UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2026

OR

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

For the transition period from _____ to _____

Commission File Number: 001-39661

Atea Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**46-0574869**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
225 Franklin Street, Suite 2100 Boston, MA	**02110**
(Address of principal executive offices)	**(Zip Code)**

(857) 284-8891
(Registrant's telephone number, including area code)

(Former name, former address and former fiscal year, if changed since last report)

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, $0.001 par value per share	AVIR	The Nasdaq Global Select Market

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

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

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

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of November 6, 2026, the registrant had 80,304,145 shares of common stock, $0.001 par value per share, outstanding.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

This Quarterly Report on Form 10-Q contains forward-looking statements. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, our clinical development timelines and results and other future conditions. The words “aim,” “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “goal,” “intend,” “may,” "objective," "on track," “plan,” “possible,” “potential,” “predict,” “project,” “seek,” “should,” “target,” “will,” “would” or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

These forward-looking statements include, among other things, statements about:

- our expectations relating to the projected costs, timing of completion and reporting of results from C-FORWARD, our Phase 3 clinical trial evaluating the fixed-dose combination of bemnifosbuvir and ruzasvir (“BEM/RZR”), our product candidate for the treatment of hepatitis C virus (“HCV”);
- our expectations relating to clinical trials evaluating AT-587, our product candidate for the treatment of hepatitis E virus ("HEV"), including projected costs, study designs and the timing for initiation, recruitment, completion, and reporting interim, top-line and final results;
- the potential therapeutic benefit of our HCV and HEV product candidates and market opportunities therefor;
- the safety profile and related adverse events of our HCV and HEV product candidates;
- our plans to research, develop and commercialize our current and future product candidates;
- the potential benefits of any future collaboration we may enter into;
- the timing of and our ability to apply for, and if successful, obtain and maintain regulatory approvals for our product candidates, including the anticipated submission to the U.S. Food and Drug Administration of a new drug application seeking approval to market BEM/RZR for the treatment of HCV in the United States;
- the expected size of the commercial market for our HCV and HEV product candidates and any other product candidate for which we may receive marketing approval;
- the rate and degree of market acceptance and clinical utility of any products for which we may receive marketing approval;
- our manufacturing and commercialization capabilities and strategy;
- the progress of, timing of and amount of expenses associated with our research, development and commercialization activities;
- our ability to comply with restrictive covenants under our Loan and Security Agreement, dated November 6, 2026 with Hercules Capital, Inc. (the “Loan and Security Agreement”);
- future available funding and our ability to satisfy interest and principal payments under the Loan and Security Agreement;
- our future financial position, capital requirements, cash runway, needs for additional financing and the availability of such financing;
- our business strategy and review of strategic alternatives;
- developments relating to our industry and our competitors, including competing HCV treatments;
- our expectations regarding federal, state and foreign laws and regulations; and
- our ability to attract, motivate, and retain key personnel.

These forward-looking statements are based on management’s current expectations, estimates, forecasts and projections about our business and the industry in which we operate. These statements are neither promises nor

guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Factors that may cause actual results to differ materially from current expectations include the initiation, execution and completion of clinical trials, uncertainties surrounding the timing of availability of results from our clinical trials, ongoing discussions with and actions by regulatory authorities, our development activities and those other factors we discuss in *Part II, Item 1A. "Risk Factors"* in this Quarterly Report on Form 10-Q. You should read these risk factors and the other cautionary statements made in this report as being applicable to all related forward-looking statements wherever they appear in this report. The risk factors are not exhaustive and other sections of this report may include additional factors which could adversely impact our business and financial performance.

Drug development and commercialization involve a high degree of risk, and only a small number of research and development programs result in commercialization of a product. Preliminary and interim results from any trial and results in early-stage clinical trials may not be indicative of full results or results from later stage or larger scale clinical trials and do not ensure regulatory approval. Moreover, we operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time, and it is not possible for our management to predict all risk factors nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in, or implied by, any forward-looking statements.

Given these uncertainties, you should not rely on these forward-looking statements as predictions of future events. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

As used in this Quarterly Report on Form 10-Q, unless otherwise specified or the context otherwise requires, the terms "we," "our," "us," and the "Company" refer to Atea Pharmaceuticals, Inc. and its subsidiary. All brand names or trademarks appearing in this Quarterly Report on Form 10-Q are the property of their respective owners.

