

**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, 2024**

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

(State or other jurisdiction of
incorporation or organization)

20-8729264

(I.R.S. Employer Identification No.)

**Two Tower Place, 7th Floor
South San Francisco, California**
(Address of principal executive offices)

94080
(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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

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 1, 2024, there were 6,356,286 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 28, 2024 (2023 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 maintain financial resources necessary to continue our research activities, clinical studies and other business operations;
- our ability to realize the potential benefits of our collaboration with Gilead Sciences, Inc. (Gilead), including all financial aspects of the collaboration and equity investments;
- our ability to initiate and complete clinical studies involving our therapeutic product candidates, including studies contemplated by our collaboration with Gilead, in the currently anticipated timeframes or at all;
- safety and efficacy data from clinical or nonclinical studies may not warrant further development of our product candidates;
- clinical and nonclinical data presented at conferences may not differentiate our product candidates from other companies’ candidates; 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, 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; 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.

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, 2024 (Unaudited)	December 31, 2023
ASSETS		
Current assets		
Cash and cash equivalents	\$ 28,452	\$ 19,841
Marketable securities	66,502	110,406
Accounts receivable from collaboration	—	43
Prepaid expenses and other current assets	3,259	3,497
Total current assets	98,213	133,787
Property and equipment, net	316	385
Operating lease right-of-use (ROU) assets	1,421	2,339
Other assets	312	312
Total assets	\$ 100,262	\$ 136,823
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 1,335	\$ 461
Accrued research and development expenses	1,586	885
Other accrued expenses	4,765	5,744
Deferred revenue from a related party - short-term	32,620	30,915
Operating lease liabilities - short-term	1,329	1,220
Total current liabilities	41,635	39,225
Deferred revenue from a related party - long-term	32,511	55,379
Operating lease liabilities - long-term	113	1,122
Total liabilities	74,259	95,726
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, 2024 and December 31, 2023; 6,354,414 and 5,482,752 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	6	5
Additional paid-in capital	841,743	826,921
Accumulated other comprehensive loss	(156)	(81)
Accumulated deficit	(815,590)	(785,748)
Total stockholders' equity	26,003	41,097
Total liabilities and stockholders' equity	\$ 100,262	\$ 136,823

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,	
	2024	2023	2024	2023
Collaboration revenue from a related party	\$ 6,845	\$ —	\$ 21,163	\$ —
Operating expenses				
Research and development	13,515	10,824	41,653	37,894
General and administrative	4,286	4,224	13,398	14,201
Total operating expenses	17,801	15,048	55,051	52,095
Loss from operations	(10,956)	(15,048)	(33,888)	(52,095)
Other income				
Interest and other income, net	1,343	628	4,452	1,829
Total other income	1,343	628	4,452	1,829
Loss before income taxes	(9,613)	(14,420)	(29,436)	(50,266)
Income tax expense	—	—	406	—
Net loss	\$ (9,613)	\$ (14,420)	\$ (29,842)	\$ (50,266)
Other comprehensive loss				
Unrealized gain (loss) on marketable securities	137	50	(75)	528
Comprehensive loss	\$ (9,476)	\$ (14,370)	\$ (29,917)	\$ (49,738)
Net loss per share, basic and diluted	\$ (1.51)	\$ (3.29)	\$ (5.12)	\$ (11.61)
Weighted average common shares outstanding, basic and diluted	6,351,431	4,380,444	5,827,750	4,329,260

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, 2024	6,345,561	\$ 6	\$ 840,946	\$ (293)	\$ (805,977)	\$ 34,682
Issuance of common stock for settlement of restricted stock units (RSUs)	8,853	—	—	—	—	—
Unrealized gain on marketable debt securities	—	—	—	137	—	137
Stock-based compensation	—	—	797	—	—	797
Net loss	—	—	—	—	(9,613)	(9,613)
Balance as of September 30, 2024	6,354,414	\$ 6	\$ 841,743	\$ (156)	\$ (815,590)	\$ 26,003
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
	Balance as of June 30, 2023	4,370,863	\$ 4	\$ 815,636	\$ (325)	\$ (760,366)
Issuance of common stock for settlement of RSUs	13,622	—	—	—	—	—
Unrealized gain on marketable debt securities	—	—	—	50	—	50
Stock-based compensation	—	—	1,135	—	—	1,135
Net loss	—	—	—	—	(14,420)	(14,420)
Balance as of September 30, 2023	4,384,485	\$ 4	\$ 816,771	\$ (275)	\$ (774,786)	\$ 41,714

	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, 2023	5,482,752	\$ 5	\$ 826,921	\$ (81)	\$ (785,748)	\$ 41,097
Issuance of common stock and warrants in a registered direct offering and a private placement, net of issuance costs	814,000	1	12,394	—	—	12,395
Issuance of common stock under Employee Stock Purchase Plan (ESPP)	7,252	—	55	—	—	55
Issuance of common stock for settlement of RSUs	49,996	—	—	—	—	—
Issuance of common stock upon exercise of stock options	414	—	4	—	—	4
Unrealized loss on marketable debt securities	—	—	—	(75)	—	(75)
Stock-based compensation	—	—	2,369	—	—	2,369
Net loss	—	—	—	—	(29,842)	(29,842)
Balance as of September 30, 2024	6,354,414	\$ 6	\$ 841,743	\$ (156)	\$ (815,590)	\$ 26,003

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
	Balance as of December 31, 2022	4,074,552	\$ 4	\$ 807,983	\$ (803)	\$ (724,520)
Issuance of common stock under at-the-market (ATM) equity offering program, net of issuance costs	261,170	—	4,546	—	—	4,546
Issuance of common stock under ESPP	7,533	—	80	—	—	80
Issuance of common stock for settlement of RSUs	41,230	—	—	—	—	—
Unrealized gain on marketable debt securities	—	—	—	528	—	528
Stock-based compensation	—	—	4,162	—	—	4,162
Net loss	—	—	—	—	(50,266)	(50,266)
Balance as of September 30, 2023	4,384,485	\$ 4	\$ 816,771	\$ (275)	\$ (774,786)	\$ 41,714

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,	
	2024	2023
Cash flows from operating activities		
Net loss	\$ (29,842)	\$ (50,266)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	97	366
Stock-based compensation	2,369	4,160
Net accretion of investments in marketable debt securities	(3,065)	(534)
Non-cash rent expense	1,064	2,525
Changes in operating assets and liabilities:		
Accounts receivable from collaboration	43	944
Prepaid expenses and other current assets	238	951
Other assets	—	337
Accounts payable	874	(1,735)
Accrued research and development expenses	701	(1,503)
Other accrued expenses	(979)	(3,429)
Deferred revenue from a related party	(21,163)	—
Operating lease liabilities	(1,047)	(2,720)
Net cash used in operating activities	(50,710)	(50,904)
Cash flows from investing activities		
Proceeds from maturities of marketable securities	96,500	46,315
Purchases of marketable securities	(49,605)	(25,615)
Purchases of property and equipment	(28)	(184)
Net cash provided by investing activities	46,867	20,516
Cash flows from financing activities		
Proceeds from the issuance of common stock and warrants in a registered direct offering and a private placement, net of issuance costs	12,395	—
Proceeds from the issuance of common stock under ATM equity offering program, net of issuance costs	—	4,546
Proceeds from the issuance of common stock under ESPP	55	80
Proceeds from the exercise of stock options	4	—
Net cash provided by financing activities	12,454	4,626
Net increase (decrease) in cash and cash equivalents	8,611	(25,762)
Cash and cash equivalents at the beginning of the period	19,841	52,418
Cash and cash equivalents at the end of the period	\$ 28,452	\$ 26,656

