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

## FORM 10-Q

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

**For the quarterly period ended September 30, 2026**

**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) | (zip code) |

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

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

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|---|---|---|
| Common Stock, par value $0.001 | ASMB | The Nasdaq Global Select Market |

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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of November 6, 2026, there were 20,477,244 shares of the registrant's common stock outstanding.

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**References to Assembly Biosciences, Inc.**

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

**Forward-Looking Statements**

This Quarterly Report on Form 10-Q contains "forward-looking statements" that are subject to certain risks and uncertainties, including, without limitation, those set forth in Part I, Item 1A of our Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (SEC) on March 19, 2026 (2025 Annual Report) and Part II, Item 1A of this Quarterly Report on Form 10-Q under the heading "Risk Factors," that could cause actual results to materially differ. Such risks and uncertainties include, among other things:

- our ability to initiate and complete clinical studies involving our therapeutic product candidates, including studies contemplated by our collaboration with Gilead Sciences, Inc. (Gilead), some of which will be conducted by 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 realize the potential benefits of our collaboration with Gilead, including all financial aspects of the collaboration;
- 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 Part II, Item 1A in this Quarterly Report on Form 10-Q for the period ended September 30, 2026.

**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 research 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.
- 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 have not been independently verified.
- 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 U.S. Food and Drug Administration 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 - FINANCIAL INFORMATION**
**Item 1. Financial Statements**

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

| | September 30, 2026 | December 31, 2025 |
|---|---|---|
| | (Unaudited) | |
| **ASSETS** | | |
| Current assets | | |
| Cash and cash equivalents | $ 29,073 | $ 58,450 |
| Marketable securities | 285,189 | 189,656 |
| Accounts receivable from collaboration with a related party | 582 | 974 |
| Prepaid expenses and other current assets | 6,316 | 5,469 |
| Total current assets | 321,160 | 254,549 |
| | | |
| Property and equipment, net | 291 | 221 |
| Operating lease right-of-use (ROU) assets | 2,081 | 2,508 |
| Other assets | 1,754 | 312 |
| **Total assets** | **$ 325,286** | **$ 257,590** |
| | | |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities | | |
| Accounts payable | $ 3,182 | $ 1,171 |
| Accrued research and development expenses | 2,168 | 2,387 |
| Other accrued expenses | 5,194 | 7,749 |
| Contract liability to a related party | 13,742 | 36,904 |
| Operating lease liabilities - short-term | 635 | 569 |
| Total current liabilities | 24,921 | 48,780 |
| | | |
| Operating lease liabilities - long-term | 1,572 | 2,059 |
| **Total liabilities** | **26,493** | **50,839** |
| | | |
| **Commitments and contingencies** | | |
| | | |
| **Stockholders' equity** | | |
| Preferred stock, $0.001 par value; 5,000,000 shares authorized; no shares issued or outstanding | — | — |
| Common stock, $0.001 par value; 150,000,000 shares authorized as of September 30, 2026 and December 31, 2025; 20,368,351 and 15,855,329 shares issued and outstanding as of September 30, 2026 and December 31, 2025, respectively | 20 | 16 |
| Additional paid-in capital | 1,165,001 | 1,038,823 |
| Accumulated other comprehensive loss | (989) | (41) |
| Accumulated deficit | (865,239) | (832,047) |
| Total stockholders' equity | 298,793 | 206,751 |
| **Total liabilities and stockholders' equity** | **$ 325,286** | **$ 257,590** |

*See Accompanying Notes to Condensed Consolidated Financial Statements*

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2026 | 2025 | 2026 | 2025 |
| **Collaboration revenue from a related party** | $ 2,956 | $ 10,789 | $ 24,543 | $ 29,834 |
| | | | | |
| **Operating expenses** | | | | |
| Research and development | 20,234 | 16,587 | 50,051 | 47,563 |
| General and administrative | 6,137 | 5,085 | 15,621 | 14,188 |
| Total operating expenses | 26,371 | 21,672 | 65,672 | 61,751 |
| **Loss from operations** | **(23,415)** | **(10,883)** | **(41,129)** | **(31,917)** |
| | | | | |
| **Other income** | | | | |
| Interest and other income, net | 3,159 | 1,687 | 7,937 | 3,705 |
| Total other income | 3,159 | 1,687 | 7,937 | 3,705 |
| **Net loss** | **$ (20,256)** | **$ (9,196)** | **$ (33,192)** | **$ (28,212)** |
| | | | | |
| **Other comprehensive loss** | | | | |
| Unrealized gain (loss) on marketable securities | (366) | 189 | (948) | 121 |
| **Comprehensive loss** | **$ (20,622)** | **$ (9,007)** | **$ (34,140)** | **$ (28,091)** |
| | | | | |
| Net loss per share, basic and diluted | $ (0.93) | $ (0.72) | $ (1.73) | $ (3.03) |
| Weighted average common shares outstanding, basic and diluted | 21,780,874 | 12,686,122 | 19,196,128 | 9,301,740 |

*See Accompanying Notes to Condensed Consolidated Financial Statements*

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

| | For the Three Month Period | | | | | |
|---|---|---|---|---|---|---|
| | Common Stock | | Additional Paid-in Capital | Accumulated Other Comprehensive Loss | Accumulated Deficit | Total Stockholders' Equity |
| | Shares | Amount | | | | |
| **Balance as of June 30, 2026** | **19,850,342** | **$ 20** | **$ 1,151,235** | **$ (623)** | **$ (844,983)** | **$ 305,649** |
| Issuance of common stock upon exercise of warrants, net of issuance costs | 510,205 | — | 10,301 | — | — | 10,301 |
| Issuance of common stock upon exercise of stock options | 7,755 | — | 142 | — | — | 142 |
| Issuance of common stock for settlement of restricted stock units (RSUs) | 49 | — | — | — | — | — |
| Unrealized loss on marketable debt securities | — | — | — | (366) | — | (366) |
| Stock-based compensation | — | — | 3,323 | — | — | 3,323 |
| Net loss | — | — | — | — | (20,256) | (20,256) |
| **Balance as of September 30, 2026** | **20,368,351** | **$ 20** | **$ 1,165,001** | **$ (989)** | **$ (865,239)** | **$ 298,793** |

| | Common Stock | | Additional Paid-in Capital | Accumulated Other Comprehensive Loss | Accumulated Deficit | Total Stockholders' Equity |
|---|---|---|---|---|---|---|
| | Shares | Amount | | | | |
| **Balance as of June 30, 2025** | **7,672,249** | **$ 8** | **$ 863,312** | **$ (279)** | **$ (844,941)** | **$ 18,100** |
| 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, net of issuance costs | 255,103 | — | 5,510 | — | — | 5,510 |
| Issuance of common stock upon exercise of stock options | 1,863 | — | 37 | — | — | 37 |
| Issuance of common stock for settlement of RSUs | 12 | — | — | — | — | — |
| Unrealized gain on marketable debt securities | — | — | — | 189 | — | 189 |
| Stock-based compensation | — | — | 1,670 | — | — | 1,670 |
| Net loss | — | — | — | — | (9,196) | (9,196) |
| **Balance as of September 30, 2025** | **15,816,987** | **$ 16** | **$ 1,036,906** | **$ (90)** | **$ (854,137)** | **$ 182,695** |

