) an orally bioavailable hepatitis delta virus entry inhibitor; and (3) a highly potent next-generation capsid assembly modulator designed to disrupt the replication cycle of hepatitis B virus (HBV) at several key points. The Company's pipeline also includes a novel, oral broad-spectrum non-nucleoside polymerase inhibitor (NNPI) for the treatment of transplant-related herpesviruses, which is currently undergoing studies to enable a regulatory filing, and it has additional research programs against multiple antiviral targets. In December 2025, pursuant to the collaboration with Gilead Sciences, Inc. (Gilead), Gilead exercised its option to license the Company's HPI program, including its long-acting investigational candidates ABI-1179 (1179) and ABI-5366 (5366). For additional information see Note 8 - Collaboration Agreements. The Company operates in one segment and is headquartered in South San Francisco, California (see Note 13 - Segment Reporting).

Liquidity

The Company has not derived any revenue from product sales to date and currently has no approved products. Once a product has been developed, it will need to be approved for sale by the U.S. Food and Drug Administration (FDA) or an applicable foreign regulatory agency. Since the Company’s initial public offering, its operations have been financed through the sale of equity securities and payments related to collaboration agreements. The Company has incurred losses from operations since inception and expects to continue to incur substantial losses for the next several years as it continues its product development efforts. The Company intends to obtain any additional funding it requires through strategic relationships, public or private equity or debt financings, grants or other arrangements. The Company cannot assure such funding will be available on reasonable terms, if at all. As of December 31, 2025, the Company held cash, cash equivalents and marketable securities of $248.1 million. Management believes the Company currently has sufficient funds to meet its operating requirements beyond one year from the date these consolidated financial statements are issued.

Note 2 - Summary of Significant Accounting Policies and Recent Accounting Pronouncements

Basis of Presentation

These consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (U.S. GAAP) and include the accounts of the Company and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that may affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

Significant estimates inherent in the preparation of the accompanying consolidated financial statements include estimates for revenue recognition, including the standalone selling price (SSP) for the allocation of transaction price to performance obligations and cost-based inputs, as well as estimates of costs incurred but not yet invoiced for research and development accruals.

The Company's estimates could be affected by external conditions, including those unique to the Company and general economic conditions. It is reasonably possible these external factors could have an effect on the Company's estimates and could cause actual results to differ materially from those estimates and assumptions.

Other Risks and Uncertainties

U.S. and global financial markets have experienced and may continue to experience volatility and disruption due to macroeconomic and geopolitical events such as rising inflation, changes in interest rates to combat inflation, the war between Russia and Ukraine, the conflicts in the Middle East, including the recent hostilities involving Iran, and in Venezuela, tensions between China and Taiwan, as well as tariffs or the imposition and enforceability of tariffs, trade wars, barriers or restrictions, or threats of such actions and the related uncertainty thereof, including uncertainties regarding the ability to obtain refunds for previously paid tariffs that have subsequently been invalidated. The Company cannot predict at this time to what extent, if at all, it and its employees, contract research organizations (CROs), vendors and/or collaborators could potentially be negatively impacted by these events.

Cash and Cash Equivalents

All highly liquid investments with original maturities of three months or less at the time of purchase are considered to be cash equivalents. All of the Company's cash equivalents have liquid markets and high credit ratings.

Investments in Marketable Securities

The Company has designated its investments in marketable securities as available-for-sale and measures these securities at their respective fair values. The Company reviews all available-for-sale securities at each period end to determine if they remain available-for-sale based on their current intent and ability to sell the security if it is required to do so. Marketable securities are classified as short-term or long-term based on the maturity date and their availability to meet current operating requirements. Marketable securities that mature in one year or less from the consolidated balance sheet date are classified as short-term available-for-sale securities, while marketable securities with maturities in one year or beyond one year from the consolidated balance sheet date are classified as long-term.

The Company periodically reviews its marketable securities for declines in fair value below the amortized cost basis to determine whether the impairment, if any, is due to credit-related or other factors. This review includes the credit worthiness of the security issuers, the severity of the unrealized losses, whether the Company has the intent to sell the securities and whether it is more likely than not the Company will be required to sell the securities before the recovery of the amortized cost basis. Unrealized gains and losses on available-for-sale securities are reported in other comprehensive loss, and as a component of stockholders' equity until their disposition, with the exception of unrealized losses believed to be related to credit losses which are recognized as an allowance for credit losses on the consolidated balance sheet with the corresponding charge in other income in the period the impairment occurs. Impairment assessments are made at the individual security level each reporting period. The Company elected to exclude accrued interest receivable from the amortized cost basis of its available-for-sale debt securities and to not measure an allowance for credit losses for accrued interest receivable. To date, there have been no credit-related declines in value or other impairments of the Company's investments in marketable securities. Realized gains and losses from the sale of marketable securities, if any, are calculated using the specific-identification method.

Leases

All of the Company's leases are operating leases for facilities and equipment. The Company recognizes a lease asset for its right to use the underlying asset and a lease liability for the corresponding lease obligation. The Company determines if an arrangement is or contains a lease at inception or modification of the arrangement. Operating leases with a duration greater than one year are included in operating lease ROU assets, operating lease liabilities - short-term, and operating lease liabilities - long-term in the Company's consolidated balance sheets. The Company elected the short-term lease exception policy, permitting it to not apply the recognition requirements to leases with terms of less than one year (short-term leases) for all classes of assets. Operating lease ROU assets and liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. In determining the net present value of lease payments, the Company uses its incremental borrowing rate based on the information available at the lease commencement date. The incremental borrowing rate represents the interest rate the Company would incur at lease commencement to borrow an amount equal to the lease payments on a collateralized basis over

the term of a lease. The Company considers a lease term to be the noncancelable period that it has the right to use the underlying asset, including any periods where it is reasonably assured the Company will exercise the option to extend the contract. Periods covered by an option to extend are included in the lease term if the lessor controls the exercise of that option.

The operating lease ROU assets also include any lease payments made and exclude lease incentives. Lease expense is recognized on a straight-line basis over the expected lease term. Variable lease expenses are recorded when incurred. The Company has elected not to separate lease and non-lease components for its leased assets and accounts for all lease and non-lease components of its agreements as a single lease component.

Impairment of Long-Lived Assets

The Company monitors the carrying value of long-lived assets, including ROU operating lease assets, for potential impairment and tests the recoverability of such assets whenever events or changes in circumstances indicate the carrying amounts may not be recoverable. If a change in circumstance occurs, the Company performs a test of recoverability by comparing the carrying value of the asset or asset group to its undiscounted expected future cash flows. If cash flows cannot be separately and independently identified for a single asset, the Company will determine whether impairment has occurred for the group of assets for which the Company can identify the projected cash flows. If the carrying values are in excess of undiscounted expected future cash flows, the Company measures any impairment by comparing the fair value of the asset or asset group to its carrying value. There was no impairment of long-lived assets during the years ended December 31, 2025 and 2024.

Fair Value Measurements

The Company follows accounting guidance on fair value measurements for financial instruments measured on a recurring basis, as well as for certain assets and liabilities that are initially recorded at their estimated fair values. Fair value is defined as the exit price, or the amount that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The Company uses the following three-level hierarchy that maximizes the use of observable inputs and minimizes the use of unobservable inputs to value its financial instruments:

Level 1: Observable inputs such as unadjusted quoted prices in active markets for identical instruments.

Level 2: Quoted prices for similar instruments that are directly or indirectly observable in the marketplace.

Level 3: Significant unobservable inputs which are supported by little or no market activity and that are financial instruments whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value requires significant judgment or estimation.

Financial instruments measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The assessment of the significance of a particular input to the fair value measurement in its entirety requires the Company to make judgments and consider factors specific to the asset or liability. The use of different assumptions and/or estimation methodologies may have a material effect on estimated fair values. Accordingly, the fair value estimates disclosed or initial amounts recorded may not be indicative of the amount the Company or holders of the instruments could realize in a current market exchange.

The carrying amounts of cash equivalents and marketable securities approximate their fair value based upon quoted market prices. Certain of the Company’s financial instruments are not measured at fair value on a recurring basis but are recorded at amounts which approximate their fair value due to their liquid or short-term nature, such as cash, accounts receivable, accounts payable and accrued expenses.

Revenue Recognition and Accounts Receivable from Collaboration

The Company analyzes its collaboration arrangements to assess whether such arrangements, or transactions between arrangement participants, involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities or are more akin to a vendor-customer relationship. In making this evaluation, the Company considers whether the activities of the collaboration are considered to be distinct and deemed to be within the scope of the collaborative arrangement accounting standard and those that are more reflective of a vendor-customer relationship and, therefore, within the scope of the revenue with contracts with customers accounting standard. This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement.

For elements of collaboration arrangements that are not accounted for pursuant to the revenue from contracts with customers accounting standard, an appropriate recognition method is determined and applied consistently, generally by analogy to the revenue from contracts with customers accounting standard. Amounts related to transactions with a counterparty in a collaborative arrangement that is not a customer are presented on a separate line item from revenue recognized from contracts with customers, if any, in the Company's consolidated statements of operations and comprehensive loss.