This Quarterly Report on Form 10-Q includes statistical and other industry and market data that we obtained from industry publications and research, surveys, and studies conducted by third parties as well as our own estimates of potential market opportunities. All of the market data used in this Quarterly Report on Form 10-Q involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such data. Industry publications and third-party research, surveys, and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. Our estimates of the potential market opportunities for our product candidates include several key assumptions based on our industry knowledge, industry publications, third-party research, and other surveys, which may be based on a small sample size and may fail to accurately reflect market opportunities. While we believe that our internal assumptions are reasonable, no independent source has verified such assumptions.

TRADEMARKS, TRADENAMES AND SERVICE MARKS

This Quarterly Report on Form 10-Q may include trademarks, tradenames and service marks that are the property of other organizations. Solely for convenience, trademarks and tradenames referred to in this Quarterly Report on Form 10-Q may appear without the ® and ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or that the applicable owner will not assert its rights, to these trademarks and tradenames.

SUMMARY RISK FACTORS

Our business is subject to numerous risks and uncertainties, including those described in Part II, Item 1A. “Risk Factors” in this Quarterly Report on Form 10-Q. The principal risks and uncertainties affecting our business include the following:

- We have a limited operating history and no history of successfully developing or commercializing any approved antiviral products, which may make it difficult to evaluate the success of our business to date and to assess the prospects for our future viability.
- We have incurred significant operating expenses since inception and we expect to continue to incur significant additional operating expenses for the foreseeable future. We have no products that have generated any commercial revenue and we may not again achieve or maintain profitability.
- We may require substantial additional financing, which may not be available on acceptable terms, or at all. A failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts.
- We may engage in strategic collaborations or other transactions that could disrupt our business, cause dilution to our stockholders, reduce our financial resources, and subject us to other risks.
- Our ability to use our net operating loss carryforwards and other tax attributes to offset taxable income may be subject to certain limitations.
- Our business is highly dependent on the success of our lead product candidate, BEM/RZR for the treatment of HCV infection. If we fail to successfully develop this product candidate or we are unable to obtain regulatory approval or successfully commercialize this or any other product candidates, or are significantly delayed in doing so, our business will be harmed.
- The regulatory approval processes of the U.S. Food and Drug Administration (“FDA”) and comparable foreign regulatory authorities are lengthy, expensive, time-consuming and inherently unpredictable.
- Clinical development, including enrollment and retention of patients in clinical trials, is an expensive, lengthy and uncertain process. We may encounter substantial delays and costs in our clinical trials, or may not be able to conduct or complete our clinical trials on the timelines we expect, if at all.
- We are developing certain of our product candidates in combination with other product candidates that we discover or acquire, which exposes us to additional risks.
- Our product candidates may be associated with serious adverse events, undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, limit their commercial potential or result in significant negative consequences.
- We currently conduct, and may in the future, conduct clinical trials of our product candidates in sites outside the United States (“US”). The FDA may not accept data from trials conducted in foreign locations.
- Interim, topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more data become available and are subject to audit and verification procedures that could result in material changes in the final data.
- The Loan and Security Agreement contains operating and financial covenants that may restrict our business and financing activities, is secured by substantially all of our assets, including our intellectual property, and we may be required to repay our outstanding indebtedness earlier than we expect, any of which could have a material adverse effect on our business.
- We may not be successful in our efforts to identify and successfully develop additional product candidates.
- Risks related to healthcare laws and other legal compliance matters may materially and adversely affect our business and financial results.
- Risks related to commercialization may materially and adversely affect our business and financial results.

- Risks related to manufacturing and our dependence on third parties may materially and adversely affect our business and financial results.
- Risks related to intellectual property may materially and adversely affect our business and financial results.
- Our future success depends on our ability to retain officers, directors and key employee and to attract, retain and motivate qualified personnel.
- Our business and operations may suffer in the event of system failures, security breaches, deficiencies or intrusions which could materially affect our results.
- We or the third parties whom we depend upon may be adversely affected by natural disasters or other unforeseen events resulting in business interruptions and our business continuity and disaster recovery plans may not adequately protect us from such business interruptions.
- Increased scrutiny of, and evolving expectations for, environmental, social, and governance initiatives could increase our costs, harm our reputation, or otherwise adversely impact our business and financial results.
- Litigation against us could be costly and time-consuming to defend and could result in additional liabilities.
- Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.
- Risks related to our common stock may materially and adversely affect our stock price.
- If we fail to maintain effective internal control over financial reporting and effective disclosure controls and procedures, we may not be able to accurately report our financial results in a timely manner or prevent fraud, which may adversely affect investor confidence in our Company.