| | For the Nine Month Period | | | | | |
|---|---|---|---|---|---|---|
| | Common Stock | | Additional Paid-in Capital | Accumulated Other Comprehensive Loss | Accumulated Deficit | Total Stockholders' Equity |
| | Shares | Amount | | | | |
| **Balance as of December 31, 2025** | **15,855,329** | **$ 16** | **$ 1,038,823** | **$ (41)** | **$ (832,047)** | **$ 206,751** |
| Issuance of common stock and pre-funded warrants in an underwritten offering, net of issuance costs (including related party purchase of 471,698 shares of common stock for $12,500) | 3,924,642 | 4 | 108,076 | — | — | 108,080 |
| Issuance of common stock upon exercise of warrants, net of issuance costs | 510,205 | — | 10,301 | — | — | 10,301 |
| Issuance of common stock under Employee Stock Purchase Plan (ESPP) | 16,488 | — | 425 | — | — | 425 |
| Issuance of common stock upon exercise of stock options | 31,915 | — | 521 | — | — | 521 |
| Issuance of common stock for settlement of RSUs | 29,772 | — | — | — | — | — |
| Unrealized loss on marketable debt securities | — | — | — | (948) | — | (948) |
| Stock-based compensation | — | — | 6,855 | — | — | 6,855 |
| Net loss | — | — | — | — | (33,192) | (33,192) |
| **Balance as of September 30, 2026** | **20,368,351** | **$ 20** | **$ 1,165,001** | **$ (989)** | **$ (865,239)** | **$ 298,793** |

| | Common Stock | | Additional Paid-in Capital | Accumulated Other Comprehensive Loss | Accumulated Deficit | Total Stockholders' Equity |
|---|---|---|---|---|---|---|
| | Shares | Amount | | | | |
| **Balance as of December 31, 2024** | **7,457,240** | **$ 7** | **$ 859,488** | **$ (211)** | **$ (825,925)** | **$ 33,359** |
| Issuance of common stock under at-the-market (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, net of issuance costs | 255,103 | — | 5,510 | — | — | 5,510 |
| Issuance of common stock under ESPP | 34,696 | — | 357 | — | — | 357 |
| Issuance of common stock upon exercise of stock options | 1,863 | — | 37 | — | — | 37 |
| Issuance of common stock for settlement of RSUs | 18,680 | — | — | — | — | — |
| Unrealized gain on marketable debt securities | — | — | — | 121 | — | 121 |
| Stock-based compensation | — | — | 3,216 | — | — | 3,216 |
| Net loss | — | — | — | — | (28,212) | (28,212) |
| **Balance as of September 30, 2025** | **15,816,987** | **$ 16** | **$ 1,036,906** | **$ (90)** | **$ (854,137)** | **$ 182,695** |

*See Accompanying Notes to Condensed Consolidated Financial Statements*

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

| | Nine Months Ended September 30, | |
|---|---|---|
| | **2026** | **2025** |
| **Cash flows from operating activities** | | |
| Net loss | $ (33,192) | $ (28,212) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 70 | 97 |
| Stock-based compensation | 6,855 | 3,216 |
| Net accretion of investments in marketable debt securities | (2,666) | (1,518) |
| Non-cash rent expense | 610 | 647 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable from collaboration with a related party | 392 | (912) |
| Prepaid expenses and other current assets | (847) | 81 |
| Other assets | (1,442) | — |
| Accounts payable | 2,011 | 1,098 |
| Accrued research and development expenses | (219) | 785 |
| Other accrued expenses | (2,555) | (1,134) |
| Contract liability to a related party | (23,162) | (28,922) |
| Operating lease liabilities | (604) | (556) |
| Net cash used in operating activities | (54,749) | (55,330) |
| | | |
| **Cash flows from investing activities** | | |
| Proceeds from maturities of marketable securities | 190,267 | 83,632 |
| Purchases of marketable securities | (284,082) | (218,281) |
| Purchases of property and equipment | (140) | (42) |
| Net cash used in investing activities | (93,955) | (134,691) |
| | | |
| **Cash flows from financing activities** | | |
| Proceeds from the issuance of common stock and pre-funded warrants in an underwritten offering, net of issuance costs ($12,500 from a related party) | 108,080 | — |
| Proceeds from the exercise of warrants, net of issuance costs | 10,301 | 5,510 |
| Proceeds from the exercise of stock options | 521 | 37 |
| Proceeds from the issuance of common stock under ESPP | 425 | 357 |
| Proceeds from the issuance of common stock, pre-funded warrants and warrants in an underwritten offering, net of issuance costs | — | 123,600 |
| Proceeds from the issuance of common stock and warrants in private placements to a related party, net of issuance costs | — | 42,785 |
| Proceeds from the issuance of common stock under ATM equity offering program, net of issuance costs | — | 1,922 |
| Net cash provided by financing activities | 119,327 | 174,211 |
| | | |
| Net decrease in cash and cash equivalents | (29,377) | (15,810) |
| Cash and cash equivalents at the beginning of the period | 58,450 | 38,344 |
| **Cash and cash equivalents at the end of the period** | **$ 29,073** | **$ 22,534** |

*See Accompanying Notes to Condensed Consolidated Financial Statements*

**ASSEMBLY BIOSCIENCES, INC.**
**NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**
(Unaudited)

## 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 small-molecule therapeutics aimed at advancing the treatment paradigm of serious viral and liver diseases and improving the lives of patients worldwide. The Company is committed to improving outcomes for people living with the chronic impacts of herpesviruses, hepatitis delta virus (HDV) infections, cholestatic liver diseases (CLDs) and hepatitis B virus (HBV) infection.

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, GS-1179 (1179) and GS-5366 (5366), which have been exclusively licensed to Gilead Sciences, Inc. (Gilead); (2) an orally bioavailable sodium taurocholate cotransporting peptide inhibitor, ABI-6250 (6250), for the treatment of (a) chronic HDV infection and (b) primary biliary cholangitis and primary sclerosing cholangitis, both CLDs; and (3) a highly potent next-generation capsid assembly modulator designed to disrupt the replication cycle of HBV at several key points, ABI-4334 (4334), which the Company does not plan to advance further without a partner. The Company's pipeline also includes a novel, oral broad-spectrum non-nucleoside polymerase inhibitor (NNPI) for the treatment of transplant-related herpesviruses, ABI-7272 (7272), which is currently undergoing studies to enable a regulatory filing, and the Company has additional research programs against multiple viral and liver disease targets.

### 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 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 September 30, 2026, the Company held cash, cash equivalents and marketable securities of $314.3 million, and the Company received the first $75.0 million extension fee from Gilead under the Option, License and Collaboration Agreement (the Gilead Collaboration Agreement) in November 2026. Management believes the Company currently has sufficient funds to meet its operating requirements beyond one year from the date these unaudited condensed consolidated financial statements are issued.

## Note 2 – Summary of Significant Accounting Policies

### Basis of Presentation

The accompanying unaudited condensed consolidated financial statements include the accounts of the Company and its subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with the accounting principles generally accepted in the United States of America (U.S. GAAP) for interim financial information and pursuant to the instructions to Form 10-Q and Rule 10-01 of Regulation S-X of the SEC. In management’s opinion, the unaudited condensed consolidated financial statements have been prepared on the same basis as the annual audited consolidated financial statements and include normal recurring adjustments necessary for the fair presentation of the Company’s financial position and its results of operations and comprehensive loss and its cash flows for the periods presented. These statements do not include all disclosures required by U.S. GAAP and should be read in conjunction with the Company’s audited consolidated financial statements and accompanying notes for the fiscal year ended December 31, 2025, which are contained in the 2025 Annual Report. The results for the three and nine months ended September 30, 2026 are not necessarily indicative of results to be expected for the entire year ending December 31, 2026 or future operating periods.

**Use of Estimates**

The preparation of the unaudited condensed 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 unaudited condensed consolidated financial statements include estimates for revenue recognition, including the standalone selling price for the allocation of the transaction price to performance obligations, cost-based inputs and the Company's estimated share of research and development costs under the Profit-Share, and 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 conflict between the United States and 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, vendors and/or collaborators could potentially be negatively impacted by these events.

**Revenue Recognition from Collaboration**

Cost-sharing under arrangements or transactions determined to be within the scope of the revenue from contracts with customers accounting standard is accounted for as described under Consideration Payable to a Customer below.

If the consideration promised in a contract includes a variable amount, the Company estimates the amount of consideration to which it will be entitled in exchange for transferring the promised goods or services to a customer. The Company determines the amount of variable consideration by using the expected value method or the most likely amount method. The Company includes the unconstrained amount of estimated variable consideration in the transaction price. 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. At the end of each subsequent reporting period, the Company re-evaluates the estimate of variable consideration included in the transaction price and any related constraint, and if necessary, adjusts the estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis in the period of adjustment.