Under certain agreements under the scope of the collaborative arrangements accounting standard, the Company has been reimbursed for a portion of its research and development expenses or participates in the cost-sharing of such research and development expenses. Such reimbursements and cost-sharing arrangements are reflected as a reduction of research and development expense in the Company's consolidated statements of operations and comprehensive loss.

For arrangements or transactions between arrangement participants determined to be within the scope of the contracts with customers accounting standard, the Company evaluates the term of the arrangement and recognizes revenue when the customer obtains control of promised goods or services in a contract for an amount that reflects the consideration the Company expects to receive in exchange for those goods or services. For contracts with customers, the Company applies the following five-step model in order to determine this amount: (1) identification of the contract(s) with a customer; (2) identification of the performance obligations in the contract, including whether they are distinct in the context of the contract; (3) measurement of the transaction price, including the constraint on variable consideration; (4) allocation of the transaction price to the performance obligations; and (5) recognition of revenue when (or as) the Company satisfies each performance obligation. Amounts of variable consideration are included in the transaction price to the extent it is probable a significant reversal in the amount of cumulative revenue recognized will not occur and when the uncertainty associated with the variable consideration is subsequently resolved.

The Company has provided standard indemnification and protection of licensed intellectual property for its customers. These provisions are part of assurance the licenses meet the agreements, representations and are not obligations to provide goods or services.

The Company only applies the five-step model to contracts when it is probable the Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. As part of the accounting for contracts with customers, the Company must develop assumptions that require judgment to determine the estimated relative SSP of each performance obligation identified in the contract. The Company then allocates the total transaction price to each performance obligation based on the SSP of each performance obligation. The Company recognizes the amount of the transaction price that is allocated to the respective performance obligation when the performance obligation is satisfied or as it is satisfied as revenue.

Contract modifications, defined as changes in the scope or price (or both) of a contract that are approved by the parties to the contract, such as a contract amendment, exist when the parties to a contract approve a modification that either creates new, or changes existing, enforceable rights and obligations of the parties to the contract. The Company accounts for contract modifications using one of the following methods depending on facts and circumstances: (i) as a separate contract if the modification adds distinct goods or services and the price reflects the SSP of those additional goods or services; (ii) as a termination of the existing contract and creation of a new contract if the remaining goods or services are distinct from those transferred before the modification; or (iii) as a cumulative catch-up adjustment to the original contract if the remaining goods or services are not distinct from those transferred before the modification.

Licenses

If a license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from license fees based on the relative value prescribed to the license compared to the total value of the arrangement. The revenue is recognized when the license is transferred to the collaborator and the collaborator is able to use and benefit from the license. For licenses that are not distinct from other obligations identified in the arrangement, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time. If the combined performance obligation is satisfied over time, the Company applies an appropriate method of measuring progress for purposes of recognizing revenue from license fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Research and Development Services

The promises under the Company's agreements may include research and development services to be performed by the Company on behalf of the counterparty. If these services are determined to be distinct from the other promises or performance obligations identified in the arrangement, the Company recognizes the transaction price allocated to these services as revenue over time based on an appropriate measure of progress when the performance by the Company does not create an asset with an alternative use and the Company either has received or has an enforceable right to payment for the performance completed to date. If these services are determined not to be distinct from the other promises or performance obligations identified in the arrangement, the Company recognizes the transaction price allocated to the combined performance obligation as the related performance obligations are satisfied.

Customer Options

If an arrangement contains customer options, the Company evaluates whether the options are material rights because they allow the customer to acquire additional goods or services for free or at a discount. If the customer options are determined to represent a material right, the material right is recognized as a separate performance obligation at the outset of the arrangement. The identification of a material right, and if identified as a material right, the allocation of the transaction price to it, is based on the SSP, which is determined using assumptions regarding estimated costs, discount rates, post-option development timeline, the probability of technical and regulatory success and the probability the customer will exercise the option. Amounts allocated to a material right are not recognized as revenue until, at the earliest, the option is exercised or expires. If the options are deemed not to be a material right, they are considered marketing offers which are excluded as performance obligations at the outset of the arrangement.

Development and Regulatory Milestone Payments

Depending on facts and circumstances, the Company may record revenues from certain milestones in a reporting period before the milestone is achieved if the Company concludes achievement of the milestone is probable and recognition of revenue related to the milestone will not result in a significant reversal in amounts recognized in future periods. The Company records a corresponding contract asset when this conclusion is reached. Milestone payments that have not been included in the transaction price to date are fully constrained. The Company re-evaluates the probability of achievement of such milestones and any related constraint each reporting period. The Company adjusts its estimate of the overall transaction price, including the amount of collaborative revenue that was recorded, if necessary.

Sales-based Milestone and Royalty Payments

The Company's customers may be required to pay the Company sales-based milestone payments or royalties on future sales of commercial products. The Company recognizes revenues related to sales-based milestone and royalty payments upon the later to occur of (i) achievement of the collaborator's underlying sales or (ii) satisfaction of any performance obligation(s) related to these sales, in each case assuming the Company's licensed intellectual property is deemed to be the predominant item to which the sales-based milestones and/or royalties relate.

The Company receives payments from its customers based on billing schedules established in the contract. Upfront payments and fees are recorded as deferred revenue upon receipt or when due until the Company performs its obligations under the arrangement. If the related performance obligation is expected to be satisfied within the next twelve months, these amounts will be classified in current liabilities. The Company recognizes a contract asset relating to its conditional right to consideration that is not subject to a constraint. Amounts are recorded as accounts receivable when the Company's right to consideration is unconditional.

A net contract asset or liability is presented for each contract with a customer. The Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the customer and the transfer of the promised goods or services to the customer will be one year or less.

At December 31, 2025, all accounts receivable from collaboration with a related party are deemed collectible. There were no accounts receivable from collaboration as of December 31, 2024.

Warrants and Pre-Funded Warrants

The Company determines the accounting classification of warrants it issues as either liability or equity-classified based on an assessment of the warrant's specific terms. The assessment considers whether the warrants are freestanding

financial instruments, whether the warrants meet the definition of a liability and whether the warrants meet all the requirements for equity classification. Equity classified warrants are accounted for using a relative fair value allocation method, with fair values determined at issuance using a Black-Scholes model.

Stock-Based Compensation

The Company measures stock-based compensation to employees and board members at fair value on the grant date of the award. The fair value of RSUs is determined based on the number of shares granted and the quoted market price of the Company's common stock on the date of grant. The fair value of performance stock units (PSUs), which include awards with performance conditions and market conditions, are determined as follows: (i) PSUs with performance conditions are measured based on the fair value of the award on the grant date, the date performance targets are established, and is expensed over the requisite service period for each separately vesting tranche when achievement of the performance condition becomes probable, and (ii) PSUs with market conditions are measured based on the grant-date fair value of the award and is expensed over the derived service period regardless of whether the underlying market condition is met.

The Company estimates the fair value of stock option grants that do not contain market-based vesting conditions using the Black-Scholes option pricing model. The assumptions used in estimating the fair value of these awards, such as expected term, expected dividend yield, volatility and risk-free interest rate, represent management's best estimates and involve inherent uncertainties and the application of management's judgment. The Company calculates the weighted average expected term of options using the simplified method where permitted by accounting guidance for stock-based compensation when there is limited history of relevant stock option exercise activity. The Company uses an expected dividend yield of zero as the Company currently does not intend to pay dividends in the foreseeable future. The Company calculates the expected volatility based on the Company's historical stock prices. The risk-free interest rate assumption is based on the rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the expected term of the stock option being valued.

If stock-based awards are granted in contemplation of or shortly before a planned release of material nonpublic information, and such information is expected to result in a material increase in the Company's share price, the Company considers whether an adjustment to the observable market price is required when estimating fair values. Compensation cost is recognized as expense on a straight-line basis over the requisite service period of the award. Stock-based awards with graded vesting schedules are recognized using the accelerated attribution method on a straight-line basis over the requisite service period for each separately vesting portion of the award. Forfeitures are recognized when they occur.

The Company assesses the probability of the performance conditions being met on a continuous basis and is also required to make estimates as to the probability of achieving the specific performance conditions. If actual results are not consistent with the Company's assumptions and judgments used in making these estimates, the Company may be required to increase or decrease compensation expense, which could be material to the Company's consolidated results of operations.

Research and Development Expense and Accruals

Research and development costs include personnel-related costs, outside contracted services including clinical study costs, facilities costs, fees paid to consultants, milestone payments prior to FDA approval, license fees prior to FDA approval, professional services, travel costs, dues and subscriptions, depreciation and materials used in clinical trials and research and development and costs incurred under the Company's collaboration agreements. Research and development costs are expensed as incurred unless there is an alternative future use in other research and development projects. Payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods or services are received. Such payments are evaluated for current or long-term classification based on when they will be realized or consumed.

The Company records expenses related to clinical studies and manufacturing development activities based on its estimates of the services received and efforts expended pursuant to contracts with multiple CROs and manufacturing vendors that conduct and manage these activities on its 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 the Company's 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 subjects and

the completion of clinical study milestones. In amortizing or accruing service fees, the Company estimates the time period over which services will be performed, enrollment of subjects, number of sites activated and the level of effort expended in each period. If the actual timing of the performance of services or the level of effort varies from the Company's estimate, the Company will adjust the accrued or prepaid expense balance accordingly. To date, there have been no material differences from the Company's estimates to the amounts actually incurred.