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 therapeutics. The Company's pipeline includes two clinical-stage helicase-primase inhibitors (HPI) for the treatment of recurrent genital herpes, an orally bioavailable hepatitis delta virus (HDV) entry inhibitor, a clinical-stage capsid assembly modulator candidate designed to disrupt the replication cycle of hepatitis B virus (HBV) and research programs focused on a non-nucleoside polymerase inhibitor (NNPI) targeting transplant-related herpesviruses and a small molecule interferon- α (IFN- α) receptor (IFNAR) agonist targeting HBV and HDV. The Company operates in one segment and is headquartered in South San Francisco, California.

Liquidity

The Company has not derived any revenue from product sales to date and currently has no approved products. Once a product has been developed, it will need to be approved for sale by the U.S. Food and Drug Administration (FDA) or an applicable foreign regulatory agency. Since inception, the Company's operations have been financed through the sale of equity securities, the proceeds from the exercise of warrants and stock options, the issuance of debt, and upfront 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. Management believes the Company currently has sufficient funds to meet its operating requirements for at least the next twelve months following the date these unaudited condensed consolidated financial statements are issued. 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. Market volatility, inflation or other factors could also adversely impact the Company's ability to access capital when and as needed.

If the Company is unable to secure additional sources of funding or generate enough revenue from its collaborations, it may be necessary to significantly reduce the current rate of spending through reductions in staff and delaying, scaling back, or stopping certain research and development programs, including more costly clinical trials.

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, 2023, which are contained in the 2023 Annual Report. The results for the three and nine months ended September 30, 2024 are not necessarily indicative of results to be expected for the entire year ending December 31, 2024 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 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 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 Israel-Hamas war and the Israel-Hezbollah war in Lebanon. 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.

Reverse Stock Split

In September 2023, the Company received a letter from the Listing Qualifications Department of the Nasdaq Stock Market notifying the Company, as the bid price for its common stock had closed below \$1.00 per share for the last 30 consecutive business days, it was not in compliance with Nasdaq Listing Rule 5450(a)(1), which is the minimum bid price requirement for continued listing on the Nasdaq Global Select Market. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), the Company was provided a 180-calendar day period, or until March 25, 2024, to regain compliance with the minimum bid price requirement. The continued listing standard would be met once the closing bid price of the Company's common stock was at least \$1.00 per share for a minimum of ten consecutive business days during the 180-calendar day period. In January 2024, the Company's stockholders approved a reverse stock split of its common stock at a range of ratios between 1-for-7 to 1-for-17, and the Company's board of directors approved the implementation of the reverse stock split at a ratio of 1-for-12 (the Reverse Stock Split). The Reverse Stock Split was effective as of February 9, 2024 and the Company regained compliance with the minimum bid price requirement in February 2024.

As of the effective time of the Reverse Stock Split, every 12 issued and outstanding shares of the Company's common stock was automatically reclassified into one issued and outstanding share of the Company's common stock. This reduced the number of shares outstanding from 65.8 million shares to 5.5 million shares. The Reverse Stock Split did not affect the number of authorized shares of common stock or the par value of the common stock. No fractional shares of common stock were issued in connection with the Reverse Stock Split and all fractional shares were rounded down to the nearest whole share with respect to outstanding shares of common stock. Any holders of common stock who would have otherwise received a fractional share of common stock pursuant to the Reverse Stock Split, received cash in lieu of the fractional share. All prior period share and per share amounts of the Company's common stock presented have been retroactively adjusted to reflect the 1-for-12 Reverse Stock Split, including reclassifying an amount equal to the reduction in par value of common stock to additional paid-in capital.

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,	
	2024	2023	2024	2023
Numerator:				
Net loss	\$ (9,613)	\$ (14,420)	\$ (29,842)	\$ (50,266)
Denominator:				
Weighted average common shares outstanding - basic and diluted	6,351,431	4,380,444	5,827,750	4,329,260
Net loss per share - basic and diluted	\$ (1.51)	\$ (3.29)	\$ (5.12)	\$ (11.61)

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

	September 30,	
	2024	2023
Warrants to purchase common stock	814,000	—
Options to purchase common stock	937,268	828,789
Common stock subject to purchase under ESPP	7,513	6,711
Unvested RSUs	69,217	90,740
Total	1,827,998	926,240

Note 3 – Related Party

In October 2023, the Company entered into an Option, License and Collaboration Agreement (the Gilead Collaboration Agreement), and a Common Stock Purchase Agreement and an Investor Rights Agreement (collectively, the Gilead Equity Agreements) under which it received aggregate gross proceeds of \$100.0 million from Gilead Sciences, Inc. (Gilead). During the three and nine months ended September 30, 2024, the Company recognized \$6.8 million and \$21.2 million of collaboration revenue under the Gilead Collaboration Agreement, respectively (see Note 8).

Pursuant to the Investor Rights Agreement, Gilead designated two directors to the Company's board of directors, who were appointed in December 2023 and February 2024.

In June 2024, the Company entered into a Securities Purchase Agreement with Gilead for the issuance and sale of 179,500 shares of the Company's common stock and a warrant to purchase up to 179,500 shares of the Company's common stock in a private placement (see Note 6). The common stock and warrant were sold at a combined offering price of \$15.46, for aggregate gross proceeds to the Company of approximately \$2.8 million. Also in June 2024, the Gilead Equity Agreements were amended to extend deadlines relating to the Company's efforts to complete an equity financing and its ability to require Gilead to purchase additional shares of the Company's common stock by three months. The extended deadlines lapsed in October 2024. The amendments also explicitly include the shares of the Company's common stock and warrant sold to Gilead in June 2024 in the definition of registrable securities. The amendments to the Gilead Equity Agreements did not have an impact to the Company's condensed consolidated financial statements.

As of September 30, 2024, Gilead held approximately 19.9% of the Company's outstanding voting common stock. Under the Gilead Equity Agreements, Gilead may elect to purchase additional shares to increase its holdings up to a maximum of 29.9% of the Company's then-outstanding voting common stock. The purchase price per share for additional shares purchased by Gilead under the Gilead Common Stock Purchase Agreement will be equal to the lesser of (1) a 35% premium to the 30 trading day volume weighted average price immediately prior to the date of purchase or (2) a 35% premium to the 30 trading day volume weighted average price immediately prior to delivery by Gilead of notice of the anticipated closing date.