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Item 1. Financial Statements.

Atea Pharmaceuticals, Inc.
Condensed Consolidated Balance Sheets

(in thousands, except share and per share amounts)
(Unaudited)

	September 30, 2026	December 31, 2025
Assets		
Current assets		
Cash and cash equivalents	$ 97,922	$ 95,713
Marketable securities	93,277	206,117
Prepaid expenses and other current assets	9,069	9,161
Total current assets	200,268	310,991
Property and equipment, net	145	457
Other assets	132	3,136
Operating lease right-of-use assets, net	161	634
Total assets	$ 200,706	$ 315,218
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 4,843	$ 12,945
Accrued expenses and other current liabilities	19,969	25,996
Current portion of operating lease liabilities	213	843
Total current liabilities	25,025	39,784
Commitments and contingencies (see Note 11)		
Stockholders' equity:		
Preferred stock, $0.001 par value per share; 10,000,000 shares authorized; no shares issued and outstanding as of September 30, 2026 and December 31, 2025, respectively	—	—
Common stock, $0.001 par value; 300,000,000 shares authorized; 80,295,084 and 78,126,796 shares issued and outstanding as of September 30, 2026 and December 31, 2025, respectively	80	78
Additional paid-in capital	808,778	797,751
Accumulated other comprehensive (loss) gain	(73)	174
Accumulated deficit	(633,104)	(522,569)
Total stockholders' equity	175,681	275,434
Total liabilities and stockholders' equity	$ 200,706	$ 315,218

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

Atea Pharmaceuticals, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	**2025**	**2026**	**2025**
Operating expenses				
Research and development	$ 27,091	$ 38,347	$ 96,375	$ 100,206
General and administrative	6,922	7,220	20,745	25,747
Total operating expenses	34,013	45,567	117,120	125,953
Loss from operations	(34,013)	(45,567)	(117,120)	(125,953)
Interest income and other, net	1,889	3,714	6,697	13,077
Loss before income taxes	(32,124)	(41,853)	(110,423)	(112,876)
Income tax expense	(38)	(196)	(112)	(606)
Net loss	$ (32,162)	$ (42,049)	$ (110,535)	$ (113,482)
Other comprehensive loss				
Unrealized gain (loss) on available-for-sale investments	23	201	(247)	5
Comprehensive loss	$ (32,139)	$ (41,848)	$ (110,782)	$ (113,477)
Net loss per share — basic and diluted	$ (0.40)	$ (0.53)	$ (1.38)	$ (1.37)
Weighted-average number of common shares — basic and diluted	80,224,959	79,052,154	79,828,321	82,623,806

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

Atea Pharmaceuticals, Inc.
Condensed Consolidated Statements of Stockholders' Equity
(in thousands, except share amounts)
(Unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance—January 1, 2026	78,126,796	$ 78	$ 797,751	$ 174	$ (522,569)	$ 275,434
Issuance of common stock upon vesting of restricted stock units	1,216,262	1	(747)	—	—	(746)
Issuance of common stock under employee stock purchase plan	53,966	—	132	—	—	132
Issuance of common stock upon exercise of stock options	630,075	1	870	—	—	871
Stock-based compensation expense	—	—	3,729	—	—	3,729
Other comprehensive loss	—	—	—	(271)	—	(271)
Net loss	—	—	—	—	(45,440)	(45,440)
Balance—March 31, 2026	80,027,099	80	801,735	(97)	(568,009)	233,709
Issuance of common stock upon vesting of restricted stock units	177,600	—	—	—	—	—
Stock-based compensation expense	—	—	3,381	—	—	3,381
Other comprehensive income	—	—	—	1	—	1
Net loss	—	—	—	—	(32,933)	(32,933)
Balance—June 30, 2026	80,204,699	80	805,116	(96)	(600,942)	204,158
Issuance of common stock under employee stock purchase plan	26,111	—	115	—	—	115
Issuance of common stock upon exercise of stock options	64,274		80			80
Stock-based compensation expense	—	—	3,467	—	—	3,467
Other comprehensive income	—	—	—	23	—	23
Net loss	—	—	—	—	(32,162)	(32,162)
Balance—September 30, 2026	80,295,084	$ 80	$ 808,778	$ (73)	$ (633,104)	$ 175,681