***Consideration Payable to a Customer***

Under agreements within the scope of the revenue from contracts with customers accounting standard, the Company may reimburse a customer for a portion of the research and development costs the customer incurs. When the Company does not receive a distinct good or service from the customer in exchange for such payments, the Company accounts for the payments as a reduction of the transaction price at the later of when the Company recognizes revenue for the transfer of the related goods or services to the customer or when the Company pays or promises to pay the consideration, even if the payment is conditional on a future event. The Company estimates amounts payable to the customer as variable consideration and reassesses the estimate in each reporting period. Changes in the estimate that relate to a performance obligation that has been satisfied are recognized as an adjustment to collaboration revenue in the period of change. Amounts payable to a customer that is a related party are presented as contract liability to a related party on the condensed consolidated balance sheets.

**Net Loss per Share**

Basic net loss per share of common stock excludes dilution and is computed by dividing net loss by the weighted average number of shares of common stock outstanding during the period. Diluted net loss per share of common stock 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, since the effects of potentially dilutive securities are antidilutive given the net loss for each period 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):

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2026 | 2025 | 2026 | 2025 |
| Numerator: | | | | |
| Net loss | $ (20,256) | $ (9,196) | $ (33,192) | $ (28,212) |
| Denominator: | | | | |
| Weighted average common shares outstanding - basic and diluted | 21,780,874 | 12,686,122 | 19,196,128 | 9,301,740 |
| Net loss per share - basic and diluted | $ (0.93) | $ (0.72) | $ (1.73) | $ (3.03) |

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

| | September 30, | |
|---|---|---|
| | 2026 | 2025 |
| Warrants to purchase common stock | 8,977,272 | 9,487,477 |
| Options to purchase common stock | 1,182,195 | 1,201,913 |
| Common stock subject to purchase under ESPP | 11,413 | 31,553 |
| Unvested RSUs | 660,914 | 85,720 |
| Unvested performance stock units (PSUs) | 215,010 | 240,832 |
| Total | 11,046,804 | 11,047,495 |

In August 2025 and May 2026, the Company sold pre-funded warrants to purchase up to 1,040,820 shares and 415,000 shares of common stock, respectively (see Note 6 - Stockholders' Equity). The pre-funded warrants are exercisable at $0.001 per share. The shares of common stock issuable upon exercise of the pre-funded warrants are considered outstanding for purposes of calculating basic and diluted net loss per share because the shares may be issued for little or no consideration and are exercisable immediately upon issuance.

**Note 3 – Related Party**

In October 2023, the Company entered into the Gilead Collaboration Agreement along with 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 September 30, 2026, Gilead is considered a related party based on its ownership of the Company's common stock and Gilead's right to designate two members of the Company's Board of Directors pursuant to the terms of the Investor Rights Agreement. See Note 6 - Stockholders’ Equity and Note 8 - Collaboration Agreement for additional details on related party transactions with Gilead.

In November 2026, the Company received the first $75.0 million extension fee from Gilead under the Gilead Collaboration Agreement, which became payable following the third anniversary of the collaboration.

**Note 4 – Fair Value Measurements and Investments in Marketable Securities**

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 that approximate their fair value due to their liquid or short-term nature, such as cash, accounts receivable, accounts payable and accrued expenses.

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 that 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.

Investments in marketable securities consisted of the following (in thousands):

| | September 30, 2026 | | | |
|---|---|---|---|---|
| | Amortized Cost | Gross Unrealized Gain | Gross Unrealized Loss | Fair Value |
| Cash equivalents | | | | |
| Money market fund | $ 28,712 | $ — | $ — | $ 28,712 |
| Total cash equivalents | 28,712 | — | — | 28,712 |
| Short-term marketable securities | | | | |
| Corporate debt securities | 61,465 | — | (179) | 61,286 |
| Asset-backed securities | 15,095 | — | (47) | 15,048 |
| U.S. treasury securities | 157,009 | — | (369) | 156,640 |
| Commercial paper | 52,336 | — | (121) | 52,215 |
| Total short-term marketable securities | 285,905 | — | (716) | 285,189 |
| Total cash equivalents and marketable securities | $ 314,617 | $ — | $ (716) | $ 313,901 |

| | 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 |

There were no realized gains and losses for the three and nine months ended September 30, 2026 and 2025. As of September 30, 2026, 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. There were no investments in an unrealized loss position as of December 31, 2025. 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 marketable securities are recorded in accumulated other comprehensive loss on the condensed consolidated balance sheets as of September 30, 2026 and December 31, 2025.

Accrued interest receivable was $1.5 million as of both September 30, 2026 and December 31, 2025, and was recorded in prepaid expenses and other current assets on the condensed consolidated balance sheets. The Company did not write off any accrued interest receivable during the three and nine months ended September 30, 2026 and 2025.

The following tables present the fair value of the Company's financial assets measured at fair value on a recurring basis (in thousands):

| | September 30, 2026 | | | |
|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Fair Value |
| Cash equivalents | | | | |
| Money market fund | $ 28,712 | $ — | $ — | $ 28,712 |
| Total cash equivalents | 28,712 | — | — | 28,712 |
| Short-term marketable securities | | | | |
| Corporate debt securities | — | 61,286 | — | 61,286 |
| Asset-backed securities | — | 15,048 | — | 15,048 |
| U.S. treasury securities | — | 156,640 | — | 156,640 |
| Commercial paper | — | 52,215 | — | 52,215 |
| Total short-term marketable securities | — | 285,189 | — | 285,189 |
| Total assets measured at fair value | $ 28,712 | $ 285,189 | $ — | $ 313,901 |

| | 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 |

The Company estimates the fair value of its investments in marketable securities 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 investments during the periods presented.

**Note 5 – Other Accrued Expenses**

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

| | September 30, 2026 | December 31, 2025 |
|---|---|---|
| Accrued expenses: | | |
| Accrued compensation | $ 4,766 | $ 7,523 |
| Accrued professional fees and other | 428 | 226 |
| Total accrued expenses | $ 5,194 | $ 7,749 |

**Note 6 – Stockholders' Equity**

**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. The Company did not sell any shares of common stock under the ATM during the three and nine months ended September 30, 2026 or during the three months ended September 30, 2025. During the nine months ended September 30, 2025, the Company sold 161,645 shares of common stock under the ATM, for which the Company received net proceeds of approximately $1.9 million, after deducting commissions, fees and expenses.

**Underwritten Offering**

In August 2025, the Company 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 net proceeds to the Company of $123.6 million, after deducting issuance costs.

In May 2026, the Company issued and sold 3,358,602 shares of common stock and pre-funded warrants to purchase up to 415,000 shares of common stock in an underwritten offering. The offering price per share of common stock was $26.50, while the purchase price per pre-funded warrant was $26.499. In addition, the Company granted the underwriters a 30-day option to purchase up to 566,040 shares of common stock on the same terms, which was exercised in full in May 2026. The Company received aggregate net proceeds of $108.1 million, after deducting underwriting discounts, commissions and offering expenses payable by the Company. Gilead purchased 471,698 of the shares of the Company's common stock sold in the underwritten offering at a purchase price of $26.50 per share, resulting in aggregate gross proceeds to the Company of approximately $12.5 million.

**Private Placement**

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 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 net proceeds of $42.8 million, after deducting issuance costs. 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 | September 30, 2026 | December 31, 2025 |
|---|---|---|---|---|---|
| 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 | 1,040,820 |
| 8/11/2025 | 8/11/2025 | 8/11/2030 [1] | $ 21.60 | 3,698,982 | 4,209,187 |
| 8/11/2025 | 11/15/2026 [2] | 12/31/2026 [2] | $ 21.60 | 4,464,290 | 4,464,290 |
| 5/26/2026 | 5/26/2026 | No expiration | $ 0.001 | 415,000 | — |
| | | | | 10,433,092 | 10,528,297 |

[1] These Class A warrants expire on the earlier of August 11, 2030 and 30 days following the public announcement the Company completed enrollment (of at least 200 patients total) in a Phase 2 clinical study evaluating 5366 versus valacyclovir.