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, 2024			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Cash equivalents				
Money market fund	\$ 27,840	\$ —	\$ —	\$ 27,840
Total cash equivalents	27,840	—	—	27,840
Short-term marketable securities				
U.S. and foreign corporate debt securities	16,468	42	—	16,510
U.S. treasury securities	47,298	64	—	47,362
U.S. and foreign commercial paper	2,619	11	—	2,630
Total short-term marketable securities	66,385	117	—	66,502
Total cash equivalents and marketable securities	\$ 94,225	\$ 117	\$ —	\$ 94,342

	December 31, 2023			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Cash equivalents				
Money market fund	\$ 18,982	\$ —	\$ —	\$ 18,982
Total cash equivalents	18,982	—	—	18,982
Short-term marketable securities				
U.S. and foreign corporate debt securities	17,595	41	(3)	17,633
U.S. treasury securities	76,891	127	—	77,018
U.S. and foreign commercial paper	15,728	27	—	15,755
Total short-term marketable securities	110,214	195	(3)	110,406
Total cash equivalents and marketable securities	\$ 129,196	\$ 195	\$ (3)	\$ 129,388

There were no realized gains and losses for the three and nine months ended September 30, 2024 and 2023. As of September 30, 2024, there were no investments in an unrealized loss position. The Company did not recognize any credit losses related to its investments and all unrealized gains and losses on available-for-sale securities are recorded in accumulated other comprehensive loss on the condensed consolidated balance sheets as of September 30, 2024 and December 31, 2023.

Accrued interest receivable was \$0.4 million and \$0.3 million as of September 30, 2024 and December 31, 2023, respectively, 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, 2024 and 2023.

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, 2024			Fair Value
	Level 1	Level 2	Level 3	
Cash equivalents				
Money market fund	\$ 27,840	\$ —	\$ —	\$ 27,840
Total cash equivalents	27,840	—	—	27,840
Short-term marketable securities				
U.S. and foreign corporate debt securities	—	16,510	—	16,510
U.S. treasury securities	—	47,362	—	47,362
U.S. and foreign commercial paper	—	2,630	—	2,630
Total short-term marketable securities	—	66,502	—	66,502
Total assets measured at fair value	\$ 27,840	\$ 66,502	\$ —	\$ 94,342

	December 31, 2023			Fair Value
	Level 1	Level 2	Level 3	
Cash equivalents				
Money market fund	\$ 18,982	\$ —	\$ —	\$ 18,982
Total cash equivalents	18,982	—	—	18,982
Short-term marketable securities				
U.S. and foreign corporate debt securities	—	17,633	—	17,633
U.S. treasury securities	—	77,018	—	77,018
U.S. and foreign commercial paper	—	15,755	—	15,755
Total short-term marketable securities	—	110,406	—	110,406
Total assets measured at fair value	\$ 18,982	\$ 110,406	\$ —	\$ 129,388

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, 2024	December 31, 2023
Accrued expenses:		
Accrued compensation	\$ 4,124	\$ 5,484
Accrued professional fees and other	641	260
Total accrued expenses	\$ 4,765	\$ 5,744

Note 6 – Sale of Common Stock and Warrants

In June 2024, the Company entered into a Securities Purchase Agreement with an investor for the issuance and sale of 634,500 shares of the Company's common stock and a warrant to purchase up to 634,500 shares of the Company's common stock in a registered direct offering, pursuant to its shelf registration statement on Form S-3 on file with the SEC. The common stock and warrant were sold at a combined offering price of \$15.46 for aggregate gross proceeds to the Company of approximately \$9.8 million. The Company also entered into a Securities Purchase Agreement with Gilead for the issuance and sale of 179,500 shares of the Company's common stock and a warrant to purchase up to 179,500 shares of the Company's common stock in a private placement. The common stock and warrant were sold at a combined offering price of \$15.46 for aggregate gross proceeds to the Company of approximately \$2.8 million. The sale of common stock to Gilead maintains Gilead's ownership of approximately 19.9% of the Company's outstanding

voting common stock as of the date of closing pursuant to the terms of Gilead's existing Investor Rights Agreement with the Company entered into in October 2023 and amended in June 2024 (see Note 3). The warrants sold to both parties have an exercise price equal to \$17.00 per share, became immediately exercisable on the date of issuance and expire on June 18, 2029. Neither party may exercise any portion of the warrants to the extent it would beneficially own more than the limits defined in the warrant agreements. The exercise price and number of shares of 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.

The warrants were classified as a component of permanent stockholders' equity within additional paid-in-capital and were recorded at the issuance date. The warrants are equity classified because they are freestanding financial instruments that are legally detachable and separately exercisable from the equity instruments, are immediately exercisable, 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 do not provide any guarantee of value or return. There were no warrants exercised during the three and nine months ended September 30, 2024.

In August 2020, 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 \$100.0 million through "at-the-market" offerings (2020 ATM), pursuant to its shelf registration statement on Form S-3 on file with the SEC. During the three months ended September 30, 2024 and 2023 and during the nine months ended September 30, 2024, the Company did not sell any shares of common stock under the 2020 ATM. During the nine months ended September 30, 2023, the Company sold 261,170 shares of common stock under the 2020 ATM, for which the Company received net proceeds of \$4.5 million, after deducting commissions, fees and expenses.

Note 7 – Stock-Based Compensation

The following table summarizes the components of total stock-based compensation expense included in the condensed consolidated statements of operations and comprehensive loss (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Research and development	\$ 395	\$ 512	\$ 1,152	\$ 1,747
General and administrative	402	623	1,217	2,413
Total stock-based compensation expense	\$ 797	\$ 1,135	\$ 2,369	\$ 4,160

As of September 30, 2024, there was \$2.9 million of total unrecognized stock-based compensation related to outstanding equity awards, which is expected to be recognized over a weighted average remaining amortization period of 1.6 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,	
	2024	2023	2024	2023
Exercise price	\$13.24	\$11.76	\$12.90 - \$15.06	\$10.68 - \$18.36
Expected volatility	80.8% - 86.2%	77.5% - 83.1%	79.1% - 86.9%	77.5% - 83.1%
Risk-free rate	4.39% - 4.40%	4.23% - 4.24%	4.16% - 4.57%	3.59% - 4.24%
Expected term (years)	5.5 - 7.0	5.5 - 7.0	5.5 - 7.5	5.5 - 7.5
Expected dividend yield	0%	0%	0%	0%

Note 8 - Collaboration Agreements

Gilead Agreement

In October 2023, the Company entered into the Gilead Collaboration Agreement and the Gilead Equity Agreements under which it received total proceeds of \$100.0 million. Under the Gilead Collaboration Agreement, Gilead exclusively licensed to the Company its HPI program and NNPI program, while retaining opt-in rights to these programs and has an option to take an exclusive license, on a program-by-program basis, to all of the Company's

other current and future pipeline programs. During the 12-year collaboration term (subject to payment of certain extension fees) and for a specified period thereafter, Gilead may exercise its opt-in rights, on a program-by-program basis, at one of two timepoints—completion of a certain Phase 1 study or completion of a certain Phase 2 study for the first product within the program—upon payment of an opt-in fee ranging from \$45.0 million to \$125.0 million per program depending on the type of program and when the option is exercised.