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance—January 1, 2025	84,463,059	$ 84	$ 802,770	$ 233	$ (364,220)	$ 438,867
Issuance of common stock upon vesting of restricted stock units	1,062,120	1	(486)	—	—	(485)
Issuance of common stock under employee stock purchase plan	54,296	—	138	—	—	138
Stock-based compensation expense	—	—	6,951	—	—	6,951
Other comprehensive loss	—	—	—	(115)	—	(115)
Net loss	—	—	—	—	(34,272)	(34,272)
Balance—March 31, 2025	85,579,475	85	809,373	118	(398,492)	411,084
Issuance of common stock upon vesting of restricted stock units	177,600	1	(1)	—	—	—
Repurchase of common stock	(4,619,597)	(5)	(14,088)	—	—	(14,093)
Stock-based compensation expense	—	—	4,667	—	—	4,667
Other comprehensive loss	—	—	—	(81)	—	(81)
Net loss	—	—	—	—	(37,161)	(37,161)
Balance—June 30, 2025	81,137,478	81	799,951	37	(435,653)	364,416
Issuance of common stock under employee stock purchase plan	26,138	—	63	—	—	63
Issuance of common stock for exercise of stock options	17,375	—	58	—	—	58
Repurchase of common stock	(3,054,195)	(3)	(11,423)	—	—	(11,426)
Stock-based compensation expense	—	—	4,517	—	—	4,517
Other comprehensive loss	—	—	—	201	—	201
Net loss	—	—	—	—	(42,049)	(42,049)
Balance—September 30, 2025	78,126,796	$ 78	$ 793,166	$ 238	$ (477,702)	$ 315,780

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

Atea Pharmaceuticals, Inc.
Condensed Consolidated Statements of Cash Flows
(in thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2026	**2025**
Cash flows from operating activities		
Net loss	$ (110,535)	$ (113,482)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	10,577	16,135
Depreciation and amortization expense	312	312
Accretion of premium and discounts on marketable securities	(1,513)	(4,136)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	92	805
Other assets	3,004	(5,278)
Accounts payable	(8,102)	(943)
Accrued expenses and other liabilities	(6,027)	2,922
Operating lease liabilities	(157)	(143)
Net cash used in operating activities	(112,349)	(103,808)
Cash flows from investing activities		
Purchases of marketable securities	(120,324)	(238,148)
Sales and maturities of marketable securities	234,430	380,349
Net cash provided by investing activities	114,106	142,201
Cash flows from financing activities		
Proceeds from issuance of common stock upon exercise of stock options	951	58
Proceeds from issuance of common stock under employee stock purchase plan	247	201
Repurchase of common stock	—	(25,519)
Issuance of restricted stock units	(746)	(485)
Net cash provided by (used in) financing activities	452	(25,745)
Net (decrease) increase in cash and cash equivalents	2,209	12,648
Cash and cash equivalents at the beginning of period	95,713	64,696
Cash and cash equivalents at the end of period	$ 97,922	$ 77,344

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

Atea Pharmaceuticals, Inc.
Notes to Condensed Consolidated Financial Statements

(in thousands, except share and per share amounts)
(Unaudited)

1. Nature of Business

Business Overview

Atea Pharmaceuticals, Inc., together with its wholly owned subsidiary, Atea Pharmaceuticals Securities Corporation, is referred to herein on a consolidated basis as “Atea” or the “Company”.

The Company is a late-stage clinical biopharmaceutical company focused on discovering, developing and commercializing oral antiviral therapeutics to improve the lives of patients suffering from serious viral infections. The Company’s lead product candidate, the fixed-dose combination of bemnifosbuvir and ruzasvir (“BEM/RZR”) is currently in Phase 3 clinical development for the treatment of hepatitis C virus (“HCV”). The Company is also developing AT-587 for the treatment of hepatitis E virus ("HEV").

Atea’s global HCV Phase 3 program consists of two randomized, open label studies: C-BEYOND which has clinical trial sites in the United States (“US”) and Canada and C-FORWARD which has clinical trial sites in countries outside of North America. The Phase 3 program is being conducted in geographically diverse regions in an effort to enroll patients with a broad array of the HCV genotypes.