(2) These Class B warrants were cancelled in November 2026 following the Company's public announcement it received the first $75.0 million extension fee under the Gilead Collaboration Agreement.

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. During the three and nine months ended September 30, 2026, holders exercised 510,205 Class A warrants. During the three and nine months ended September 30, 2025, holders exercised 255,103 Class A warrants.

**Note 7 – Stock-Based Compensation**

The following tables summarize the components of total stock-based compensation expense included in the condensed consolidated statements of operations and comprehensive loss (in thousands), classified by expense type and award type:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2026 | 2025 | 2026 | 2025 |
| Research and development | $ 1,877 | $ 962 | $ 3,945 | $ 1,786 |
| General and administrative | 1,446 | 708 | 2,910 | 1,430 |
| Total stock-based compensation expense | $ 3,323 | $ 1,670 | $ 6,855 | $ 3,216 |

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2026 | 2025 | 2026 | 2025 |
| Stock options | $ 502 | $ 622 | $ 1,349 | $ 1,819 |
| RSUs | 2,246 | 115 | 4,107 | 313 |
| PSUs | 531 | 853 | 1,204 | 853 |
| ESPP | 44 | 80 | 195 | 231 |
| Total stock-based compensation expense | $ 3,323 | $ 1,670 | $ 6,855 | $ 3,216 |

As of September 30, 2026, there was $15.1 million of total unrecognized stock-based compensation related to all outstanding equity awards, which is expected to be recognized over a weighted average remaining amortization period of 2.0 years.

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:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2026 | 2025 | 2026 | 2025 |
| Exercise price | $25.36 - $35.18 | $17.73 | $24.11 - $35.18 | $10.62 - $17.73 |
| Expected volatility | 62.9% - 82.1% | 82.5% - 85.6% | 62.9% - 83.5% | 81.9% - 86.4% |
| Risk-free rate | 4.22% - 4.60% | 3.85% - 3.99% | 3.76% - 4.60% | 3.85% - 4.42% |
| Expected term (years) | 5.5 - 7.0 | 5.5 - 7.0 | 5.5 - 7.5 | 5.5 - 7.0 |
| Expected dividend yield | 0% | 0% | 0% | 0% |

**Note 8 – Collaboration Agreement**

The following tables summarize the collaboration revenue recognized from a related party (in thousands):

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2026 | 2025 | 2026 | 2025 |
| R&D Services | $ 13,893 | $ 10,789 | $ 34,670 | $ 29,834 |
| HPI Program License | (10,937) | — | (10,127) | — |
| Total collaboration revenue from a related party | $ 2,956 | $ 10,789 | $ 24,543 | $ 29,834 |

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2026 | 2025 | 2026 | 2025 |
| Amounts included in contract liability to a related party at the beginning of the period | $ 13,893 | $ 10,576 | $ 34,670 | $ 29,620 |
| Performance obligations satisfied in previous period | $ (10,937) | $ — | $ (10,127) | $ — |

**Background**

In October 2023, the Company entered into the 12-year Gilead Collaboration Agreement with Gilead to advance the research and development of novel antiviral therapies. Under the Gilead Collaboration Agreement, Gilead may exercise its option for a program at any time through completion of a specified Phase 1 study for a $45.0 million option fee or pay a $25.0 million deferral fee to retain its option through completion of a specified Phase 2 study for an additional $75.0 million option fee. In December 2024, the Company and Gilead amended the option structure for 6250 to provide for a single option exercise period through completion of the Phase 2 clinical study of 6250, with a $90.0 million option fee payable upon exercise.

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 losses in the United States for products within the program (the Profit-Share) in lieu of receiving milestones and royalties for that program in the United States. For programs for which the Company does not participate in the Profit-Share, the Company is eligible to receive up to $330.0 million in development, regulatory and commercial milestone payments and tiered royalties ranging from the high single-digits to the high teens, depending on the timing of Gilead's option exercise. For programs for which the Company participates in the Profit-Share, the Company remains eligible to receive up to $280.0 million in development, regulatory and commercial milestone payments, as well as tiered royalties outside the United States. Prior to Gilead's potential exercise of its option, the Company is primarily responsible for all discovery, research and development on its programs. Following Gilead's exercise of its option, Gilead controls 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. The Company also retains certain co-promotion rights for future programs not identified at the time the Company entered into the Gilead Collaboration Agreement.

The Gilead Collaboration Agreement also provides for extension payments of $75.0 million on the third, fifth and seventh anniversaries of the collaboration term.

In July 2025, the Company entered into a letter agreement with Gilead under which Gilead 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.

As of September 30, 2026, Gilead has exercised its option for the Company's HPI program, and in September 2026, the Company elected to participate in the Profit-Share for the HPI program.

The Gilead Collaboration Agreement contains customary termination provisions, including termination rights relating to material breach, insolvency and, in certain circumstances, termination for convenience with respect to individual programs.

**R&D Services**

At the commencement of the arrangement and after subsequent amendments, 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 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 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.

The transaction price for the R&D Services as of September 30, 2026 was determined to be $54.4 million. There were no changes to the transaction price for the R&D Services during the three and nine months ended September 30, 2026. The transaction price is reflected as collaboration revenue when realized in the Company’s condensed consolidated statements of operations.

The amount of collaboration revenue recognized during the nine months ended September 30, 2026 included a cumulative catch-up adjustment of $6.7 million, resulting from revisions made to estimated costs to complete the remaining performance obligation under the Gilead Collaboration Agreement. The adjustments resulted in a decrease in the Company's net loss of $6.7 million, decreasing basic and diluted net loss per share by $0.35 for the nine months ended September 30, 2026.

In November 2026, the Company received the first $75.0 million extension fee from Gilead under the Gilead Collaboration Agreement, which became payable following the third anniversary of the collaboration. The Company will account for the extension fee as a new contract within the scope of the revenue from contracts with customers guidance, beginning in the fourth quarter of 2026.

**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. Under the terms of the Gilead Collaboration Agreement, the Company received a $35.0 million payment in connection with Gilead’s exercise of its option for the HPI program. The $35.0 million payment reflects a $45.0 million opt-in fee, net of $10.0 million in accelerated funding the Company received in December 2024 under the First Amendment to the Gilead Collaboration Agreement, which was creditable against future payments. Gilead received an exclusive license to the HPI program and has the sole right and responsibility for further clinical development and commercialization. In September 2026, the Company elected to participate in the Profit-Share for the HPI program.

The Company determined the exclusive license granted to Gilead for the HPI program was a new contract under the revenue from contracts with customers guidance 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 payment was included in the fixed transaction price and recognized as collaboration revenue at a point in time upon transfer of the license in December 2025.

The Company determined its election to participate in the Profit-Share for the HPI program in September 2026 is a modification of the existing contract within the scope of the revenue from contracts with customers guidance. The Company concluded the Profit-Share did not add any distinct performance obligations and the remaining services under the Profit-Share are not distinct from the transfer of the HPI license. Accordingly, the Company reduced the transaction price for the HPI program license by the estimated share of research and development costs under the Profit-Share that it estimates are probable of being incurred and reimbursed to Gilead, and that was recognized as a cumulative catch-up adjustment on the date of the modification. This amount is variable consideration because the Company’s share depends on the costs Gilead actually incurs and the successful development of the HPI program. The Company will update its estimate of such variable consideration at each reporting period.

The Company recognized $11.3 million as a reduction of collaboration revenue during the three and nine months ended September 30, 2026 for its estimated share of research and development costs under the Profit-Share, which is included in contract liability to a related party on the condensed consolidated balance sheet as of September 30, 2026. The Company also recognized cost reimbursements from Gilead for transition services the Company performed related to the HPI program license during the three and nine months ended September 30, 2026, which were not material.