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

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

The Company concluded Gilead is a customer and accordingly, the Gilead Collaboration Agreement is 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 during the collaboration term (the R&D Services). As of September 30, 2024, the total transaction price of the Gilead Collaboration Agreement was determined to be \$90.7 million. The Company will reevaluate the transaction price in each reporting period as uncertain events are resolved or other changes in circumstances occur.

The transaction price is reflected as collaboration revenue when realized in the Company’s condensed consolidated statements of operations. The Company will recognize revenue over time using a cost-based input method over the initial non-cancellable term of three years since this method best reflects the transfer of services to Gilead. In applying a cost-based input method of revenue recognition, the Company uses actual costs incurred relative to estimated total costs to fulfill each performance obligation.

The Company recognized collaboration revenue of \$6.8 million and \$21.2 million during the three and nine months ended September 30, 2024. The transaction price for future collaborative activities was recorded as deferred revenue on the condensed consolidated balance sheet as of September 30, 2024, of which \$32.6 million was short-term and \$32.5 million was long-term. The reimbursable expenses incurred by the Company during the three months ended September 30, 2024 were insignificant. During the nine months ended September 30, 2024, the Company incurred \$0.3 million in reimbursable expenses due to Gilead.

The following table presents changes in the Company’s contract liabilities (in thousands):

	Balance at Beginning of Period	Additions	Deductions	Balance at End of Period
Nine Months Ended September 30, 2024				
Contract liabilities:				
Deferred revenue	\$ 86,294	\$ —	\$ (21,163)	\$ 65,131

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Collaboration revenue recognized in the period from				
Amounts included in deferred revenue at the beginning of the period	\$ 6,845	\$ —	\$ 21,163	\$ —
Performance obligations satisfied in previous period	\$ —	\$ —	\$ —	\$ —

Arbutus Biopharma Agreement

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

Reimbursements and cost-sharing portions from Arbutus Biopharma are reflected as a reduction of research and development expense when realized in the Company's condensed consolidated statements of operations. During the three and nine months ended September 30, 2024, the Company recognized research and development expenses of \$0.3 million for net amounts refundable to Arbutus Biopharma after the final reconciliation of clinical trial costs. Amounts refundable to Arbutus Biopharma are recorded as accrued research and development expenses on the condensed consolidated balance sheet as of September 30, 2024. During the three and nine months ended September 30, 2023, the Company recognized a reduction of research and development expenses of \$0.1 million and \$1.2 million, respectively, under the Arbutus Biopharma Agreement.

Note 9 - Milestones and Research Agreements

HBV Research Agreement with Indiana University

Since September 2013, the Company was party to an exclusive License Agreement dated September 3, 2013 with Indiana University Research and Technology Corporation (IURTC) from whom it licensed aspects of the Company's HBV program held by IURTC. The license agreement required the Company to make milestone payments based upon the successful accomplishment of clinical and regulatory milestones. The aggregate amount of all performance milestone payments under the IURTC license agreement, if all milestones through development were met, was \$0.8 million, with a portion having been paid. The Company was obligated to pay IURTC royalty payments based on net sales of the licensed technology as well as a portion of any sublicensing revenue Assembly received. The Company was also required to pay diligence maintenance fees each year to the extent that the royalty, sublicensing, and milestone payments to IURTC were less than such fees for that year. Following its decision to discontinue further development or partnering for ABI-H3733, the Company terminated the IURTC license agreement effective April 2024. There were no fees paid to IURTC during the three months ended September 30, 2024 or 2023. The Company paid IURTC \$0.1 million in diligence maintenance fees during both the nine months ended September 30, 2024 and 2023.

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, 2023 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, 2023 filed with the U.S. Securities and Exchange Commission on March 28, 2024 (2023 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 2023 Annual Report and “Part II. Item 1A. Risk Factors” in this report.

Overview

We are a biotechnology company developing innovative therapeutics targeting serious viral diseases with the potential to improve the lives of patients worldwide. Our pipeline includes two clinical-stage helicase-primase inhibitors (HPI) for the treatment of recurrent genital herpes, an orally bioavailable hepatitis delta virus (HDV) entry inhibitor, a clinical-stage capsid assembly modulator (CAM) designed to disrupt the replication cycle of hepatitis B virus (HBV) and research programs focused on a non-nucleoside polymerase inhibitor (NNPI) targeting transplant-related herpesviruses and a small molecule interferon- α (IFN- α) receptor (IFNAR) agonist targeting HBV and HDV.

Our Clinical Programs and CTA-Enabling Programs

To date, in 2024, we initiated the Phase 1a portion of a Phase 1a/b study of ABI-5366 (5366), a long-acting HPI for recurrent genital herpes and announced interim results from the Phase 1a portion of the study in the third quarter of 2024. In 2024, we also initiated the Phase 1b portion of the Phase 1a/b study of 5366 and initiated a Phase 1b study of ABI-4334 (4334), a highly potent, next-generation CAM for chronic HBV infection. By the end of 2024, we expect to initiate a Phase 1a study of ABI-6250 (6250), an orally bioavailable HDV entry inhibitor; and the Phase 1a portion of a Phase 1a/b study of ABI-1179 (1179), a long-acting HPI for recurrent genital herpes contributed by Gilead Sciences, Inc. (Gilead) through the Gilead Collaboration (as defined below). We also expect to announce interim results from the Phase 1b study of 4334 by the end of 2024.

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 patient’s life and periodically reactivate, with the virus spreading and replicating in epithelial tissues. Initial infection can be asymptomatic or can be marked by symptoms, including painful skin lesions, swelling of lymph nodes and urinary problems that can persist for two to three weeks. Genital herpes recurrence is common and can cause painful genital lesions that can lead to increased transmission and debilitate patients, and symptoms may become more serious with additional episodes. Additional complications include increased risk of HIV infection, as 30% of incident HIV infections acquired through sexual transmission is 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 patients may experience more severe and prolonged symptoms due to increased recurrence rates. While genital herpes can be caused by either HSV-1 or HSV-2, recurrences are more likely to be experienced by patients infected by HSV-2.

HPIs are antiviral agents in development for 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 three or more recurrences per year, including over four million people in the United States and France, Germany, Italy and Spain (collectively, the EU4) and the United Kingdom (UK). Currently, there are three antiviral drugs (all nucleoside analogs) that have been approved in the United States and the EU4/UK for the treatment of genital herpes. However, no new drugs have been

approved in these regions to treat genital herpes for more than 25 years. In addition to the approved nucleoside analogs, agents such as local anesthetics or analgesics may be used to alleviate local symptoms of minor pain and discomfort.