The Company has entered and may continue to enter into license agreements to access and utilize certain technology. In each case, the Company evaluates if the license agreement results in the acquisition of an asset or a business. To date, none of the Company's license agreements have been considered to be acquisitions of businesses. For asset acquisitions, the upfront payments to acquire such licenses, as well as any future milestone payments, are immediately recognized as research and development expense when paid, provided there is no alternative future use of the rights in other research and development projects. These license agreements may also include contingent consideration in the form of cash payments to be made for future milestone events. The Company assesses whether such contingent consideration meets the definition of a derivative and to date the Company has determined that such contingent consideration are not derivatives.

Income Taxes

The Company records income taxes using the asset and liability method. Deferred income tax assets and liabilities are recognized for the future tax effects attributable to temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective income tax bases, and operating loss and tax credit carryforwards. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date. The Company establishes a valuation allowance if it is more likely than not the deferred tax assets will not be realized based on an evaluation of objective verifiable evidence.

The Company recognizes and measures tax benefits from uncertain tax positions only if it is more likely than not the tax position will be sustained in an audit, including resolution of any related appeals or litigation processes. The tax benefit recognized for a particular tax position is based on the largest amount that is more than 50% likely to be realized upon ultimate settlement. Significant judgment is required to evaluate uncertain tax positions. The Company evaluates uncertain tax positions on a regular basis. The evaluations are based on a number of factors, including changes in facts and circumstances, changes in tax law, correspondence with tax authorities during the course of the audit, and effective settlement of audit issues. The provision for income taxes includes the effects of any accruals which the Company believes are appropriate. It is the Company's policy to recognize interest and penalties related to income tax matters in income tax expense.

In July 2025, the U.S. enacted tax reform legislation through the One Big Beautiful Bill Act (OBBBA). Some of the provisions of the new tax law affecting corporations include but are not limited to current deduction of domestic research expenses, increasing the limit of the deduction of interest expense deduction to thirty percent of earnings before interest, tax, depreciation and amortization, and one hundred percent bonus depreciation on eligible property acquired after January 19, 2025. The Company has evaluated the impact the new tax law had on its financial condition and results of operations. The impact of the tax law changes from the OBBBA is included in the Company's consolidated financial statements.

Net Loss per Share

Basic net loss per common share excludes dilution and is computed by dividing net loss by the weighted average number of common shares outstanding during the period. Diluted net loss per common share reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock or resulted in the issuance of common stock that then shared in the earnings of the entity unless inclusion of such shares would be anti-dilutive. Diluted net loss per share is the same as basic net loss per share in the years reported, since the effects of potentially dilutive securities are antidilutive given the net loss for each year presented.

A reconciliation of the numerators and the denominators of the basic and diluted net loss per common share computations is as follows (in thousands, except for share and per share amounts):

	Year Ended December 31,	
	2025	2024
Numerator:		
Net loss	$ (6,122)	$ (40,177)
Denominator:		
Weighted average common shares outstanding - basic and diluted	11,210,934	6,004,560
Net loss per share - basic and diluted	$ (0.55)	$ (6.69)

Securities excluded from the computation of diluted net loss per share because including them would have been antidilutive are as follows:

	December 31,	
	2025	2024
Warrants to purchase common stock	9,487,477	814,000
Options to purchase common stock	1,193,442	942,193
Common stock subject to purchase under ESPP	6,093	9,386
Unvested RSUs	85,583	52,222
Unvested PSUs	240,832	15,832
Total	11,013,427	1,833,633

In August 2025, the Company sold pre-funded warrants to purchase up to 1,040,820 shares of common stock (see Note 6 - Stockholders' Equity). The pre-funded warrants are exercisable at $0.001 per share. The shares of common stock into which the pre-funded warrants may be exercised are considered outstanding for purposes of computing earnings per share because the shares may be issued for little or no consideration, they are fully vested, and are exercisable after the original issuance date.

Comprehensive Loss

Comprehensive loss is comprised of net loss and adjustments for the change in unrealized gains and losses on investments in available-for-sale marketable securities. The Company displays comprehensive loss and its components in the consolidated statements of operations and comprehensive loss, net of tax effects if any.

Concentrations of Risk

Credit Risk

Financial instruments which potentially subject the Company to credit risk consist primarily of cash, cash equivalents and marketable securities. The Company holds these investments in highly rated financial institutions, and, by policy, limits the amounts of credit exposure to any one financial institution. These amounts as of and at times during the year ended December 31, 2025 exceeded federally insured limits. The Company has not experienced any credit losses in such accounts and does not believe it is exposed to any significant credit risk on these funds. The Company has no off-balance sheet concentrations of credit risk, such as foreign currency exchange contracts, option contracts or other hedging arrangements.

Supplier Risk

Certain materials and key components the Company utilizes in its operations are obtained through single suppliers. Since the suppliers of key components and materials must be named in a New Drug Application filed with the FDA for a product, significant delays can occur if the qualification of a new supplier is required. If delivery of material from the Company's suppliers were interrupted for any reason, the Company may be unable to supply any of its product candidates for clinical trials.

Customer Risk

During the year ended December 31, 2025, 100% of the Company's collaboration revenue was recognized from a related party, Gilead, under the Gilead Collaboration Agreement (see Note 8 - Collaboration Agreements). If the collaboration with Gilead does not result in the successful development and commercialization of products or if Gilead terminates the Gilead Collaboration Agreement, the Company may not receive any future payments under the collaboration.

Recently Adopted Accounting Standards

In December 2023, the Financial Accounting Standards Board (the FASB) issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* (ASU 2023-09). The update requires a public business entity to disclose, on an annual basis, a tabular rate reconciliation using both percentages and currency amounts, broken out into specified categories with certain reconciling items further broken out by nature and jurisdiction to the extent those items exceed a specified threshold. In addition, all entities are required to disclose income taxes paid, net of refunds received disaggregated by federal, state/local, and foreign and by jurisdiction if the amount is at least 5% of total income tax payments, net of refunds received. The Company adopted ASU 2023-09 on a prospective basis during the year ended December 31, 2025. See Note 10 - Income Taxes for further details.

Accounting Pronouncements to Be Adopted

In November 2024, the FASB issued ASU 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses* (ASU 2024-03), which requires the disaggregation of certain expense captions into specified categories in disclosures within the notes to the financial statements to provide enhanced transparency into the expense captions presented on the face of the income statement. ASU 2024-03 is effective for annual reporting periods beginning after December 15, 2026 and interim periods beginning after December 15, 2027, with early adoption permitted, and may be applied either prospectively or retrospectively to financial statements issued for reporting periods after the effective date of ASU 2024-03 or retrospectively to any or all prior periods presented in the financial statements. The Company does not expect the potential impact of adopting ASU 2024-03 to have a material impact on its disclosures.

In December 2025, the FASB issued ASU 2025-11, *Interim Reporting (Topic 270): Narrow-Scope Improvements* (ASU 2025-11), which clarifies the guidance in Topic 270 to improve the consistency of interim financial reporting. The ASU provides a comprehensive list of required interim disclosures and introduces a disclosure principle requiring entities to disclose events since the end of the last annual reporting period that have a material impact on the entity. ASU 2025-11 is effective for fiscal years beginning after December 15, 2027, including interim periods within those fiscal years, with early adoption permitted. The Company does not expect the impact of adopting ASU 2025-11 to have a material impact on its financial statements.

Note 3 - Related Party

In October 2023, the Company entered into the Option, License and Collaboration Agreement (Gilead Collaboration Agreement), and a Common Stock Purchase Agreement and an Investor Rights Agreement (collectively, the Gilead Equity Agreements) with Gilead. Following the Company entering into the Gilead Equity Agreements, and as of December 31, 2025, Gilead is considered a related party based on its ownership of the Company's common stock.

Gilead Equity Agreements

In June 2024, the Company entered into a Securities Purchase Agreement with Gilead for the issuance and sale of 179,500 shares of common stock and a warrant to purchase up to 179,500 shares of common stock in a private

placement (the June 2024 Private Placement). This transaction, which generated aggregate gross proceeds of $2.8 million, was executed concurrently with the June 2024 Registered Direct Offering (as defined below). See Note 6 - Stockholders' Equity for additional details. Also in June 2024, the Gilead Equity Agreements were amended. The amendments did not have an impact on the Company's consolidated financial statements.

In December 2024, Gilead exercised its right under the Gilead Equity Agreements to purchase additional shares of common stock from the Company at a purchase price of $21.37 per share, for aggregate proceeds of $20.1 million, resulting in Gilead owning 29.9% of the Company's then-outstanding voting common stock.

In August 2025, the Company entered into a Securities Purchase Agreement with Gilead for the issuance and sale of 2,295,920 shares of common stock and accompanying Class A and Class B warrants to purchase up to an aggregate of 2,295,920 shares of common stock in a private placement (collectively, the August 2025 Private Placement). This transaction, which generated aggregate gross proceeds of $45.0 million, was executed concurrently with the August 2025 Underwritten Offering (as defined below). See Note 6 - Stockholders' Equity for additional details.

Gilead Collaboration Agreement

In December 2024, the Company and Gilead entered into the First Amendment to the Gilead Collaboration Agreement, which restructured the timing of specific options exercisable in the agreement and the fees payable to the Company to support an accelerated development plan for ABI-6250 (6250), under which the Company received a non-refundable payment of $10.0 million.