In the Phase 3 trials, BEM/RZR is compared to the fixed-dose combination of sofosbuvir and velpatasvir (marketed in the US under the brand Epclusa®) in patients with chronic HCV with and without cirrhosis. In patients without cirrhosis, eight weeks of treatment with BEM/RZR administered once daily is being compared to 12 weeks of treatment with the sofosbuvir and velpatasvir regimen administered once daily. In patients with cirrhosis, treatment is 12 weeks with each regimen.

In July 2026, the Company announced positive topline results from C-BEYOND with BEM/RZR demonstrating statistical non-inferiority to the regimen of sofosbuvir and velpatasvir in the modified intent to treat population and achieving the trial’s primary endpoint. Statistical non-inferiority was also met in secondary endpoints, including the per-protocol analysis. These C-BEYOND results highlight the potential of BEM/RZR to deliver robust antiviral efficacy with a shorter treatment duration (eight rather than 12 weeks) for patients without cirrhosis. In the US, approximately 80-90% of people living with HCV do not have cirrhosis. Together with its potential advantages of a shorter treatment duration for most patients, low risk of drug-drug interactions and no food effect, the results from C-BEYOND further reinforce the potential of BEM/RZR as a differentiated, best-in-class treatment option for people with HCV.

In June 2026, the Company completed enrollment of patients in C-FORWARD. Currently, the Company expects to report topline results from C-FORWARD in the first quarter of 2027 and, if the C-FORWARD results are positive, the Company is targeting the second quarter of 2027 for submission to the U.S. Food and Drug Administration (“FDA”) of a New Drug Application (“NDA”) for marketing approval.

Clinical development of AT-587, the Company’s product candidate for the treatment of HEV, was initiated in a first-in-human clinical trial in July 2026. This Phase 1 clinical trial is designed to evaluate the safety, tolerability and pharmacokinetics of AT-587 in healthy volunteers.

Liquidity and Capital Resources

As of September 30, 2026, the Company had $191,199 in cash, cash equivalents and marketable securities, which the Company believes will be sufficient to fund its operations for a period through at least twelve months from the issuance date of these interim condensed consolidated financial statements.

The Company is a party to an amended and restated open market sales agreement (“Sales Agreement”) with Jefferies LLC (“Jefferies”), under which the Company may from time to time offer and sell shares of its common stock (“Common Stock”) for an aggregate offering price of up to $200,000, through or to Jefferies, acting as sales agent or principal. The shares will be offered and sold under the Company’s shelf registration statement on Form S-3 and a related prospectus declared effective by the Securities and Exchange Commission (the “SEC”) on November 19, 2024. The Company has agreed to pay Jefferies a commission of 3.0% of the aggregate gross

proceeds from each sale of shares, reimburse legal fees and disbursements and provide Jefferies with customary indemnification and contribution rights. As of September 30, 2026, no shares have been issued under the Sales Agreement.

Risks and Uncertainties

The Company is subject to risks and uncertainties common to late-stage clinical biopharmaceutical companies. These risks include, but are not limited to, potential failure of preclinical studies and clinical trials, uncertainties associated with research and development activities generally, competition from technical innovations of others, dependence upon key personnel, compliance with governmental regulations, the need to obtain marketing approval for any product candidate that the Company may develop, the need to gain broad acceptance among patients, payers and healthcare providers to successfully commercialize any product for which marketing approval is obtained and the need to secure and maintain adequate intellectual property protection for the Company's proprietary technology and products. Further, the Company is dependent on third-party service providers for the conduct of its preclinical research, clinical development and manufacturing activities. Product candidates currently under development, including BEM/RZR for the treatment of HCV, will require significant amounts of additional capital and additional research and development efforts, and all will require regulatory approval, prior to commercialization. Even if the Company is able to generate revenues from the sale of its product candidates, if any are approved and commercialized, it may not become profitable. If the Company fails to become profitable or is unable to sustain profitability on a continuing basis, then it may be unable to continue its operations at planned levels and be forced to reduce its operations.

The Company may seek additional capital through one or more of a combination of financing through the sale of additional equity securities, debt financing, or funding in connection with any new collaborative relationships it may enter into or other arrangements. There can be no assurance that the Company will be able to obtain such additional funding, on terms acceptable to the Company, on a timely basis or at all. The terms of any financing may adversely affect the holdings or the rights of the Company's existing stockholders. The Company's cost of financing and its access to potential sources of future liquidity may be adversely impacted by a number of factors, including, without limitation, then current geopolitical events and the conditions in the financial markets including market volatility and rates of interest and inflation.