Nucleoside analogs can be administered as episodic therapy as individual outbreaks arise or daily as chronic suppressive therapy for those with high post-exposure recurrences. However, these agents are only partially effective at controlling the infection or reducing transmission risk. With current nucleoside analog therapies, only one out of three recurrent genital herpes patients 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.

Based on the limitations of current therapies, we see a path to advancing the treatment paradigm for patients suffering from recurrent genital herpes. To reach that goal, we discovered and are developing 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 Good Laboratory Practice (GLP) toxicology studies, with high safety margins and minimal potential for off-target effects.

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

In September 2024, we announced positive interim data for the Phase 1a portion of the 5366 study. Interim results exceeded our objectives for this Phase 1a study and support 5366's progression into Phase 1b. Across the Part A (Phase 1a) cohorts evaluated as of the September 23, 2024 data cutoff date, 5366 had a mean half-life of approximately 20 days when dosed orally, supporting once-weekly oral dosing, the target profile for 5366, as well as showing the potential for once-monthly oral dosing. 5366 doses within the range tested are projected, with weekly or monthly dosing, to maintain the target plasma concentrations for antiviral activity established by pharmacokinetic (PK) modeling. We plan to explore both once-weekly and once-monthly oral dosing regimens in the Part B (Phase 1b) portion of the study.

In these cohorts as of the September 23, 2024 data cutoff date, 5366 has been well-tolerated with a favorable safety profile observed with exposure of up to 70 days. Treatment-emergent adverse events (AEs) were all mild to moderate in intensity and all were considered not related to study treatment by the study investigators; there have been no serious AEs in any dose arm. There were no treatment-related Grade 3 or 4 laboratory abnormalities and no protocol-defined stopping criteria were met. There were no clinically significant electrocardiogram abnormalities or patterns of AEs or laboratory abnormalities noted.

We initiated the Phase 1b portion of the 5366 study during the third quarter of 2024, and we expect interim data to be available during the first half of 2025.

In addition to 5366, we are also advancing 1179, a structurally-differentiated HPI with single digit nanomolar potency against HSV-1 and HSV-2 and a nonclinical PK and safety profile to date that is supportive of a potential long-acting treatment by once-weekly oral administration. GLP toxicology studies have been completed. We submitted the CTA for a Phase 1a/b study of 1179 in September 2024, which was approved in October 2024, and the Phase 1a portion of the clinical study is expected to begin by the end of 2024. We acquired rights to 1179, Gilead's HPI program, as part of the Gilead Collaboration in October 2023.

In July 2024, we highlighted nonclinical data for both 5366 and 1179 at the International Herpesvirus Workshop through poster presentations for each, as well as an oral presentation for 1179.

HBV and HDV

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

The current standard of care for chronic HBV infection, nucleos(t)ide analog reverse transcriptase inhibitors (NrtIs), are taken life-long and reduce, but do not eliminate, the virus and result in very low cure rates. No new mechanisms

of action (MOA) have been approved for the treatment of chronic HBV infection in over 25 years. The focus of our HBV program is to improve outcomes and increase the number of patients diagnosed and treated through the development of finite and curative therapies targeting an orthogonal MOA.

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

The current standard of care treatment for HDV is off-label pegylated IFN- α injected weekly or, in some regions, a large, complex molecule that requires daily injections. There are no approved HDV treatments in the United States, and there is only one approved HDV treatment in the EU. We believe a safe and effective oral small molecule entry inhibitor would be a significant innovation for patients living with HDV, which face a significant and immediate disease burden.

HDV Entry Inhibitor Program

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

The inhibition of HBV and HDV infection by molecules that bind NTCP has been demonstrated in vitro, in animal models and clinically. Notably, bulevirtide, a peptide blocker of NTCP, is the only approved therapy for HDV (approved in the EU). 6250 uses the same clinically validated MOA as bulevirtide. The binding of NTCP-targeted HBV/HDV entry inhibitors to NTCP has also been shown to inhibit the transport of certain bile acids into cells, which results in plasma elevations of bile acids; this effect has been well tolerated clinically and may serve as a biomarker of pharmacologically active concentrations of drug in the plasma.

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

In September 2023, we nominated 6250, a novel, orally bioavailable small molecule designed to inhibit entry of HBV and HDV by targeting NTCP. In nonclinical studies, 6250 demonstrated low nanomolar potency against all tested HBV/HDV genotypes, favorable selectivity for NTCP versus other bile acid transporters, good oral bioavailability and a PK profile in nonclinical species projected to support once-daily oral dosing. In GLP toxicology studies, 6250 demonstrated a favorable nonclinical safety profile with wide safety margins.

At the European Association for the Study of the Liver's International Liver Congress™ in June 2024 and the International HBV Meeting in September 2024, we presented nonclinical profiling of 6250. In addition, 6250 was featured in an oral presentation at the Science of HBV Cure Meeting 2024. We expect to initiate a Phase 1a clinical study of 6250 by the end of 2024.

Capsid Assembly Modulator Program

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, which makes molecules that can modulate cccDNA generation or disrupt its function highly sought after in the HBV field. 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 has been 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 cccDNA formation (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. In addition, the PK data support 4334 as a once daily oral therapy and predicts best in class activity against both MOA #1 and MOA #2. During the second quarter of 2024, we dosed our first participant in a Phase 1b clinical study of 4334. Interim clinical results from this study are expected by the end of 2024.

Research Programs

Transplant-Associated Herpesviruses

In August 2022, in connection with our announcement of our HPI program, we also introduced our NNPI research program, targeting transplant-associated herpesviruses. In a transplant setting, when people 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 and varicella zoster virus (VZV). Each of these herpesviruses are highly prevalent, as approximately (1) 60% of people receiving transplants are CMV-positive; (2) 60% of people receiving transplants are HSV-positive; and (3) 80% of people receiving transplants are VZV-positive. These viruses establish lifelong latent infections and frequently reactivate in people receiving transplants due to the use of immunosuppressive drugs following the transplant. These uncontrolled viral 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 broad spectrum 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 a potent oral pan-herpes NNPI for these transplant-associated herpesvirus infections, which could greatly advance treatment. Our research team has discovered multiple chemical series of potent, broad-spectrum herpesvirus NNPIs. In addition, Gilead exclusively licensed us its NNPI program, and we believe the combined effort will accelerate candidate nomination and enhance our chance of clinical success.

IFNAR Agonist

In July 2022, we introduced our research program advancing a novel, small molecule IFNAR agonist designed to selectively activate the IFN- α pathway within the liver and offer the convenience of oral dosing. IFN- α is a subcutaneous injectable immune modulatory therapy approved for HBV that has demonstrated functional cure in some HBV infected people, but its poor tolerability profile significantly limits its use. Substantial side effects include flu-like symptoms, cytopenias, serious depression and psychiatric effects. In addition, multiple contraindications limit its use, and it requires weekly injections that result in systemic exposure for up to a year.