In July 2025, the Company entered into a letter agreement with Gilead under which Gilead has agreed to reimburse the Company up to $1.5 million for certain nonclinical study activities, subject to the terms and conditions set forth in the agreement. The letter agreement does not amend any terms of the Gilead Collaboration Agreement.

In December 2025, Gilead exercised its combined option to obtain an exclusive license to the Company's HPI program, including 5366 and 1179. Upon exercise of the option, the Company received an opt-in payment of $35.0 million.

As of December 31, 2025, the Company recorded $1.0 million in accounts receivable from collaboration on the consolidated balance sheet for reimbursable costs incurred under the Gilead Collaboration Agreement.

The Company recognized $72.3 million and $28.5 million of collaboration revenue under the Gilead Collaboration Agreement during the years ended December 31, 2025 and 2024, respectively. See Note 8 - Collaboration Agreement for additional details.

Note 4 - Investments in Marketable Securities

Investments in marketable available-for-sale securities consisted of the following (in thousands):

	December 31, 2025			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Cash equivalents				
Money market fund	$ 57,994	$ —	$ —	$ 57,994
Total cash equivalents	57,994	—	—	57,994
Short-term marketable securities				
Corporate debt securities	37,329	34	—	37,363
Asset-backed securities	11,970	19	—	11,989
U.S. treasury securities	123,267	170	—	123,437
Commercial paper	16,858	9	—	16,867
Total short-term marketable securities	189,424	232	—	189,656
Total cash equivalents and marketable securities	$ 247,418	$ 232	$ —	$ 247,650

	December 31, 2024			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Cash equivalents				
Money market fund	$ 29,066	$ —	$ —	$ 29,066
U.S. treasury securities	8,437	—	—	8,437
Total cash equivalents	37,503	—	—	37,503
Short-term marketable securities				
Corporate debt securities	20,971	20	(3)	20,988
U.S. treasury securities	48,077	40	—	48,117
Commercial paper	4,625	5	—	4,630
Total short-term marketable securities	73,673	65	(3)	73,735
Total cash equivalents and marketable securities	$ 111,176	$ 65	$ (3)	$ 111,238

Short-term marketable securities held as of December 31, 2025 and 2024 had contractual maturities of less than one year.

The realized gains on investments in marketable debt securities for the year ended December 31, 2025 were not material. There were no realized gains and losses for the years ended December 31, 2024.

There were no investments in an unrealized loss position as of December 31, 2025. As of December 31, 2024, investments which were in an unrealized loss position were not material and generally due to interest rate fluctuations, as opposed to declines in credit quality. The Company determined it has the intent and ability to hold all marketable securities that have been in a continuous loss position until recovery of their amortized cost basis, which may be until maturity. As a result, the Company did not recognize any credit losses related to its investments and all unrealized gains and losses on available-for-sale securities are recorded in accumulated other comprehensive loss on the consolidated balance sheets during the years ended December 31, 2025 and 2024.

Accrued interest receivable was $1.5 million and $0.4 million as of December 31, 2025 and 2024, respectively, and was recorded in prepaid expenses and other current assets on the consolidated balance sheets. The Company did not write off any accrued interest receivable during the years ended December 31, 2025 and 2024.

Fair Value Measurement

The following tables presents the Company's financial assets measured at fair value on a recurring basis by level within the fair value hierarchy (in thousands):

	December 31, 2025			
	Level 1	Level 2	Level 3	Fair Value
Cash equivalents				
Money market fund	$ 57,994	$ —	$ —	$ 57,994
Total cash equivalents	57,994	—	—	57,994
Short-term marketable securities				
Corporate debt securities	—	37,363	—	37,363
Asset-backed securities	—	11,989	—	11,989
U.S. treasury securities	—	123,437	—	123,437
Commercial paper	—	16,867	—	16,867
Total short-term marketable securities	—	189,656	—	189,656
Total assets measured at fair value	$ 57,994	$ 189,656	$ —	$ 247,650

	December 31, 2024			
	Level 1	Level 2	Level 3	Fair Value
Cash equivalents				
Money market fund	$ 29,066	$ —	$ —	$ 29,066
U.S. treasury securities	—	8,437	—	8,437
Total cash equivalents	29,066	8,437	—	37,503
Short-term marketable securities				
Corporate debt securities	—	20,988	—	20,988
U.S. treasury securities	—	48,117	—	48,117
Commercial paper	—	4,630	—	4,630
Total short-term marketable securities	—	73,735	—	73,735
Total assets measured at fair value	$ 29,066	$ 82,172	$ —	$ 111,238

Money market funds are highly liquid and actively traded marketable securities that generally transact at a stable $1.00 net asset value representing its estimated fair value. The Company estimates the fair value of its U.S. and foreign corporate debt securities, U.S. treasury securities and U.S. and foreign commercial paper by taking into consideration valuations obtained from third-party pricing services. The pricing services utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities, issuer credit spreads; benchmark securities; prepayment/default projections based on historical data; and other observable inputs.

There were no transfers between Level 1, Level 2 or Level 3 for any of the years presented.

Note 5 – Other Accrued Expenses

Other accrued expenses consist of the following (in thousands):

	December 31,	
	2025	2024
Accrued expenses:		
Accrued compensation	$ 7,523	$ 6,478
Accrued professional fees and other	226	384
Total accrued expenses	$ 7,749	$ 6,862

Note 6 - Stockholders' Equity

The Company is authorized to issue 5,000,000 shares of preferred stock as of December 31, 2025 and 2024. As of December 31, 2025 and 2024, no shares of preferred stock were issued and outstanding. The Company is authorized to issue 150,000,000 shares of common stock as of December 31, 2025 and 2024.

Reverse Stock Split

In January 2024, the Company's stockholders approved a reverse stock split of its common stock at a range of ratios between 1-for-7 to 1-for-17, and the Company's board of directors approved the implementation of the reverse stock split at a ratio of 1-for-12 (the Reverse Stock Split). The Reverse Stock Split was undertaken to enable the Company to regain compliance with the minimum bid price requirement for continued listing on the Nasdaq Global Select Market, as referenced in the deficiency notice received from the Nasdaq Listing Qualifications Department in September 2023. The Reverse Stock Split became effective in February 2024, at which time the Company regained compliance with the minimum bid price requirement.

As of the effective time of the Reverse Stock Split, every 12 issued and outstanding shares of the Company's common stock was automatically reclassified into one issued and outstanding share of the Company's common stock. This reduced the number of shares outstanding from 65.8 million shares to 5.5 million shares. No fractional shares of common stock were issued in connection with the Reverse Stock Split and all fractional shares were rounded down to the nearest whole share with respect to outstanding shares of common stock. Any holders of common stock who would

have otherwise received a fractional share of common stock pursuant to the Reverse Stock Split, received cash in lieu of the fractional share. The Reverse Stock Split did not affect the par value of the common stock. The Company's authorized shares of common stock remained at 150,000,000 and its authorized shares of preferred stock remained at 5,000,000.

Sale of Common Stock and Warrants

At-The-Market Offering

In November 2024, the Company entered into a sales agreement under which the Company may offer and sell shares of its common stock having an aggregate offering price of up to $75.0 million through "at-the-market" offerings (the ATM), pursuant to its shelf registration statement on Form S-3 (File No. 333-270760), which became effective in April 2023. During the year ended December 31, 2025, the Company issued and sold 161,645 shares of its common stock under the ATM, for which the Company received net proceeds of $1.9 million, after deducting commissions, fees and expenses. During the year ended December 31, 2024, the Company issued and sold 152,666 shares of its common stock under the ATM, for which the Company received net proceeds of $2.0 million, after deducting commissions, fees and expenses.

Registered Direct Offering

In June 2024, the Company issued and sold 634,500 shares of common stock and a warrant to purchase up to 634,500 shares of common stock in a registered direct offering pursuant to its shelf registration statement on Form S-3 on file with the SEC (the June 2024 Registered Direct Offering). The common stock and warrant were sold at a combined offering price of $15.46 per share for aggregate gross proceeds to the Company of $9.8 million. After deducting issuance costs, net proceeds totaled $9.7 million.

Underwritten Offering

In August 2025, the Company issued and sold an aggregate of 5,591,840 shares of common stock and pre-funded warrants to purchase up to 1,040,820 shares of common stock, together with accompanying 3,316,330 Class A and 3,316,330 Class B warrants to purchase up to an aggregated total of 6,632,660 shares of common stock in an underwritten offering (the August 2025 Underwritten Offering). The combined price per share of common stock with the accompanying Class A and Class B warrants was $19.60, while the combined price per pre-funded warrant with accompanying Class A and Class B warrants was $19.599. The offering generated aggregate gross proceeds to the Company of $130.0 million. After deducting issuance costs, net proceeds totaled $123.6 million.

Private Placements

In June 2024, the Company issued and sold 179,500 shares of common stock and a warrant to purchase up to 179,500 shares of common stock under the June 2024 Private Placement with Gilead (as defined in Note 3 - Related Party). This transaction was executed concurrently with the June 2024 Registered Direct Offering pursuant to anti-dilution provisions in the Investor Rights Agreement, with the common stock and warrant sold at the same combined offering price of $15.46 per share for aggregate gross proceeds to the Company of $2.8 million. After deducting issuance costs, net proceeds totaled $2.7 million.