2. Summary of Significant Accounting Policies

Basis of Presentation and Use of Estimates

The unaudited interim condensed consolidated financial statements of the Company included herein have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP") as found in the Accounting Standards Codification ("ASC"), Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB") and the rules and regulations of the SEC. Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted from this report, as is permitted by such SEC rules and regulations. Accordingly, these unaudited interim condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and the notes thereto for the year ended December 31, 2025 included in the Company's Annual Report on Form 10-K filed with the SEC on March 5, 2026.

Unaudited Interim Financial Information

The accompanying condensed consolidated balance sheet as of September 30, 2026, the condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2026 and 2025, the condensed consolidated statements of stockholders' equity for the three and nine months ended September 30, 2026 and 2025, and the condensed consolidated statements of cash flows for the nine months ended September 30, 2026 and 2025 are unaudited. The unaudited interim financial statements have been prepared on the same basis as the audited annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair statement of the Company's financial position as of September 30, 2026, the results of its operations for the three and nine months ended September 30, 2026 and 2025 and its cash flows for the nine months ended September

30, 2026 and 2025. The results for the nine months ended September 30, 2026 are not necessarily indicative of results to be expected for the year ending December 31, 2026, or any other interim period.

Principles of Consolidation

The condensed consolidated financial statements include the accounts of Atea Pharmaceuticals, Inc. and its wholly-owned subsidiary, Atea Pharmaceuticals Securities Corporation. All intercompany amounts have been eliminated in consolidation.

Significant Accounting Policies

The significant accounting policies used in the preparation of these condensed consolidated financial statements are consistent with those as described in the Annual Report on Form 10-K for the year ended December 31, 2025 filed with the SEC on March 5, 2026.

Recently Issued Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies that the Company adopts as of the specified effective date. The Company does not believe that the adoption of recently issued standards have or may have a material impact on its condensed consolidated financial statements and disclosures.

3. Marketable Securities

	As of September 30, 2026			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Marketable Securities				
US Treasury obligations	$ 29,800	$ —	$ (24)	$ 29,776
Asset-backed securities	2,001	—	—	2,001
Commercial paper	6,989	—	(2)	6,987
Corporate bonds	54,560	1	(48)	54,513
Total	$ 93,350	$ 1	$ (74)	$ 93,277

	As of December 31, 2025			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Marketable Securities				
US Treasury obligations	$ 59,786	$ 59	$ —	$ 59,845
Asset-backed securities	43,183	54	—	43,237
Commercial paper	9,418	4	—	9,422
Corporate bonds	93,556	59	(2)	93,613
Total	$ 205,943	$ 176	$ (2)	$ 206,117

As of September 30, 2026 and December 31, 2025, the Company held 21 and one securities, respectively, that were in an unrealized loss position of $74 and $2, respectively. The Company has the intent and ability to hold such securities until recovery. As a result, the Company did not record any charges for credit-related impairments for its marketable debt securities for the nine months ended September 30, 2026.

The fair value of available-for-sale marketable securities by contractual maturity was as follows as of September 30, 2026:

	As of September 30, 2026
Maturing in one year or less	$ 91,276
Maturing after one year through five years	2,001
Total	$ 93,277

The Company received proceeds of $234,430 and $380,349 from sales and maturities of marketable securities during the nine months ended September 30, 2026 and 2025.

4. Fair Value Measurements

The following tables present information about the Company's financial assets measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values:

	Fair Value Measurements as of September 30, 2026			
	Level 1	Level 2	Level 3	Total
Cash equivalents				
Money market funds	$ 92,709	$ —	$ —	$ 92,709
Marketable Securities				
US Treasury obligations	—	29,776	—	29,776
Asset-backed securities	—	2,001	—	2,001
Commercial paper	—	6,987	—	6,987
Corporate bonds	—	54,513	—	54,513
Total	$ 92,709	$ 93,277	$ —	$ 185,986

	Fair Value Measurements as of December 31, 2025			
	Level 1	Level 2	Level 3	Total
Cash equivalents				
Money market funds	$ 87,584	$ —	$ —	$ 87,584
Marketable Securities				
US Treasury obligations	—	59,845	—	59,845
Asset-backed securities	—	43,237	—	43,237
Commercial paper	—	9,422	—	9,422
Corporate bonds	—	93,613	—	93,613
Total	$ 87,584	$ 206,117	$ —	$ 293,701

The Company's assets with fair value categorized as Level 1 within the fair value hierarchy include money market funds. Money market funds are publicly traded mutual funds and are presented as cash equivalents on the unaudited condensed consolidated balance sheets as of September 30, 2026 and December 31, 2025.