By focusing exposure on the liver, our investigational IFNAR agonist program aims to engage IFN- α 's validated antiviral and immune modulatory mechanisms, retaining the efficacy of IFN- α while reducing systemic exposure to improve tolerability. Lead optimization of multiple IFNAR agonists is in progress.

Gilead Collaboration

On October 15, 2023, we entered into an Option, License and Collaboration agreement (the Gilead Collaboration Agreement) with Gilead pursuant to which Gilead (1) exclusively licensed to us its HPI program and its NNPI program, while retaining opt-in rights to these programs and (2) has an option to take an exclusive license, on a program-by-program basis, to all of our other current and future pipeline programs. During the 12-year collaboration term (subject to payment of certain extension fees) and for a specified period thereafter, Gilead may exercise its opt-in rights, on a program-by-program basis, at one of two timepoints—completion of a certain Phase 1 study or completion of a certain Phase 2 study for the first product within the program—upon payment of an opt-in fee ranging from \$45.0 million to \$125.0 million per program depending on the type of program and when the option is exercised. Pursuant to the Gilead Collaboration Agreement, Gilead made an \$84.8 million upfront cash payment to us.

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

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

We and Gilead also entered into a Common Stock Purchase Agreement and an Investor Rights Agreement (together, the Gilead Equity Agreements), which were both amended in June 2024 in connection with a financing transaction (the 2024 Financing Transaction). Pursuant to the Gilead Equity Agreements, Gilead made an upfront equity investment of \$15.2 million by purchasing from us 1,089,472 shares of our common stock at a purchase price of \$13.92 per share. Gilead may elect to purchase additional shares of common stock from us in an amount that results in Gilead owning 29.9% of our then-outstanding voting common stock. The purchase price per share for additional shares purchased by Gilead will be equal to the lesser of (1) a 35% premium to the 30 trading day volume weighted average price immediately prior to the date of purchase or (2) a 35% premium to the 30 trading day volume weighted average price immediately prior to delivery by Gilead of notice of the anticipated closing date. The Gilead Equity Agreements also include a three-year standstill provision and a two-year lockup provision, each with customary exceptions, and provide Gilead with certain other stock purchase rights and registration rights, as well as the right to designate two directors (or, alternatively, board observers at Gilead's election) to our board of directors. In December 2023, Gilead designated Tomas Cihlar, Ph.D. to serve on our board of directors, and in March 2024, Gilead designated Robert D. Cook II to serve on our board of directors.

As a part of the 2024 Financing Transaction, we and Gilead entered into a Securities Purchase Agreement for the issuance and sale, in a private placement, of 179,500 shares of our common stock and a warrant to purchase up to 179,500 shares of our common stock. The common stock and warrant were sold to Gilead pursuant to the terms of the Investor Rights Agreement. The warrant sold to Gilead has an exercise price equal to \$17.00 per share, became immediately exercisable on the date of issuance and will expire on June 18, 2029. Neither Gilead nor its affiliates may exercise any portion of the warrant to the extent that Gilead would own more than 19.9% of the number of our shares of common stock outstanding immediately after giving effect to such exercise.

Operations

We currently have corporate and administrative offices and research laboratory space in South San Francisco, California.

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

We have generated significant losses to date, and we expect to continue to generate losses as we develop our product candidates. As of September 30, 2024, we had an accumulated deficit of \$815.6 million. Because we do not generate revenue from any of our product candidates, our losses will continue as we further develop and seek regulatory approval for, and commercialize, our product candidates. Additionally, we expect our research and development expenses to increase over the next few years due to the Gilead Collaboration Agreement. As a result, our operating losses are likely to be substantial over the next several years as we continue the development of our product candidates and thereafter if none are approved or successfully launched. We are unable to predict the extent of any future losses or when we will become profitable, if at all.

Critical Accounting Estimates

Our management’s discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States (U.S. GAAP). The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses.

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

Our critical accounting policies and significant estimates are detailed in our 2023 Annual Report. Our critical accounting policies and significant estimates have not changed from those previously disclosed in our 2023 Annual Report.

Results of Operations

Comparison of the Three Months Ended September 30, 2024 and 2023

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 2024 vs. 2023	% Change 2024 vs. 2023
	2024	2023		
Collaboration revenue from a related party	\$ 6,845	\$ —	\$ 6,845	100%

Collaboration revenue for the three months ended September 30, 2024 includes the recognition of \$6.8 million under the Gilead Collaboration Agreement entered into in October 2023. There was no revenue for the three months ended September 30, 2023.

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 costs represent a significant portion of our research and development expenses, which we track on a program-by-program basis following the nomination of a development candidate. 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 2024 vs. 2023	% Change 2024 vs. 2023
	2024	2023		
External expenses:				
Research and discovery	\$ 2,251	\$ 2,404	\$ (153)	(6%)
5366	1,797	1,116	681	61%
6250	1,298	—	1,298	100%
4334	842	184	658	358%
1179	654	—	654	100%
ABI-H3733 (3733)	—	437	(437)	(100%)
Vebicorvir (VBR)	(67) ⁽¹⁾	118	(185)	(157%)
Total external expenses	6,775	4,259	2,516	59%
Employee and contractor-related expenses	6,072	4,725	1,347	29%
Facility and other expenses	668	1,840	(1,172)	(64%)
Total research and development expenses	\$ 13,515	\$ 10,824	\$ 2,691	25%

⁽¹⁾ Reflects net amounts refundable to us after the final reconciliation of costs of the clinical trial conducted pursuant to the Clinical Trial Collaboration Agreement with Arbutus Biopharma Corporation (the Arbutus Biopharma Agreement), which was terminated in February 2023.

Research and development expenses were \$13.5 million for the three months ended September 30, 2024 compared to \$10.8 million for the same period in 2023. The \$2.7 million increase in research and development expenses was primarily driven by increases in external expenses from the advancement and expansion of our pipeline, most notably from the nomination of our HDV entry inhibitor, 6250, partially offset by savings from the discontinuation of 3733 and VBR. We also experienced a \$1.3 million increase in employee and contractor-related expenses due to higher headcount and increased travel costs. This increase was largely offset by a \$1.2 million decrease in facility and other expenses, reflecting cost savings in rent and related expenses from our corporate headquarters sublease, which commenced in November 2023.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries, consulting fees and other related costs, professional fees for legal services, accounting and tax services, insurance and travel expenses, as well as stock-based compensation expense associated with equity awards to our employees and directors.

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 2024 vs. 2023	% Change 2024 vs. 2023
	2024	2023		
General and administrative expenses	\$ 4,286	\$ 4,224	\$ 62	1%

General and administrative expenses were \$4.3 million for the three months ended September 30, 2024 compared to \$4.2 million for the same period in 2023. Overall, general and administrative expenses remained consistent as increases in our professional fees for legal and tax services were substantially offset by decreases in stock-based compensation expense due to the lower grant date fair value of our awards vesting during the period.