In December 2024, Gilead exercised its right under the Gilead Equity Agreements to purchase an additional 940,499 shares of common stock from the Company at a purchase price of $21.37 per share, which represents a 35% premium to the 30 trading day volume weighted average price immediately prior to the date of purchase. The Company received aggregate proceeds of $20.1 million, of which $5.2 million was determined to be a premium on the purchase of the Company’s common stock and allocated to the single combined performance obligation under the Gilead Collaboration Agreement (see Note 8 - Collaboration Agreements). The fair value of Gilead's common stock purchase was $14.9 million.

In August 2025, the Company entered into the August 2025 Private Placement (as defined in Note 3 - Related Party) with Gilead, which involved the issuance and sale of 2,295,920 shares of common stock and accompanying 1,147,960 Class A and 1,147,960 Class B warrants to purchase up to an aggregate of 2,295,920 shares of common stock in a private placement. This transaction was executed concurrently with the August 2025 Underwritten Offering.

The combined price per share of common stock with the accompanying Class A and Class B warrants was $19.60, generating aggregate gross proceeds of $45.0 million. After deducting issuance costs, net proceeds totaled $42.8 million. These warrants have the same exercise price and terms as the warrants sold in the August 2025 Underwritten Offering.

Warrants

The following warrants and pre-funded warrants to purchase shares of the Company's common stock were issued and outstanding:

Issue Date	Exercisable Date	Expiration Date	Exercise Price per Share	December 31, 2025	December 31, 2024
6/16/2024	6/16/2024	6/18/2029	$ 17.00	634,500	634,500
6/17/2024	6/17/2024	6/18/2029	$ 17.00	179,500	179,500
8/11/2025	8/11/2025	No expiration	$ 0.001	1,040,820	—
8/11/2025	8/11/2025	8/11/2030 [1]	$ 21.60	4,209,187	—
8/11/2025	11/15/2026 [2]	12/31/2026 [2]	$ 21.60	4,464,290	—
				10,528,297	814,000

(1) These Class A warrants will expire 30 days following the public announcement that the Company completed enrollment (of at least 200 patients total) in the ABI-5366 Phase 2 clinical study if prior to August 11, 2030.

(2) These Class B warrants will be cancelled if the Company publicly announces the receipt of at least $75.0 million in the aggregate of non-dilutive capital in connection with a collaboration agreement prior to November 15, 2026.

There were 255,103 Class A warrants exercised during December 31, 2025. No warrants were exercised during December 31, 2024.

The Company’s warrants and pre-funded warrants are classified as a component of permanent stockholders’ equity within additional paid-in capital and were recorded at their respective issuance date using a relative fair value allocation method. Of the total proceeds from the issuance of warrants in the August 2025 Underwritten Offering and the August 2025 Private Placement, $16.4 million was allocated to pre-funded warrants, $24.6 million to Class A warrants and $1.2 million to Class B warrants.

The warrants and pre-funded warrants are equity classified because they are freestanding financial instruments that are legally detachable and separately exercisable from the equity instruments, do not embody an obligation for the Company to repurchase its shares, permit the holders to receive a fixed number of common shares upon exercise, are indexed to the Company’s common stock and meet the equity classification criteria. In addition, such warrants and pre-funded warrants do not provide any guarantee of value or return.

Holders of all warrants and pre-funded warrants cannot exercise any portion of the warrants to the extent they would beneficially own more than the limits defined in the warrant agreements. The exercise price and number of shares of the Company's common stock issuable upon the exercise of the warrants are subject to adjustment in the event of any stock dividends and distributions, stock splits, stock combinations or stock reclassifications, as described in the respective warrant agreements. Under certain circumstances, the warrants may be exercised on a “cashless” basis.

Note 7 - Stock-Based Compensation

Equity Incentive Plans

In June 2025, the Company's stockholders approved an amendment to the Assembly Biosciences, Inc. Amended and Restated 2018 Stock Incentive Plan (the 2018 Plan), which increased the aggregate number of shares of common stock reserved under the 2018 Plan to 1,703,333.

As of December 31, 2025, the Company had awards outstanding under the following shareholder approved plans: 2010 Equity Incentive Plan (the 2010 Plan), which has been frozen since 2016; the Assembly Biosciences, Inc.

Amended and Restated 2014 Stock Incentive Plan (the 2014 Plan); and the 2018 Plan. Shares of common stock underlying awards forfeited under the 2010 Plan on or after June 2, 2016 become available for issuance under the 2014 Plan. As of December 31, 2025, the Company also had awards outstanding under the following plans that are not approved by shareholders: the Assembly Biosciences, Inc. 2017 Inducement Award Plan, the Assembly Biosciences, Inc. 2019 Inducement Award Plan, and the Assembly Biosciences, Inc. 2020 Inducement Award Plan.

The Company issues new shares of common stock to settle options exercised and vested RSUs or PSUs. The Company also issues new shares of common stock in connection with purchases of shares of common stock by eligible employees under the ESPP.

Stock Plan Activity

Stock Options

The following tables summarize the stock option activity and related information for 2025 (in thousands, except for share and per share amounts):

	Number of Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (Years)	Total Intrinsic Value (in thousands)
Outstanding as of December 31, 2024	942,193	$ 54.24	7.3	$ 1,383
Granted	275,225	11.14		
Exercised	(5,743)	22.58		
Forfeited	(11,584)	109.69		
Expired	(6,649)	123.26		
Outstanding as of December 31, 2025	1,193,442	$ 43.53	7.0	$ 17,215
Options vested and exercisable as of December 31, 2025	714,173	$ 64.31	5.9	$ 6,934
Options expected to vest as of December 31, 2025	1,193,442	$ 43.53	7.0	$ 17,215

	Year Ended December 31,	
	2025	2024
Weighted-average grant-date fair value of options granted	$ 8.23	$ 10.04
Total intrinsic value of options exercised	$ 44	$ 2

The fair value of stock options granted during the periods indicated was estimated using the Black-Scholes option pricing model, based on the following assumptions:

	Year Ended December 31,	
	2025	2024
Exercise price	$10.62 - $24.61	$12.90 - $16.75
Expected volatility	81.1% - 86.4%	79.1% - 86.9%
Risk-free rate	3.70% - 4.42%	3.50% - 4.57%
Expected term (years)	5.5 - 7.0	5.5 - 7.5
Expected dividend yield	0%	0%

RSUs

The following tables summarize RSU activity and related information for 2025 (in thousands, except for share and per share amounts):

	Number of RSUs	Weighted Average Fair Value Per RSU at Grant Price
Nonvested as of December 31, 2024	52,222	$ 17.99
Granted	53,933	10.69
Vested	(18,855)	21.87
Forfeited	(1,717)	11.85
Nonvested as of December 31, 2025	85,583	$ 12.65

	Year Ended December 31,	
	2025	2024
Total fair value of RSUs vested and settled	$ 412	$ 1,131
Total intrinsic value of RSUs vested and settled	$ 203	$ 228

PSUs

The following tables summarize PSU activity and related information for 2025 (in thousands, except for share and per share amounts):

	Number of PSUs	Weighted Average Fair Value Per PSU at Grant Price
Nonvested as of December 31, 2024	15,832	$ 20.88
Granted	225,000	17.24
Nonvested as of December 31, 2025	240,832	$ 17.48

	Year Ended December 31,	
	2025	2024
Total fair value of PSUs vested and settled	$ —	$ 1,029
Total intrinsic value of PSUs vested and settled	$ —	$ 488

ESPP

In June 2025, the Company's stockholders approved an amendment to the ESPP, which increased the aggregate number of shares of common stock available for purchase by employees up to 225,000 shares at a discount to the market price.

Eligible employees may participate through payroll deductions of up to 15% of such employee’s compensation for each pay period subject to annual statutory limits.

Eligible employees can purchase the Company’s common stock at the end of a predetermined offering period at 85% of the lower of the fair market value at the beginning or end of the offering period. Under the ESPP, the offering periods end on the last business day occurring on or before May 14 or November 14. The ESPP is compensatory and results in stock-based compensation expense.

In May and November 2025, employees purchased 34,696 and 34,624 shares of common stock, respectively, under the ESPP. In May and November 2024, employees purchased 7,252 and 7,685 shares of common stock, respectively, under the ESPP. As of December 31, 2025, 86,097 shares of common stock are available for future sale under the Company’s ESPP.

The fair value of ESPP purchase rights were not material for any period presented.

Stock-Based Compensation Expense

The Company recognized stock-based compensation expense included in the consolidated statement of operations and comprehensive loss for the years presented (in thousands), classified by expense type and award type:

	Year Ended December 31,	
	2025	2024
Research and development	$ 2,628	$ 1,531
General and administrative	2,049	1,589
Total stock-based compensation expense	$ 4,677	$ 3,120

	Year Ended December 31,	
	2025	2024
Stock options	$ 2,387	$ 2,511
RSUs	427	368
PSUs	1,552	139
ESPP	311	102
Total stock-based compensation expense	$ 4,677	$ 3,120

As of December 31, 2025, there was $4.6 million of total unrecognized stock-based compensation cost related to outstanding unvested equity awards, which is expected to be recognized over a weighted average remaining amortization period of 1.3 years.