Variable consideration related to regulatory and commercial milestone payments, royalties and the Company's share of profits and operating losses in the United States for the HPI program has not been included in the transaction price as of September 30, 2026 because such amounts are 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. The Company will reevaluate the transaction price and variable consideration each reporting period as uncertain events are resolved or other circumstances change.

**Note 9 – Segment Reporting**

The Company operates as a single operating segment focusing on developing innovative small-molecule therapeutics aimed at advancing the treatment paradigm of serious viral and liver diseases and improving the lives of patients worldwide. 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 condensed consolidated statements of operations. This measure is used by the CODM to assess the Company's 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.

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2026 | 2025 | 2026 | 2025 |
| Collaboration revenue from a related party | $ 2,956 | $ 10,789 | $ 24,543 | $ 29,834 |
| Less: | | | | |
| External program expenses: | | | | |
| 5366 | 67 | 2,430 | 787 | 7,158 |
| 1179 | 459 | 2,982 | 3,084 | 5,047 |
| 6250 [1] | 1,505 | 714 | 3,603 | 4,617 |
| HDV | 1,777 | — | 2,257 | — |
| CLD | 2,244 | — | 2,344 | — |
| 4334 | — | 113 | 2 | 919 |
| 7272 | 1,010 | 354 | 2,203 | 2,004 |
| Research and discovery | 3,715 | 2,190 | 9,708 | 5,839 |
| Total external program expenses | 10,777 | 8,783 | 23,988 | 25,584 |
| Employee and contractor-related expenses [2] | 8,272 | 6,934 | 22,839 | 19,365 |
| Facility and other expenses | 1,185 | 870 | 3,224 | 2,614 |
| Total research and development | 20,234 | 16,587 | 50,051 | 47,563 |
| General and administrative [2] | 6,137 | 5,085 | 15,621 | 14,188 |
| Interest and other income, net | (3,159) | (1,687) | (7,937) | (3,705) |
| **Net loss** | **$ (20,256)** | **$ (9,196)** | **$ (33,192)** | **$ (28,212)** |

(1) Amounts for 6250 include shared external program expenses supporting both the HDV and CLD indications. External program expenses directly attributable to a specific indication are reflected separately within the applicable HDV and CLD amounts.

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

## Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

*The condensed consolidated financial statements and this Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the consolidated financial statements and notes thereto for the year ended December 31, 2025 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K for the fiscal year ended December 31, 2025 filed with the U.S. Securities and Exchange Commission on March 19, 2026 (2025 Annual Report). In addition to historical information, this discussion and analysis 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 under "Part I. Item 1A. Risk Factors" in our 2025 Annual Report and "Part II. Item 1A. Risk Factors" in this report.*

### Overview

We are a biotechnology company developing innovative small-molecule therapeutics aimed at advancing the treatment paradigm of serious viral and liver diseases and improving the lives of patients worldwide. Led by an accomplished leadership team in antiviral and liver disease drug development, we are committed to improving outcomes for people living with the chronic impacts of herpesviruses, hepatitis delta virus (HDV) infections, cholestatic liver diseases (CLDs) and hepatitis B virus (HBV) infection.

Our pipeline includes multiple clinical-stage investigational therapies, including: (1) two long-acting helicase-primase inhibitors (HPI) for the treatment of recurrent genital herpes, GS-1179 (1179) and GS-5366 (5366), which have been exclusively licensed to Gilead Sciences, Inc. (Gilead); (2) an orally bioavailable sodium taurocholate cotransporting peptide (NTCP) inhibitor, ABI-6250 (6250), for the treatment of (a) chronic HDV infection and (b) primary biliary cholangitis (PBC) and primary sclerosing cholangitis (PSC), both CLDs; and (3) a highly potent next-generation capsid assembly modulator (CAM) designed to disrupt the replication cycle of HBV at several key points, ABI-4334 (4334). Our pipeline also includes a novel, oral broad-spectrum non-nucleoside polymerase inhibitor (NNPI) for the treatment of transplant-related herpesviruses, ABI-7272 (7272), which is currently undergoing studies to enable a regulatory filing, and we have additional research programs against multiple viral and liver disease targets.

### Our Clinical Programs and Regulatory Filing-Enabling Programs

In the third quarter of 2026, recent updates for our investigational product candidates, 1179, 5366, 6250, 7272 and 4334, include the following:

- 1179 and 5366 – Following receipt and review of Gilead's clinical development plan (the CDP) for the HPI program, we elected to cover 40% of the U.S. development costs and share 40% of the operating profits and losses in the U.S. for the HPI program (the Profit-Share). For additional information about the CDP and the Profit-Share, see "Collaboration and License Agreement—Gilead Sciences, Inc."
- 6250
  - HDV – We initiated dosing in a Phase 2 study in October 2026 and also initiated a Phase 1 hepatic impairment study in October 2026.
  - CLD – In September 2026, we received a Study May Proceed letter from the U.S. Food and Drug Administration (the FDA) for our planned Phase 2 study in PBC and PSC and are preparing to initiate the study in the first quarter of 2027.
- 7272 – Completed Good Laboratory Practice (GLP) toxicology studies and is currently completing other regulatory filing-enabling studies.
- 4334 – Continuing process to identify potential partners that was initiated in the first quarter of 2026; we do not plan to advance 4334 further without a partner.

In October 2026, we nominated a development candidate, ABI-8914 (8914), targeting the respiratory virus space. Discovered by the research team, 8914 is currently advancing into 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, only one new drug, which was approved in the United States for the treatment of acyclovir-resistant HSV in immunocompromised adults, has 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 FDA's 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 1179 and 5366, development is now in Gilead's sole control. Initiation of a Phase 2 study of 1179 is expected by the end of 2026. We do not expect that Gilead will develop 5366 further at this time. For additional information regarding the option exercise, see "Collaboration and License Agreement—Gilead Sciences, Inc."

We conducted a Phase 1a/b clinical study of 1179, which has single digit nanomolar potency against HSV-1 and HSV-2 and a nonclinical pharmacokinetics (PK) and safety profile that is supportive of a potential long-acting treatment by once-weekly oral administration. For the powered antiviral endpoint, HSV-2 shedding rate, highly potent antiviral activity was observed with a 97% 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 92% reduction in virologically confirmed lesion rate compared to placebo ($p<0.01$) with the 50 mg weekly dose. There was also a 100% reduction in the number of samples with high viral load, a potential surrogate for HSV-2 transmission and a secondary endpoint.

Across all 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 adverse events (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. No serious AEs have been reported to date. One Grade 3 AE of migraine was reported in a participant enrolled in the placebo cohort.

The Phase 1b portion of the 1179 study is complete. With these data, 1179 can move directly into a Phase 2 study for a once-weekly treatment regimen, and additional chronic toxicology studies are currently being conducted by Gilead. The 1179 data reported in December 2025 was presented in a poster presentation at The Congress of the European Society of Clinical Microbiology and Infectious Diseases (ESCMID) in April 2026. Gilead presented final Phase 1b data in two posters at IDWeek in October 2026.

We also conducted a Phase 1 a/b study of 5366, a structurally-differentiated HPI, and we reported interim data from the Phase 1b portion of the study in August 2025, focused on two different oral doses of 5366 administered on a once-weekly basis, and in December 2025, which included a once-monthly cohort. 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 virologically confirmed genital lesion rate, a 97% reduction compared to placebo ($p<0.05$) 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. 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 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 as well as the monthly oral cohort are complete and unblinded safety data has been reported. 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. There were three participants with treatment-emergent Grade 3 lab abnormalities across all cohorts, 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 mg 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.

The Phase 1b portion of the 5366 study is complete. Additionally, all chronic toxicology studies have been completed. With these data, 5366 is ready to move into a Phase 2 clinical study; however, 5366 development is in Gilead's sole control, and we do not expect that Gilead will develop 5366 further at this time.

The 5366 data reported in August and December 2025 were presented in an oral presentation and two poster presentations at ESCMID in Munich, Germany in April 2026.