Interest and Other Income, Net

Interest income consists of interest earned on our cash and cash equivalents and available-for-sale 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 2024 vs. 2023	% Change 2024 vs. 2023
	2024	2023		
Interest and other income, net	\$ 1,343	\$ 628	\$ 715	114 %

Interest and other income, net was \$1.3 million for the three months ended September 30, 2024, compared to \$0.6 million for the same period in 2023. The \$0.7 million increase was primarily due to more interest income earned on marketable securities resulting from a larger portfolio balance after the receipt of \$100.0 million upon entering into the Gilead Collaboration in October 2023 and \$12.6 million upon entering into the 2024 Financing Transaction in June 2024.

Comparison of the Nine Months Ended September 30, 2024 and 2023

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 2024 vs. 2023	% Change 2024 vs. 2023
	2024	2023		
Collaboration revenue from a related party	\$ 21,163	\$ —	\$ 21,163	100 %

Collaboration revenue for the nine months ended September 30, 2024 includes the recognition of \$21.2 million under the Gilead Collaboration Agreement entered into in October 2023. There was no revenue for the nine months ended September 30, 2023.

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 2024 vs. 2023	% Change 2024 vs. 2023
	2024	2023		
External expenses:				
Research and discovery	\$ 6,753	\$ 7,828	\$ (1,075)	(14 %)
6250	5,361	—	5,361	100 %
5366	3,933	1,654	2,279	138 %
1179	3,531	—	3,531	100 %
4334	1,939	1,923	16	1 %
3733	—	2,945	(2,945)	(100 %)
VBR	(67) ⁽¹⁾	1,463	(1,530)	(105 %)
ABI-H2158	—	121	(121)	(100 %)
Total external expenses	21,450	15,934	5,516	35 %
Employee and contractor-related expenses	18,081	17,730	351	2 %
Facility and other expenses	2,122	4,230	(2,108)	(50 %)
Total research and development expenses	\$ 41,653	\$ 37,894	\$ 3,759	10 %

⁽¹⁾ Reflects net amounts refundable to us after the final reconciliation of costs of the clinical trial conducted pursuant to the Arbutus Biopharma Agreement, which was terminated in February 2023.

Research and development expenses were \$41.7 million for the nine months ended September 30, 2024 compared to \$37.9 million for the same period in 2023. The \$3.8 million increase in research and development expenses was primarily driven by increases in external expenses from the advancement and expansion of our pipeline, most notably from the nomination of our HDV entry inhibitor, 6250, and acquiring the rights to 1179, Gilead's HPI program, in

October 2023. The overall increase in external expenses was partially offset by decreases from our discontinuation of 3733 and VBR. We also experienced a decrease of \$2.1 million in facility and other expenses primarily due to cost savings in rent and related expenses attributable to our corporate headquarters sublease, which commenced in November 2023.

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 2024 vs. 2023	% Change 2024 vs. 2023
	2024	2023		
General and administrative expenses	\$ 13,398	\$ 14,201	\$ (803)	(6%)

General and administrative expenses were \$13.4 million for the nine months ended September 30, 2024 compared to \$14.2 million for the same period in 2023. The \$0.8 million decrease in general and administrative expenses was primarily due to a decrease in stock-based compensation expense because of the lower grant date fair value of our awards vesting during the period.

Interest and Other Income, Net

Interest income consists of interest earned on our cash and cash equivalents and available-for-sale securities. 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 2024 vs. 2023	% Change 2024 vs. 2023
	2024	2023		
Interest and other income, net	\$ 4,452	\$ 1,829	\$ 2,623	143%

Interest and other income, net was \$4.5 million for the nine months ended September 30, 2024, compared to \$1.8 million for the same period in 2023. The \$2.6 million increase was primarily due to more interest income earned on marketable securities resulting from a larger portfolio balance after the receipt of \$100.0 million upon entering into the Gilead Collaboration in October 2023 and \$12.6 million upon entering into the 2024 Financing Transaction in June 2024.

Income Tax Expense

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

	Nine Months Ended September 30,		\$ Change 2024 vs. 2023	% Change 2024 vs. 2023
	2024	2023		
Income tax expense	\$ 406	\$ —	\$ 406	100%

Income tax expense was \$0.4 million for the nine months ended September 30, 2024 due to the estimated taxable income from the upfront payments received under the Gilead Collaboration in 2023. There was no income tax expense recognized during the nine months ended September 30, 2023.

Liquidity and Capital Resources

Sources of Liquidity

As a result of our significant research and development expenditures and the lack of any FDA-approved products to generate product sales revenue, we have not been profitable and have generated operating losses since we were incorporated in October 2005. We have funded our operations through September 30, 2024 principally through equity financings, raising an aggregate of \$631.2 million in net proceeds, and strategic collaborations, raising an aggregate of \$185.7 million through upfront payments.

Cash Flows for the Nine Months Ended September 30, 2024 and 2023

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

	Nine Months Ended September 30,	
	2024	2023
Operating activities	\$ (50,710)	\$ (50,904)
Investing activities	46,867	20,516
Financing activities	12,454	4,626
Net increase (decrease) in cash and cash equivalents	\$ 8,611	\$ (25,762)

Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2024 was \$50.7 million, compared to \$50.9 million for the same period in 2023. The change was primarily attributable to cost savings in rent and related expenses attributable to our corporate headquarters sublease, which commenced in November 2023, and the timing of vendor invoicing and payments.

Investing Activities

Net cash provided by investing activities for the nine months ended September 30, 2024 was \$46.9 million compared to \$20.5 million for the same period in 2023. The change was due to an increase in net proceeds from maturities of our marketable securities.

Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2024 was \$12.5 million compared to \$4.6 million for the same period in 2023. The change was due to the increase in proceeds from the registered direct offering and private placement in June 2024 compared to the shares sold of our common stock under the 2020 ATM in the nine months ended September 30, 2023.

Funding Requirements

We expect our future operating expenses to gradually increase over the coming years as we continue to advance our candidates into the clinic. We expect our existing cash, cash equivalents and marketable securities will enable us to fund our operating expenses and capital expenditure requirements into 2026. However, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to secure additional sources of funding when needed or on attractive terms, we could be forced to reduce staff and delay, scale back or stop certain research and development programs or future commercialization efforts.

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, most recently in June 2024. We expect to continue to raise capital when and as needed and at the time and in the manner most advantageous to us.

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

- our ability to raise capital despite macroeconomic and geopolitical events impacting financial markets, such as rising inflation and market volatility;
- 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;
- 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.