Note 8 - Collaboration Agreements

The following table presents changes in the Company's contract liabilities under the Gilead Agreements (in thousands):

	Year Ended December 31,	
Contract liabilities:	2025	2024
Deferred revenue balance at beginning of period	$ 73,000	$ 86,294
Cash received	35,233	10,000
Accounts receivable from collaboration with a related party	974	—
Premium on purchase of the Company's common stock	—	5,226
Revenue recognized	(72,303)	(28,520)
Deferred revenue balance at end of period	$ 36,904	$ 73,000
Less: current portion	$ (36,904)	$ (37,622)
Deferred revenue from a related party - long-term	$ —	$ 35,378

	Year Ended December 31,	
	2025	2024
Collaboration revenue from a related party recognized in the period from:		
Amounts included in deferred revenue from a related party at the beginning of the period	$ 36,841	$ 28,271
Performance obligations satisfied in previous period	$ —	$ —

Gilead Agreements

In October 2023, the Company entered into the Gilead Collaboration Agreement and the Gilead Equity Agreements under which it received total proceeds of $100.0 million. Under the Gilead Collaboration Agreement, Gilead exclusively licensed to the Company its HPI program and NNPI program, while retaining opt-in rights to these programs and has an option to take an exclusive license, on a program-by-program basis, to all of the Company's other current and future pipeline programs. During the 12-year collaboration term (subject to payment of certain

extension fees) and for a specified period thereafter, Gilead may exercise its opt-in rights, on a program-by-program basis, at one of two timepoints—completion of a certain Phase 1 study or, upon payment of a deferral fee and completion of a certain Phase 2 study for the first product within the program—upon payment of an opt-in fee ranging from $45.0 million to $125.0 million per program depending on the type of program and when the option is exercised.

In December 2024, the Company and Gilead entered into the First Amendment to the Gilead Collaboration Agreement, which restructured the timing of specific options exercisable in the agreement and the fees payable to the Company to support an accelerated development plan for 6250. To facilitate this development plan, the Company received a non-refundable payment of $10.0 million from Gilead and the opt-in fee payable by Gilead in connection with 6250 was restructured, though it remains in the range of opt-in fees detailed above. The $10.0 million payment received in connection with the First Amendment to the Gilead Collaboration Agreement is creditable towards future collaboration-related payments payable by Gilead. This credit was applied toward Gilead's opt-in fee paid for the HPI program in December 2025.

In July 2025, the Company entered into a letter agreement with Gilead under which Gilead has agreed to reimburse the Company up to $1.5 million for certain nonclinical study activities, subject to the terms and conditions set forth in the agreement. The letter agreement does not amend any terms of the Gilead Collaboration Agreement.

If Gilead exercises its opt-in right to any current or future program under the collaboration, the Company is eligible to receive up to $330.0 million in potential regulatory and commercial milestones on that program, in addition to royalties ranging from the high single-digits to high teens, depending on the clinical stage of the program at the time of the opt-in. Following Gilead’s exercise of its option for each program, the Company may opt-in to cover 40% of the research and development costs in the United States and share 40% of the profits and operating loss in the United States for products within the program in lieu of receiving milestones and royalties for that program in the United States, unless the Company later opts out of the cost/profit share for the program. Prior to Gilead’s potential exercise of its opt-in, the Company will be primarily responsible for all discovery, research and development on its programs and the two Gilead-contributed programs. Following Gilead’s opt-in, Gilead will control the further discovery, research, development, and commercialization on any optioned programs, and is responsible for all related costs unless the Company opts in to share 40% of all costs and profits in the United States. During the term, Gilead will continue to support the collaboration through extension fees of $75.0 million in each of the third, fifth and seventh anniversaries of the collaboration.

The Gilead Collaboration Agreement is subject to termination by either party for the other party’s uncured, material breach or insolvency. Subject to certain limitations, the Company and Gilead both have certain termination for convenience rights, upon sufficient prior written notice, with respect to programs that one party in-licenses from the other (subject to Gilead’s option rights), and with respect to Gilead, for programs it has option rights to (subject to certain time limitations with respect to existing Company programs). Gilead also has a right to terminate the collaborative activities under the Gilead Collaboration Agreement at certain specified points during the collaboration term. Other customary termination rights are further provided in the Gilead Collaboration Agreement.

R&D Services

At the commencement of the arrangement, the Company concluded Gilead was a customer and accordingly, the Gilead Collaboration Agreement was within the scope of the revenue from contracts with customers guidance. The Company initially identified a single combined performance obligation for the discovery, research and development services (the R&D Services) consisting of a series of distinct services that are substantially the same and have the same pattern of transfer. The Company concluded the R&D Services were distinct from Gilead's right to obtain an exclusive license to any of the Company's programs as Gilead benefits from the knowledge and expertise gained from the R&D Services and the Company's know-how is not highly specialized in nature. Gilead could perform the R&D Services themselves, particularly considering Gilead contributed its HPI and NNPI programs and Gilead may continue to conduct development activities on programs being developed under the Gilead Collaboration Agreement. None of the options in the contract were deemed to be separate performance obligations as the options did not provide any discounts or other rights which would be considered a material right in the arrangement.

In December 2024, Gilead exercised its right under the Gilead Equity Agreements to purchase additional shares of the Company's common stock for aggregate proceeds of $20.1 million, of which $5.2 million was determined to be a

premium on the purchase of the Company's common stock and allocated to the single combined performance obligation under the Gilead Collaboration Agreement.

In December 2024, the Company determined the First Amendment to the Gilead Collaboration Agreement represented a contract modification within the scope of the revenue from contracts with customers guidance. In July 2025, upon its execution, the Company similarly concluded the letter agreement represented a contract modification under the same guidance. For both modifications, the Company determined no new distinct performance obligations were introduced, there continues to be a single combined performance obligation consisting of a series of distinct R&D Services, and therefore, the remaining services under the modified Gilead Collaboration Agreement are distinct from the R&D Services already provided.

Accordingly, the Company accounted for each modification as a termination of the existing contract and the creation of a new contract. The Company reassessed the transaction price upon each modification and recognized revenue prospectively by reassessing the transaction price and allocating it to the remaining R&D Services.

The amended transaction price as a result of the modification upon entering into the letter agreement in July 2025 was determined to be $54.4 million, consisting of the unrecognized portion of the transaction price under the contract immediately before the modification and $1.5 million of variable consideration for reimbursable costs expected to be incurred pursuant to the letter agreement.

The variable consideration related to the regulatory milestones has not been included in the transaction price as of December 31, 2025, as these amounts remain highly susceptible to factors outside the Company's influence. Any variable consideration related to commercial milestones and royalties will be recognized when the related sales occur pursuant to the Gilead Collaboration Agreement. The Company will reevaluate the transaction price in each reporting period as uncertain events are resolved or other changes in circumstances occur.

The transaction price is reflected as collaboration revenue when realized in the Company's consolidated statements of operations. The Company recognizes revenue over time using a cost-based input method, based on internal and external labor cost effort to perform the services, over the initial non-cancellable term of three years since this method best reflects the transfer of services to Gilead. In applying a cost-based input method of revenue recognition, the Company uses actual costs incurred relative to estimated total costs to fulfill each performance obligation. A cost-based input method of revenue recognition requires the Company to make estimates of costs to complete the performance obligation. The cumulative effect of any revisions to estimated costs to complete the performance obligation and associated variable consideration will be recorded in the period in which changes are identified and amounts can be reasonably estimated. A significant change in these assumptions and estimates could have a material impact on the timing and amount of revenue recognized in future periods.

The Company recognized $37.3 million and $28.5 million of collaboration revenue for R&D Services performed under the Gilead Collaboration Agreement during the years ended December 31, 2025 and 2024, respectively. The Company incurred $0.1 million and $0.3 million in reimbursable expenses due to Gilead during the years ended December 31, 2025 and 2024, respectively.

HPI Program License

In December 2025, Gilead exercised its option to exclusively license the Company's HPI program for the treatment of recurrent genital herpes, including 5366 and 1179. Under the terms of the Gilead Collaboration Agreement, the Company received a $35.0 million payment in connection with Gilead's exercise of its HPI program. The $35.0 million payment reflects a $45.0 million option fee, net of $10.0 million in accelerated funding the Company received under the First Amendment to the Gilead Collaboration Agreement, which was creditable against future payments. Gilead received an exclusive license to 5366 and 1179 and will have the sole right and responsibility for further clinical development and commercialization of the HPI program.

The Company remains eligible to receive up to $330.0 million in regulatory and commercial milestones, as well as tiered royalties on net sales ranging from the high single-digits to low teens. The Company also has the right to opt in to share 40% of all costs and profits in the United States (the Profit-Share) in lieu of receiving milestones and royalties for that program in the United States after receipt of a development plan and budget from Gilead; The Company has not opted into the Profit-Share as of the date of this report.

The Company determined the exclusive license granted to Gilead for the HPI program was a new contract under the contracts from customers accounting standard as it was deemed an exercise of a marketing offer made pursuant to the original terms of the Gilead Collaboration Agreement and First Amendment. The Company concluded the exclusive license granted to Gilead for the HPI program represents a distinct performance obligation because Gilead can benefit from the license together with readily available resources and its ability to sublicense the rights. The $35.0 million opt-in fee is included in the fixed transaction price. Variable consideration related to regulatory and commercial milestone payments, royalties and cost reimbursements are constrained because such amounts are highly susceptible to factors outside the Company's influence.