In December 2025, Gilead exercised its option early to license our HPI program for the treatment of recurrent genital herpes, including 1179 and 5366. Following receipt and review of the CDP for the HPI program, we exercised our Profit-Share option in the third quarter of 2026. Under the CDP, Gilead is expected to advance 1179 into a Phase 2 clinical study in participants with recurrent genital herpes by the end of 2026, and potentially evaluate 1179 as part of a combination strategy with HIV PrEP. For more information regarding Gilead's exercise of its option and our exercise of our option related to the Profit-Share, see "Collaboration and License Agreement—Gilead Sciences, Inc."

***Our Liver Disease Programs***

*HDV and HBV*

The World Health Organization (WHO) estimates that 240 million people worldwide were chronically infected with HBV as of 2024, and 0.9 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 2024 from HBV, mostly due to cirrhosis and hepatocellular carcinoma (primary liver cancer). Of the 240 million people living with chronic HBV infection, only approximately 65 million, or 27%, were aware of their infection, and only approximately 10 million, or 4%, 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.

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 million HBV infected people. These individuals infected with HDV, which comprise an estimated nearly 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 the last few years, and the first HDV-targeted therapy is only approved in the European Economic Area (EEA), the UK, Switzerland, Australia, Canada and the United States.

The current standard of care treatment for HDV is off-label pegylated interferon-α (IFN-α) injected weekly or, in the EEA, the UK, Switzerland, Australia, Canada and the United States, a large, complex peptide inhibitor that requires daily injections, bulevirtide. 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.

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 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, 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 inhibitor of NTCP, is the only approved therapy for HDV. 6250 has the same clinically-validated MOA as bulevirtide. The binding of 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.

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.

Top-line clinical data, including PK, biomarker and safety data for the Phase 1a study of 6250 was presented at the European Association for the Study of the Liver Congress that took place in Barcelona, Spain in May 2026. Across all cohorts, 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 eight-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 at levels similar to or greater than those seen with steady-state dosing of bulevirtide, 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 alanine transaminase (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, including placebo. 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.

The Phase 1a study is complete. The chronic toxicology studies to enable longer term dosing are complete. We initiated Phase 2 clinical studies in October 2026, and we also initiated a Phase 1 hepatic impairment study in October 2026.

Two posters featuring additional Phase 1a data from our 6250 HDV program were presented at The Liver Meeting® 2026, the Annual Meeting of the American Association for the Study of Liver Diseases (AASLD) in November 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. We reported interim Phase 1b 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 log10 IU/mL and 3.2 log10 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 log10 U/mL and 2.3 log10 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. Final data for this Phase 1b study was presented at AASLD in November 2025.

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, we retain 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 do not plan to advance 4334 further without a partner.

*PBC and PSC*

PBC and PSC are chronic, autoimmune CLDs characterized by impaired bile flow, accumulation of bile acids in the liver and progressive liver damage. Clinical symptoms for both PBC and PSC include itch and fatigue, with development of fibrosis and cirrhosis as the diseases progress.

PBC affects intrahepatic bile ducts, with complications including cirrhosis and hepatocellular carcinoma. PBC is also associated with Sjogren's Syndrome. There are approximately 150,000 adults diagnosed with PBC in the United States, and approximately 40% of patients fail first line therapy. In 2024, two peroxisome proliferator-activated receptor (PPAR) agonists were approved in the European Union and the United States as second-line therapy for PBC. However, at least one-third of patients receiving these treatments failed to achieve biochemical responses in Phase 3 studies. Therefore, there remains an unmet medical need for improved treatment of PBC.

PSC affects intrahepatic and extrahepatic bile ducts, and has complications including cirrhosis, cholangiocarcinoma and cholangitis. PSC is also associated with inflammatory bowel disease. There are approximately 30,000 adults diagnosed with PSC in the United States. The ten-year overall mortality rate for PSC patients is approximately 35%. We believe there is a significant unmet medical need for the management of PSC as there are currently no approved therapies.

Nonclinical data with 6250 demonstrate potent inhibition of bile acid uptake in liver cells, a mechanism directly relevant to CLD, where bile acid accumulation drives liver inflammation and liver injury. In addition, animal studies as well as the Phase 1a study with 6250 demonstrated elevations in serum bile acids, which we believe to be a biomarker for NTCP engagement that reflects reductions of bile acids in the liver.

In May 2026, we announced that we expanded 6250 clinical development beyond HDV into CLD, targeting PBC and PSC. Further, in May 2026, we conducted a pre-IND meeting with the FDA to discuss our planned development of 6250 in CLD. In September 2026, we received a Study May Proceed letter from the FDA for the Phase 2 study in PBC and PSC. We are preparing for Phase 2 clinical studies, with Phase 2 initiation expected in the first quarter of

2027.

***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.

7272, our development candidate in our NNPI program, has completed GLP toxicology studies and is currently completing other regulatory filing-enabling nonclinical studies.

**Research Programs**

Our research team continues to actively focus on proprietary research to discover and nominate novel molecules to treat serious viral and liver diseases. In October 2026, we nominated a development candidate, 8914, targeting the respiratory virus space. Discovered by the research team, 8914 is currently advancing into regulatory filing-enabling studies.

**Collaboration and License Agreement**

***Gilead Sciences, Inc.***

In October 2023, we entered into a 12-year Option, License and Collaboration Agreement (the Gilead Collaboration Agreement) with Gilead to advance the research and development of novel antiviral therapies. Under the Gilead Collaboration Agreement, Gilead may exercise its option for a program at any time through completion of a specified Phase 1 study for a $45.0 million option fee or pay a $25.0 million deferral fee to retain its option through completion of a specified Phase 2 study for an additional $75.0 million option fee. In December 2024, we and Gilead amended the option structure for 6250 to provide for a single option exercise period through completion of the Phase 2 clinical study of 6250, with a $90.0 million option fee payable upon exercise.

Following Gilead’s exercise of its option for each program, we may elect to cover 40% of the research and development costs in the United States and share 40% of the profits and operating losses in the United States for products within the program in lieu of receiving milestones and royalties for that program in the United States. For programs for which we do not participate in the Profit-Share, we are eligible to receive up to $330.0 million in development, regulatory and commercial milestone payments and tiered royalties ranging from the high-single digits to the high teens, depending on the timing of Gilead's option exercise. For programs for which we participate in the Profit-Share, we remain eligible to receive up to $280.0 million in development, regulatory and commercial milestone payments, as well as royalties outside the United States. Prior to Gilead’s exercise of its option, we are primarily responsible for all discovery, research and development activities for our programs. Following Gilead’s exercise of its option, Gilead controls further discovery, research, development and commercialization of any optioned programs, and is responsible for all related costs unless we opt in to the Profit-Share. We also retain certain co-promotion rights for future programs not identified at the time we entered into the Gilead Collaboration Agreement.

The Gilead Collaboration Agreement also provides for extension payments of $75.0 million on the third, fifth and seventh anniversaries of the collaboration term. In November 2026, Gilead paid the first $75.0 million extension fee.

To date, Gilead has exercised its option for our HPI program, and in the third quarter of 2026, we elected to participate

in the Profit-Share for the HPI program.

The Gilead Collaboration Agreement contains customary termination provisions, including termination rights relating to material breach, insolvency and, in certain circumstances, termination for convenience with respect to individual programs.

Also in October 2023, we and Gilead entered into a Common Stock Purchase Agreement and an Investor Rights Agreement (together, the Gilead Equity Agreements), which were both amended in June 2024. The Gilead Equity Agreements provide Gilead with certain 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.

As of September 30, 2026, Gilead held approximately 24.4% of our outstanding common stock and warrants to purchase up to 179,500 shares of our common stock at a price of $17.00 per share that expires on June 18, 2029 and a warrant to purchase up to 1,147,960 shares of our common stock at a price of $21.60 per share that expires on August 11, 2030. Neither of the warrants are currently exercisable due to certain blocker provisions in the warrant agreements. As of September 30, 2026, Gilead also held a warrant to purchase an additional 1,147,960 shares of our common stock at a price of $21.60 per share, which was cancelled in November 2026 following our public announcement that we received the first $75.0 million extension fee under the Gilead Collaboration Agreement.