Identifying potential product candidates and conducting nonclinical testing and clinical studies is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will likely be derived from sales of medicines that we do not expect to be commercially available for years, if at all. Accordingly, we will need to continue to rely on additional financings to achieve our business objectives. Adequate additional financings may not be available to us on acceptable terms, or at all.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise funds through additional collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to reduce staff, delay, scale back or discontinue our product development and clinical studies or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

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 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 Chief Executive Officer and President 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, 2024 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 a new drug application (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 pivotal studies are appropriate. These pivotal studies are necessary to support regulatory approval, and it may be years before these larger, pivotal 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 the recent and potential future disruptions in access to bank deposits and lending commitments due to bank failures, 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, 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, sacrifice attractive 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. In addition, if we are unable to generate sufficient revenue or raise capital, we may conclude there is a substantial doubt about our ability to continue as a going concern, and future reports from our independent registered public accounting firm may also contain statements expressing substantial doubt about our ability to continue as a going concern.

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. 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.
- We may not be successful in this collaboration due to various other factors, including our ability to demonstrate proof of concept in one or more clinical studies so that Gilead will exercise its option to these programs. In addition, even if we demonstrate clinical proof of concept of a candidate, Gilead may choose not to exercise its option.
- Gilead has the right to designate (and has designated) two directors for appointment to our board of directors pursuant to the terms of the investor rights agreement and owns approximately 19.9% of our outstanding common stock. Gilead also has the right to acquire additional shares from us, and 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 disease 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 under 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;
- 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;
- 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, 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 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 Israel-Hamas war, the Israel-Hezbollah war, as well as tariffs, other wars, acts of terrorism, natural disasters or outbreaks of disease;
- different regulatory requirements for drug approvals or increased scrutiny on CROs located in foreign countries, including China;
- 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;
- unexpected changes in tariffs, trade barriers and 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 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 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. 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.

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 intellectual property, proprietary business information and personal information. It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We have outsourced elements of our information technology infrastructure and, as a result, a number of third-party vendors may or could have access to our confidential information. Our internal information technology systems and infrastructure, and those of our current and any future collaborators, contractors and consultants and other third parties on which we rely, are vulnerable to damage from computer viruses, malware, natural disasters, system outages, terrorism, war, telecommunication and electrical failures, cyberattacks, cybersecurity incidents or cyber intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization.

The risk of a cybersecurity incident or security breach or disruption, particularly through cyberattacks or cyber intrusion, has escalated as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. In addition, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information or other intellectual property. The costs to us to mitigate network security problems, bugs, viruses, worms, malicious software programs, system outages and security vulnerabilities or incidents could be significant, and our efforts to address these problems may not be successful. If unsuccessful, these problems could cause interruptions, delays, cessation of service and other harm to our business and our competitive position, including material disruption of our product development 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.

If a computer security breach affects our systems or results in the unauthorized release of personally identifiable information, our reputation could be materially damaged. In addition, such a breach may require notification to governmental agencies, the media or individuals pursuant to various federal, state and non-U.S. privacy and security laws, if applicable, including the Health Insurance Portability and Accountability Act of 1996 (HIPAA), as amended by the Health Information Technology for Clinical Health Act of 2009, and its implementing rules and regulations, as well as regulations promulgated by the Federal Trade Commission, state breach notification law and the European Union (EU) General Data Protection Regulation (EU GDPR). We would also be exposed to a risk of loss or litigation and potential liability, which could materially adversely affect our business, results of operations and financial condition.

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

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

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

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

indication or field we might pursue, and successfully commercialize those treatments, our business and prospects could be materially harmed.

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

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

The clinical and commercial success of our potential products will depend in part on the public and clinical communities' acceptance of novel classes of product candidates. Moreover, our success depends upon physicians prescribing, and their patients being willing to receive, treatments that involve the use of our product candidates we may develop in lieu of, or in addition to, existing treatments with which they are already familiar and for which more clinical data may be available. Adverse events 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, 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.

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

We have net operating loss carryforwards due to prior period losses generated before January 1, 2024, which if not utilized, will begin to expire in 2027 for net operating loss carryforwards prior to 2018. If we are unable to generate sufficient taxable income to utilize our net operating loss carryforwards, pre-2018 carryforwards could expire unused and be unavailable to offset future income tax liabilities.

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the Code), a corporation that undergoes an "ownership change" (generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period) is subject to annual limitations on its ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post-change income or taxes. We have experienced ownership changes in the past, and recent 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, 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 market approval 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 applications, 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 approval process might also be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during our regulatory review. Delays in obtaining regulatory approvals might: delay commercialization of, and our ability to derive product revenues from, our product candidates; impose costly procedures on us; and diminish any competitive advantages that we might otherwise enjoy.

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

We and our collaborators may be subject, directly or indirectly, to applicable U.S. federal and state anti-kickback, false claims laws, physician payment transparency laws, 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, 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. In addition, we may be subject to patient privacy regulation by both the federal government and the states and foreign jurisdictions in which we conduct our business. If we fail to comply with any applicable federal, state or foreign legal requirement, we could be subject to penalties.

Regulators globally are imposing greater monetary fines for privacy violations. The EU GDPR applies to any company established in the EU as well as to those outside the EU if they collect and use personal data in connection with the offering of goods or services to individuals in the EU or the monitoring of their behavior. The EU GDPR enhances data protection obligations for processors and controllers of personal data, including, for example, expanded disclosures about how personal information is to be used, limitations on retention of information, mandatory data

breach notification requirements and onerous new obligations on services providers. Noncompliance with the EU GDPR may result in monetary penalties of up to €20 million or 4% of worldwide revenue, whichever is higher. The EU GDPR may increase our responsibility and liability in relation to personal data that we process and we may be required to put in place additional mechanisms to ensure compliance with the EU GDPR, including as implemented by individual countries. Compliance with the EU GDPR and other changes in laws or regulations associated with the enhanced protection of certain types of personal data, such as healthcare data or other sensitive information, could greatly increase our cost of developing our products or even prevent us from offering certain products in jurisdictions that we may operate in.

The California Consumer Privacy Act (CCPA) also created new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA requires covered companies to provide certain disclosures to consumers about its data collection, use and sharing practices, and to provide affected California residents with ways to opt-out of certain sales or transfers of personal information. While there is currently an exception for protected health information that is subject to HIPAA and clinical study regulations, as currently written, the CCPA may impact our business activities. The uncertainty surrounding the implementation of the CCPA exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information.

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

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

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

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

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

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

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

Our employees, independent contractors, consultants, collaborators and CROs may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, 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 might 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 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

None.

Item 6. Exhibits

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

<u>Exhibit Number</u>	<u>Description of Document</u>	<u>Filed Herewith</u>	<u>Incorporated by Reference from</u>	<u>Date</u>	<u>Number</u>
31.1	Certification of Chief Executive 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			
101.SCH	Inline XBRL Taxonomy Extension Schema Document.	X			
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.	X			
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.	X			
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.	X			
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.	X			
104	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information 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 7, 2024

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

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 7, 2024

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

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, 2024 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 and Principal Financial Officer)

Date: November 7, 2024