The Company recognized $35.0 million of collaboration revenue related to the exclusive license granted for the HPI program at a point in time upon transfer of the license, when Gilead obtained the ability to use and benefit from the license, during the year ended December 31, 2025.

Arbutus Biopharma Agreement

In August 2020, the Company and Arbutus Biopharma Corporation (Arbutus Biopharma) entered into a Clinical Trial Collaboration Agreement (the Arbutus Biopharma Agreement) to conduct a randomized, multi-center, open-label Phase 2 clinical trial to explore the safety, pharmacokinetics and antiviral activity of the triple combination of vebicorvir (VBR), AB-729 and a nucleos(t)ide analog reverse transcriptase inhibitor (NrtI) compared to the double combinations of VBR with a NrtI and AB-729 with a NrtI. Under the Arbutus Biopharma Agreement, Assembly and Arbutus Biopharma shared responsibility for the costs of the trial equally, excluding manufacturing supply which were the burden of each company to supply their respective drugs, VBR and AB-729. Assembly was responsible for conducting this clinical trial with Arbutus Biopharma reimbursing Assembly its share of expenses. In February 2023, Assembly and Arbutus Biopharma terminated the Phase 2 clinical trial early, at the end of the 48-week on-treatment period.

The Arbutus Biopharma Agreement was within the scope of the collaborative arrangements guidance as both parties were active participants and were exposed to significant risks and rewards dependent on the success of the collaborative activity. Reimbursements and cost-sharing portions from Arbutus Biopharma were reflected as a reduction of research and development expense when realized in the Company’s consolidated statements of operations. During the year ended December 31, 2024, the Company recognized research and development expenses of $0.3 million for net amounts refundable to Arbutus Biopharma after the final reconciliation of clinical trial costs.

Amounts refundable to Arbutus Biopharma were recorded as accrued research and development expenses on the consolidated balance sheet as of December 31, 2024.

Note 9 – HBV Research Agreement with Indiana University

Since September 2013, the Company was party to an exclusive License Agreement with Indiana University Research and Technology Corporation (IURTC) from whom it licensed aspects of the Company’s HBV program held by IURTC. The license agreement required the Company to make milestone payments based upon the successful accomplishment of clinical and regulatory milestones. The aggregate amount of all performance milestone payments under the IURTC license agreement, if all milestones through development were met, was $0.8 million, with a portion having been paid. The Company was obligated to pay IURTC royalty payments based on net sales of the licensed technology as well as a portion of any sublicensing revenue Assembly received. The Company was also required to pay diligence maintenance fees each year to the extent that the royalty, sublicensing, and milestone payments to IURTC were less than such fees for that year. The Company terminated the IURTC license agreement effective April 2024. The Company paid IURTC $0.1 million in diligence maintenance fees during the year ended December 31, 2024, which were included in research and development expenses in the consolidated statements of operations and comprehensive loss.

Note 10 - Income Taxes

Income tax expense is as follows (in thousands):

	Year Ended December 31,	
	2025	2024
Current:		
State	$ —	$ 330
Income tax expense	$ —	$ 330

The Company adopted ASU 2023-09 prospectively for the year ended December 31, 2025. Prior period disclosures have not been retrospectively adjusted and may not be comparable to the current year presentation under the new standard. The reconciliation between the federal statutory tax rate applied to loss before income taxes and the Company's effective tax rate is summarized as follows (in thousands, except percentages):

	Year Ended December 31, 2025	
	Amount	Percent
Tax computed at federal statutory rate	$ (1,286)	21.0%
State tax, net of federal income tax effect [1]	(118)	1.9%
Non-taxable or nondeductible items:		
Permanent items	24	-0.4%
Covered employee compensation	121	-2.0%
Share-based payment awards	615	-10.0%
Changes in valuation allowance	(12,986)	212.1%
Tax credits:		
Federal research and development tax credits	17,027	-278.1%
Changes in unrecognized tax benefits	(3,397)	55.5%
Income tax expense / Effective tax rate	—	0.0%

[1] State taxes in California comprise the majority (greater than 50.0%) of the tax effect in this category.

The effective tax rate of the Company's provision for income taxes differs from the federal statutory rate as follows:

	Year Ended December 31,
	2024
Statutory federal income tax rate	21.0%
State taxes, net of federal tax benefit	8.1%
Research and development tax credits	8.4%
Return to provision adjustments	-4.8%
Uncertain tax positions	-1.7%
Stock-based compensation	-8.4%
Other	-0.5%
Change in valuation allowance	-22.9%
Income taxes provision (benefit)	-0.8%

Income taxes paid, net of refunds received, were not material during the year ended December 31, 2025. The Company paid $0.4 million of income taxes during the year ended December 31, 2024.

Significant components of the Company's deferred taxes are as follows (in thousands):

	As of December 31,	
	2025	2024
Deferred tax assets:		
Federal and state-operating loss carryforwards	$ 123,615	$ 131,994
Stock-based compensation	7,359	7,078
Capitalized research expense	29,377	35,593
Deferred revenue	9,382	18,484
Operating lease liabilities	668	782
Research and development credits	5,377	18,436
Other	32	53
Total deferred tax assets	175,810	212,420
Valuation allowance	(175,113)	(211,614)
Deferred tax asset, net of valuation allowance	$ 697	$ 806
Deferred tax liabilities:		
Operating lease right-of-use assets	$ (638)	$ (777)
Other	(59)	(29)
Total deferred tax liabilities	(697)	(806)
Net deferred tax liability	$ —	$ —

The Company maintains a valuation allowance on deferred tax assets due to the uncertainty regarding the ability to utilize these deferred tax assets in the future. The valuation allowance decreased by $36.5 million for the year ended December 31, 2025, primarily due to a reduction in the Company's research and development credits and federal and state net operating loss carryforwards resulting from an ownership change under Internal Revenue Code (IRC) Sections 382 and 383 (see below). The valuation allowance increased by $9.2 million for the year ended December 31, 2024, primarily due to an increase in the Company's federal and state net operating loss carryforwards generated during the year.

Net operating loss and tax credit carryforwards as of December 31, 2025 are as follows (in thousands):

	Amount	Expiration Years
Net operating losses, federal (post December 31, 2017)	$ 432,835	Indefinite
Net operating losses, federal (pre January 1, 2018)	67,208	2029 - 2037
Net operating loss, state (Indefinite)	880	Indefinite
Net operating loss, state (Definite)	315,530	2029 - 2054
Research and development tax credits, federal	793	2040 - 2045
Research and development tax credits, state	7,521	Indefinite

Pursuant to IRC Sections 382 and 383, use of the Company's U.S. federal and state net operating loss and research and development income tax credit carryforwards may be limited in the event of a cumulative change in ownership of more than 50% within a three-year period. The Company performed an ownership change study through August 2025 and determined a change in ownership, as defined by IRC Section 382, occurred in December 2010, January 2013, October 2014 and August 2025. As a result, the Company adjusted its federal and California deferred tax assets for net operating loss and research and development carryforwards to reflect attributes which will expire due to the limitation, with a corresponding change to the valuation allowance recorded against such assets. The Company has not completed a similar analysis with respect to its other remaining state net operating loss carryforwards, which totaled $224.1 million as of December 31, 2025, and accordingly, it is possible additional limitations or expirations exist that have not yet been reflected. If further ownership changes occur, additional net operating loss and tax credit carryforwards could be eliminated or restricted. If eliminated, the related deferred tax asset would be removed with a corresponding reduction in the valuation allowance.

The following table summarizes activity related to the Company's gross unrecognized tax benefits (in thousands):

	As of December 31,	
	2025	2024
Balances as of beginning of year	$ 5,175	$ 4,495
Decreases related to prior year tax positions	(3,687)	(31)
Increases related to current year tax positions	317	711
Balances as of end of year	$ 1,805	$ 5,175

The unrecognized tax benefits, if recognized, would not have an impact on the Company's effective tax rate assuming the Company continues to maintain a full valuation allowance position. Based on the prior year's operations and experience, the Company does not expect a significant change to its unrecognized tax benefits over the next twelve months. The unrecognized tax benefits may increase or change during the next year for unexpected or unusual items that arise in the ordinary course of business. In subsequent periods, any interest and penalties related to uncertain tax positions will be recognized as a component of income tax expense. Interest and penalties related to unrecognized tax benefits were not material for the years ended December 31, 2025 and 2024.

The Company files income tax returns in the U.S. federal, California and other state and foreign jurisdictions and is not currently under examination by federal, state, or local taxing authorities for any open tax years. Due to net operating loss carryforwards, all years effectively remain open for income tax examination by tax authorities in the U.S. and states in which the Company files tax returns.

Note 11 - Operating Leases

In August 2023, the Company entered into a sublease agreement for office and laboratory space in South San Francisco, California to serve as the Company's corporate headquarters. The sublease originally expired in October 2025, with an option to extend through September 2029. In December 2024, the Company amended the sublease to extend the term through September 2029 and modify the base rent payments beginning in January 2025, with scheduled annual rent increases over the remaining lease term. The Company dissolved its China subsidiary in 2024, allowing the lease for its registrational office in Shanghai to expire in March 2024. The Company also leased certain laboratory equipment accounted for as operating leases, the last of which expired in 2025.