**Results of Operations**

***Comparison of the Three Months Ended September 30, 2026 and 2025***

*Collaboration Revenue*

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

| | Three Months Ended September 30, | | $ Change | % Change |
|---|---|---|---|---|
| | 2026 | 2025 | 2026 vs. 2025 | 2026 vs. 2025 |
| Collaboration revenue from a related party | $ 2,956 | $ 10,789 | $ (7,833) | (73%) |

Collaboration revenue was $3.0 million for the three months ended September 30, 2026 compared to $10.8 million for the same period in 2025. The $7.8 million decrease was primarily driven by an $11.3 million reduction in the transaction price of the HPI program license, reflecting research and development costs we estimate are probable of being reimbursed to Gilead under the Profit-Share, partially offset by an increase in research and development activities we performed under the Gilead Collaboration Agreement.

*Research and Development Expenses*

Research and development expenses consist primarily of employee-related expenses, fees paid to contract research organizations and contract manufacturing organizations, 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):

| | Three Months Ended September 30, | | $ Change | % Change |
|---|---|---|---|---|
| | 2026 | 2025 | 2026 vs. 2025 | 2026 vs. 2025 |
| External program expenses: | | | | |
| 5366 | $ 67 | $ 2,430 | $ (2,363) | (97%) |
| 1179 | 459 | 2,982 | (2,523) | (85%) |
| 6250 [1] | 1,505 | 714 | 791 | 111% |
| HDV | 1,777 | — | 1,777 | 100% |
| CLD | 2,244 | — | 2,244 | 100% |
| 4334 | — | 113 | (113) | (100%) |
| 7272 | 1,010 | 354 | 656 | 185% |
| Research and discovery | 3,715 | 2,190 | 1,525 | 70% |
| Total external program expenses | 10,777 | 8,783 | 1,994 | 23% |
| Employee and contractor-related expenses | 8,272 | 6,934 | 1,338 | 19% |
| Facility and other expenses | 1,185 | 870 | 315 | 36% |
| Total research and development expenses | $ 20,234 | $ 16,587 | $ 3,647 | 22% |

[1] Amounts for 6250 include shared external program expenses supporting both the HDV and CLD indications. External program expenses directly attributable to a specific indication are reflected separately within the applicable HDV and CLD amounts.

Research and development expenses were $20.2 million for the three months ended September 30, 2026 compared to $16.6 million for the same period in 2025. The $3.6 million increase was primarily driven by higher external program expenses, reflecting the start-up of multiple clinical trials for 6250 and increases in our research and discovery efforts, as well as higher employee-related expenses due to increased headcount, annual salary adjustments and stock-based compensation expense related to restricted stock units granted in 2026. These increases were partially offset by lower external program expenses for 1179 and 5366 following completion of their Phase 1 clinical trials.

*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 changes in our general and administrative expenses (in thousands, except for percentages):

| | Three Months Ended September 30, | | $ Change | % Change |
|---|---|---|---|---|
| | 2026 | 2025 | 2026 vs. 2025 | 2026 vs. 2025 |
| General and administrative expenses | $ 6,137 | $ 5,085 | $ 1,052 | 21% |

General and administrative expenses were $6.1 million for the three months ended September 30, 2026 compared to $5.1 million for the same period in 2025. The $1.1 million increase was primarily driven by higher stock-based compensation expense related to restricted stock units granted in 2026 and increased commercial planning and market research expenses.

*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):

| | Three Months Ended September 30, | | $ Change | % Change |
|---|---|---|---|---|
| | 2026 | 2025 | 2026 vs. 2025 | 2026 vs. 2025 |
| Interest and other income, net | $ 3,159 | $ 1,687 | $ 1,472 | 87% |

Interest and other income, net was $3.2 million for the three months ended September 30, 2026, compared to $1.7 million for the same period in 2025. The $1.5 million increase was primarily due to a larger portfolio balance resulting from the investment of cash proceeds from our financing completed in May 2026 and the payment received from Gilead in December 2025 for a license to our HPI program.

***Comparison of the Nine Months Ended September 30, 2026 and 2025***

*Collaboration Revenue*

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

| | Nine Months Ended September 30, | | $ Change | % Change |
|---|---|---|---|---|
| | 2026 | 2025 | 2026 vs. 2025 | 2026 vs. 2025 |
| Collaboration revenue from a related party | $ 24,543 | $ 29,834 | $ (5,291) | (18%) |

Collaboration revenue was $24.5 million for the nine months ended September 30, 2026 compared to $29.8 million for the same period in 2025. The $5.3 million decrease was primarily driven by an $11.3 million reduction in the transaction price of the HPI program license, reflecting research and development costs we estimate are probable of being reimbursed to Gilead under the Profit-Share. This decrease was partially offset by an increase in research and development activities we performed under the Gilead Collaboration Agreement, and includes a $6.7 million cumulative catch-up adjustment recognized during the nine months ended September 30, 2026 related to updated estimates of future activities under the collaboration.

*Research and Development Expenses*

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

| | Nine Months Ended September 30, | | $ Change | % Change |
|---|---|---|---|---|
| | 2026 | 2025 | 2026 vs. 2025 | 2026 vs. 2025 |
| External program expenses: | | | | |
| 5366 | $ 787 | $ 7,158 | $ (6,371) | (89%) |
| 1179 | 3,084 | 5,047 | (1,963) | (39%) |
| 6250 [(1)] | 3,603 | 4,617 | (1,014) | (22%) |
| HDV | 2,257 | — | 2,257 | 100% |
| CLD | 2,344 | — | 2,344 | 100% |
| 4334 | 2 | 919 | (917) | (100%) |
| 7272 | 2,203 | 2,004 | 199 | 10% |
| Research and discovery | 9,708 | 5,839 | 3,869 | 66% |
| Total external program expenses | 23,988 | 25,584 | (1,596) | (6%) |
| Employee and contractor-related expenses | 22,839 | 19,365 | 3,474 | 18% |
| Facility and other expenses | 3,224 | 2,614 | 610 | 23% |
| Total research and development expenses | $ 50,051 | $ 47,563 | $ 2,488 | 5% |

(1) Amounts for 6250 include shared external program expenses supporting both the HDV and CLD indications. External program expenses directly attributable to a specific indication are reflected separately within the applicable HDV and CLD amounts.

Research and development expenses were $50.1 million for the nine months ended September 30, 2026 compared to $47.6 million for the same period in 2025. The $2.5 million increase was primarily driven by higher external program expenses for 6250, reflecting the start-up of multiple clinical trials, and increased research and discovery efforts, as well as higher employee-related expenses due to increased headcount, annual salary adjustments and stock-based compensation expense related to restricted stock units granted in 2026. These increases were partially offset by lower external program expenses for 5366, 1179 and 4334 following the completion of their Phase 1 clinical trials.

*General and Administrative Expenses*

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

| | Nine Months Ended September 30, | | $ Change | % Change |
|---|---|---|---|---|
| | 2026 | 2025 | 2026 vs. 2025 | 2026 vs. 2025 |
| General and administrative expenses | $ 15,621 | $ 14,188 | $ 1,433 | 10% |

General and administrative expenses were $15.6 million for the nine months ended September 30, 2026 compared to $14.2 million for the same period in 2025. The $1.4 million increase was primarily driven by higher stock-based compensation expense associated with restricted stock units granted in June 2026.

*Interest and Other Income, Net*

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

| | Nine Months Ended September 30, | | $ Change | % Change |
|---|---|---|---|---|
| | 2026 | 2025 | 2026 vs. 2025 | 2026 vs. 2025 |
| Interest and other income, net | $ 7,937 | $ 3,705 | $ 4,232 | 114% |

Interest and other income, net was $7.9 million for the nine months ended September 30, 2026, compared to $3.7 million for the same period in 2025. The $4.2 million increase was primarily due to a larger portfolio balance resulting from the investment of cash proceeds from our financings completed in August 2025 and May 2026 and the payment received from Gilead in December 2025 for a license to our HPI program.