When the Company cannot determine the implicit rate in its leasing arrangements, the Company uses its incremental borrowing rate as the discount rate when measuring operating lease liabilities. The incremental borrowing rate represents an estimate of the interest rate the Company would incur at lease commencement to borrow an amount equal to the lease payments on a collateralized basis over the term of a lease within a particular currency environment.

At December 31, 2025, the Company had operating lease liabilities of $2.6 million and ROU assets of $2.5 million.

The following summarizes quantitative information about the Company's operating leases (in thousands):

	Year Ended December 31,	
	2025	2024
Lease cost		
Operating lease cost	$ 851	$ 1,417
Short-term lease cost	—	1
Variable lease cost	817	727
Total lease cost, net	$ 1,668	$ 2,145

As of December 31, 2025, the weighted-average remaining lease term for operating leases was 3.8 years and the weighted-average discount rate for operating leases was 10.0%.

As of December 31, 2025, the maturities of the Company's operating lease liabilities were as follows (in thousands):

2026	$	806
2027		834
2028		863
2029		671
Total		3,174
Less: present value discount		(546)
Operating lease liabilities	$	2,628

Note 12 - Employee Benefit Plan

In January 2018, the Company established a defined contribution 401(k) plan (the Plan) for all employees who are at least 21 years of age. Employees are eligible to participate in the Plan upon commencement of employment. Under the terms of the Plan, employees may make voluntary contributions as a percentage of compensation. The Plan also permits the Company to make discretionary matching contributions. The Company made discretionary matching contributions of $0.8 million and $0.7 million for the Plan during the years ended December 31, 2025 and 2024, respectively.

Note 13 - Segment Reporting

The Company operates as a single operating segment focusing on developing innovative therapeutics targeting serious viral diseases. The Company's chief operating decision maker (CODM) is its Chief Executive Officer and President, who reviews financial information presented on a consolidated basis for purposes of making operating decisions, assessing financial performance, and allocating resources.

The measure of segment profit or loss used by the CODM to evaluate performance and allocate resources is consolidated net loss as reported in the Company's consolidated statements of operations. This measure is used by the CODM to assess its cash runway and make strategic decisions about resource allocation. The CODM does not use asset measures to evaluate segment performance or make resource allocation decisions.

Operating expenses include all costs necessary to operate the Company's business, primarily consisting of research and development and general and administrative expenses directly related to advancing the Company's programs. These expenses are reviewed by the CODM on a consolidated basis as part of evaluating the Company's overall financial performance. During the years ended December 31, 2025 and 2024, the Company generated all of its collaboration revenue from Gilead, who is a related party (see Notes 3 - Related Party and 8 - Collaboration Agreements). For the years ended December 31, 2025 and 2024, all of the Company's revenue and long-lived assets were in the United States.

The following table presents the significant segment expenses and other segment items regularly reviewed by the Company's CODM:

	Year Ended December 31,	
	2025	2024
Collaboration revenue from a related party	$ 72,303	$ 28,520
Less:		
External program expenses:		
ABI-5366	9,353	6,215
ABI-1179	8,119	4,239
ABI-6250	5,780	6,396
ABI-4334	890	2,646
ABI-7272 [1]	2,300	—
Research and discovery	8,161	8,985
Vebicorvir	—	(43) [2]
Total external program expenses	34,603	28,438
Employee and contractor-related expenses [3]	26,729	23,819
Facility and other expenses	3,481	3,676
Total research and development	64,813	55,933
General and administrative [3]	19,608	18,007
Interest and other income, net	(5,996)	(5,573)
Income tax expense	—	330
Net loss	**$ (6,122)**	**$ (40,177)**

(1) In October 2025, the Company transitioned its discovery and development from ABI-7423 to its parent molecule, ABI-7272, which is currently in regulatory filing-enabling preclinical studies.

(2) Reflects net amounts refundable to the Company after the final reconciliation of costs of the clinical trial conducted pursuant to the Arbutus Biopharma Agreement, which was terminated in February 2023.

(3) Includes stock-based compensation expense, see Note 7 - Stock-Based Compensation for further details.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-3 No. 333-270760) of Assembly Biosciences, Inc.,

(2) Registration Statement (Form S-3 No. 333-285970) of Assembly Biosciences, Inc.,

(3) Registration Statement (Form S-3MEF No. 333-289395) of Assembly Biosciences, Inc.,

(4) Registration Statement (Form S-3 No. 333-290866) of Assembly Biosciences, Inc.,

(5) Registration Statement (Form S-8 No. 333-173613) pertaining to the Ventrus Biosciences, Inc. 2007 Stock Incentive Plan and the Ventrus Biosciences, Inc. 2010 Equity Incentive Plan,

(6) Registration Statement (Form S-8 No. 333-182167) pertaining to the Ventrus Biosciences, Inc. 2010 Equity Incentive Plan,

(7) Registration Statement (Form S-8 No. 333-198803) pertaining to the Assembly Biosciences, Inc. 2014 Stock Incentive Plan,

(8) Registration Statement (Form S-8 No. 333-213019) pertaining to the Assembly Biosciences, Inc. Amended and Restated 2014 Stock Incentive Plan,

(9) Registration Statement (Form S-8 No. 333-216902) pertaining to certain Non-Qualified Stock Option Agreements dated May 16, 2014,

(10) Registration Statement (Form S-8 No. 333-219919) pertaining to the Assembly Biosciences, Inc. 2017 Inducement Award Plan,

(11) Registration Statement (Form S-8 No. 333-226703) pertaining to the Assembly Biosciences, Inc. 2018 Stock Incentive Plan and the Assembly Biosciences, Inc. 2018 Employee Stock Purchase Plan,

(12) Registration Statement (Form S-8 No. 333-233030) pertaining to the Assembly Biosciences, Inc. 2018 Stock Incentive Plan,

(13) Registration Statement (Form S-8 No. 333-234580) pertaining to the Assembly Biosciences, Inc. 2019 Inducement Award Plan and the Assembly Biosciences, Inc. Amended and Restated 2014 Stock Incentive Plan,

(14) Registration Statement (Form S-8 No. 333-248476) pertaining to the Assembly Biosciences, Inc. 2018 Stock Incentive Plan and the Assembly Biosciences, Inc. 2020 Inducement Award Plan,

(15) Registration Statement (Form S-8 No. 333-258516) pertaining to the Assembly Biosciences, Inc. 2018 Stock Incentive Plan and the Assembly Biosciences, Inc. Amended and Restated 2018 Employee Stock Purchase Plan,

(16) Registration Statement (Form S-8 No. 333-266711) pertaining to the Assembly Biosciences, Inc. 2018 Stock Incentive Plan,

(17) Registration Statement (Form S-8 No. 333-273836) pertaining to the Assembly Biosciences, Inc. 2018 Stock Incentive Plan and the Assembly Biosciences, Inc. Amended and Restated 2014 Stock Incentive Plan,

(18) Registration Statement (Form S-8 No. 333-281388) pertaining to the Assembly Biosciences, Inc. Amended and Restated 2018 Stock Incentive Plan and the Assembly Biosciences, Inc. Second Amended and Restated 2018 Employee Stock Purchase Plan, and

(19) Registration Statement (Form S-8 No. 333-289300) pertaining to the Assembly Biosciences, Inc. Amended and Restated 2018 Stock Incentive Plan and the Assembly Biosciences, Inc. Second Amended and Restated 2018 Employee Stock Purchase Plan:

of our report dated March 19, 2026, with respect to the consolidated financial statements of Assembly Biosciences, Inc. included in this Annual Report (Form 10-K) of Assembly Biosciences, Inc. for the year ended December 31, 2025.

/s/ Ernst & Young LLP

San Jose, California
March 19, 2026

Exhibit 31.1

CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jason A. Okazaki, certify that:

(1) I have reviewed this annual report on Form 10-K for the year ended December 31, 2025 of Assembly Biosciences, 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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

(5) The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: March 19, 2026

/s/ Jason A. Okazaki

Jason A. Okazaki
Chief Executive Officer and President
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF THE PRINCIPAL FINANCIAL OFFICER PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jeanette M. Bjorkquist, certify that:

(1) I have reviewed this annual report on Form 10-K for the year ended December 31, 2025 of Assembly Biosciences, 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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

(5) The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: March 19, 2026

/s/ Jeanette M. Bjorkquist

Jeanette M. Bjorkquist
VP, Finance
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the annual report on Form 10-K of Assembly Biosciences, Inc. (the Company) for the fiscal year ended December 31, 2025, as filed with the Securities and Exchange Commission on the date hereof (the Report), I, Jason A. Okazaki, Chief Executive Officer and President (Principal Executive Officer) of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 19, 2026

/s/ Jason A. Okazaki

Jason A. Okazaki
Chief Executive Officer and President
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION OF THE PRINCIPAL FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the annual report on Form 10-K of Assembly Biosciences, Inc. (the Company) for the fiscal year ended December 31, 2025, as filed with the Securities and Exchange Commission on the date hereof (the Report), I, Jeanette M. Bjorkquist (Principal Financial Officer) of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 19, 2026

/s/ Jeanette M. Bjorkquist

Jeanette M. Bjorkquist
VP, Finance
(Principal Financial Officer)