**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 September 30, 2026 principally through equity financings, raising an aggregate of $940.2 million in net proceeds, and strategic collaborations, raising an aggregate of $238.0 million.

***Cash Flows for the Nine Months Ended September 30, 2026 and 2025***

The following table summarizes our cash flow activities (in thousands):

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2026 | 2025 |
| Net cash used in operating activities | $ (54,749) | $ (55,330) |
| Net cash used in investing activities | (93,955) | (134,691) |
| Net cash provided by financing activities | 119,327 | 174,211 |
| Net decrease in cash and cash equivalents | $ (29,377) | $ (15,810) |

*Operating Activities*

Net cash used in operating activities was $54.7 million for the nine months ended September 30, 2026, compared to $55.3 million for the same period in 2025. The decrease was primarily attributable to approximately $1.8 million received under the Gilead Collaboration Agreement in 2026.

*Investing Activities*

Net cash used in investing activities was $94.0 million for the nine months ended September 30, 2026, compared to net cash used in investing activities of $134.7 million for the same period in 2025. The decrease was primarily due to higher maturities of marketable securities, partially offset by higher purchases of marketable securities, as we invested the $108.1 million net proceeds received from our underwritten offering in May 2026.

*Financing Activities*

Net cash provided by financing activities was $119.3 million for the nine months ended September 30, 2026, compared to $174.2 million for the same period in 2025. The decrease was primarily attributable to lower net proceeds from our underwritten offering in May 2026, compared to the net proceeds from our underwritten offering and concurrent private placement with Gilead in August 2025, partially offset by larger proceeds from the exercise of warrants in 2026.

***Funding Requirements***

We expect our future operating expenses to increase over the coming years as we continue to advance our candidates and expand our pipeline. 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 September 30, 2026, we held cash, cash equivalents and marketable securities of $314.3 million. Based on our current operating plan and including the $75.0 million collaboration extension payment we received from Gilead in November 2026, we believe we have sufficient funds to meet our operating requirements into 2029. 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 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 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, including studies conducted by Gilead;
- 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.

**Critical Accounting Estimates**

Our critical accounting policies and significant estimates are detailed in our 2025 Annual Report. There have been no material changes to our significant estimates from those previously disclosed in our 2025 Annual Report.

**Item 3. Quantitative and Qualitative Disclosures About Market Risk**

Not applicable.

**Item 4. Controls and Procedures**

**Evaluation of Disclosure Controls and Procedures**

We maintain a system of disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act, that is designed to provide reasonable assurance that information that 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 the period covered by this report, 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 Vice President, 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 Rules 13a-15(b) and 15d-15(b) as of the end of the period covered by this report. Based upon that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures as of the end of the period covered by this report were effective at the reasonable assurance level.

**Changes in Internal Control over Financial Reporting**

There were no changes in our internal control over financial reporting in the quarter ended September 30, 2026 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**PART II – OTHER INFORMATION**

**Item 1. Legal Proceedings**

We are not a party to any material legal proceedings. In the future, we may from time to time become involved in litigation relating to claims arising from our ordinary course of business.

**Item 1A. Risk Factors**

*You should carefully consider the following risk factors, together with all other information in this report, including our condensed 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, and in May 2026, Gilead purchased 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. Following receipt and review of Gilead's clinical development plan for the HPI program, in in the third quarter of 2026 we exercised our option to cover 40% of the U.S. development costs and share 40% of the operating profits and losses in the U.S. for the HPI program, and in November 2026, Gilead paid the first $75.0 million extension fee due under the Gilead Collaboration Agreement.

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 owned approximately 24.4% of our outstanding common stock as of September 30, 2026. 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 current good manufacturing practice (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, Good Clinical Practices (GCPs), 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 conflict between the United States and 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.

***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, CLD, 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, CLD, 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 losses generated before January 1, 2018, which if not utilized, will begin to expire in 2029. 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 requirements, the FDA might ultimately refuse to approve one or more of our NDAs. We cannot be sure that we will ever obtain regulatory approval to 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. Additionally, clinical trial activities can present enforcement risk where data integrity issues arise or there are concerns regarding the financial arrangements between clinical trial sponsors and physician employees or consultants, investigators or sites when federal healthcare programs reimburse trial-related costs. 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 we or any of the physicians or other providers or entities with whom we do business with are found to be not in compliance with applicable laws, such noncompliance 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 2. Unregistered Sales of Equity Securities and Use of Proceeds**

None.

**Item 3. Defaults upon Senior Securities**

None.

**Item 4. Mine Safety Disclosures**

Not applicable.

**Item 5. Other Information**

**10b5-1 Trading Plans**

During the three months ended September 30, 2026, the following officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted, modified, or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K. All trading plans are intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act.

- Jason A. Okazaki, Chief Executive Officer and President, adopted a new trading plan on September 10, 2026 (with the first trade possible under the new plan no sooner than December 10, 2026). The trading plan will be effective until December 22, 2027 and covers the potential sale of up to 58,292 shares of common stock.

- Nicole S. White, Chief Manufacturing Officer, adopted a new trading plan on September 24, 2026 (with the first trade possible under the new plan no sooner than December 24, 2026). The trading plan will be effective until June 28, 2027 and covers the potential sale of up to 25,006 shares of common stock.

**Item 6. Exhibits**

(a) *Exhibits.* The following exhibits are filed or furnished, as applicable, as part of this quarterly report on Form 10-Q:

| Exhibit Number | Description of Document | Filed Herewith | Incorporated by Reference from | Date | Number |
|---|---|---|---|---|---|
| 31.1 | Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. | X | | | |
| 31.2 | Certification of Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. | X | | | |
| 32.1* | Certification of Chief Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. | X | | | |
| 32.2* | Certification of Principal Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. | X | | | |
| 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 | X | | | |
| 101.SCH | Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents | X | | | |
| 104 | Cover page formatted as inline XBRL and contained in Exhibits 101 | X | | | |

* The certification attached as Exhibit 32.1 that accompanies this Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

In accordance with the requirements of the Securities Exchange Act of 1934, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**Assembly Biosciences, Inc.**

Date: November 12, 2026

By: /s/ Jason A. Okazaki
Jason A. Okazaki
Chief Executive Officer and President
(Principal Executive Officer)

Date: November 12, 2026

By: /s/ Jeanette M. Bjorkquist
Jeanette M. Bjorkquist
Vice President, Finance
(Principal Financial Officer and Principal Accounting Officer)

**EXHIBIT 31.1**

**CERTIFICATION**

I, Jason A. Okazaki, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q 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 and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Date: November 12, 2026

By: /s/ Jason A. Okazaki
Jason A. Okazaki
Chief Executive Officer and President
(Principal Executive Officer)

**EXHIBIT 31.2**

**CERTIFICATION**

I, Jeanette M. Bjorkquist, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q 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 and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Date: November 12, 2026

By: /s/ Jeanette M. Bjorkquist
Jeanette M. Bjorkquist
VP, Finance
(Principal Financial Officer)

**EXHIBIT 32.1**

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

In connection with the Quarterly Report on Form 10-Q of Assembly Biosciences, Inc. (the Company) for the period ended September 30, 2026 as filed with the Securities and Exchange Commission on or about the date hereof (the Report), I, Jason A. Okazaki, Chief Executive Officer and President, hereby 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 as of, and for, the periods presented in the Report.

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

Date: November 12, 2026

**EXHIBIT 32.2**

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

In connection with the Quarterly Report on Form 10-Q of Assembly Biosciences, Inc. (the Company) for the period ended September 30, 2026 as filed with the Securities and Exchange Commission on or about the date hereof (the Report), I, Jeanette M. Bjorkquist, VP, Finance, hereby 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 as of, and for, the periods presented in the Report.

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

Date: November 12, 2026