The Company's assets with fair value categorized as Level 2 within the fair value hierarchy include US Treasury obligations, asset-backed securities, commercial paper and corporate bonds with fair values determined by utilizing information from third party pricing sources for identical or similar assets and liabilities in an active market.

There were no transfers between Level 1, Level 2 or Level 3 categories during the nine months ended September 30, 2026.

5. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following:

	September 30, 2026	December 31, 2025
Research and development, including manufacturing and clinical expenditures	$ 10,901	$ 18,886
Payroll and payroll related	5,220	6,438
Professional fees and other	3,848	672
Total accrued expenses and other current liabilities	$ 19,969	$ 25,996

6. Common Stock

As of September 30, 2026, the authorized capital of the Company included 300,000,000 shares of Common Stock, of which 80,295,084 shares of the Common Stock were issued and outstanding. On all matters to be voted upon by the holders of the Common Stock, holders of the Common Stock are entitled to one vote per share. The holders of the Common Stock have no preemptive, redemption or conversion rights.

7. Stock-based Compensation

In October 2020, the Company's stockholders approved the Company's 2020 Incentive Award Plan ("2020 Plan"). The 2020 Plan initially provided for the issuance of up to 7,924,000 shares of Common Stock and for the grant of incentive stock options and other incentive awards to employees, officers, directors and consultants of the Company. The number of shares of Common Stock that may be issued under the 2020 Plan is subject to increase on the first day of each calendar year equal to the lesser of i) 5% of the aggregate number of shares of Common Stock outstanding on the final day of the immediately preceding calendar year or ii) such smaller number of shares as is determined by the board of directors. Through December 31, 2025, the shares available under the 2020 Plan had been increased by an aggregate of 20,845,291 shares. In January 2026, the number of shares of Common Stock available for future issuance under the 2020 Plan was further increased by 3,906,339 shares. To the extent outstanding restricted stock unit or stock option awards granted under the 2020 Plan are cancelled, the shares of Common Stock underlying such cancelled awards are available for future grant under the 2020 Plan. As of September 30, 2026, 6,953,894 shares of Common Stock were available for future issuance under the 2020 Plan.

The 2020 Plan replaced and is the successor of the Company's 2013 Equity Incentive Plan, as amended ("2013 Plan"). In the event of any cancellation of an outstanding option award under the 2013 Plan, the shares of Common Stock underlying the cancelled option award will be made available for grant under the 2020 Plan.

Stock Options

The following table summarizes stock option activity:

	Number of Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value ($000s)
Outstanding at January 1, 2026	22,842,960	$ 12.17	6.0	$ 8,436
Granted	2,185,540	$ 4.29		
Exercised	(694,349)	$ 1.36		
Cancelled	(2,546,459)	$ 57.97		
Outstanding at September 30, 2026	21,787,692	$ 6.37	6.0	$ 24,186
Vested and expected to vest at September 30, 2026	21,787,692	$ 6.37	6.0	$ 24,186
Vested and exercisable at September 30, 2026	17,036,921	$ 7.08	5.3	$ 17,580

During the nine months ended September 30, 2026, the Company granted 2,185,540 stock options with an aggregate grant date fair value of $6,667 under the 2020 Plan.

The aggregate intrinsic value of options granted is calculated as the difference between the exercise price of the options and the estimated fair value of the Common Stock for those options that had exercise prices lower than the fair value of the Common Stock.

Option awards granted to employees generally vest over a service period of four years and option awards granted to members of the board of directors generally vest over a service period of one or three years. All options have a contractual term of ten years. As of September 30, 2026, total unrecognized compensation expense related to stock option awards was $12,978, which is being recognized over a remaining weighted average period of 2.1 years.

Restricted Stock Units

During the nine months ended September 30, 2026, the Company granted 708,200 restricted stock units to employees and directors under the 2020 Plan with an aggregate grant date fair market value of $3,028. These restricted stock unit awards vest in three annual installments.

Below is the activity related to restricted stock units for the nine months ended September 30, 2026.

	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding at January 1, 2026	2,247,064	$ 3.79
Granted	708,200	$ 4.28
Released	(1,388,728)	$ 4.03
Cancelled	(13,999)	$ 4.08
Unvested at September 30, 2026	1,552,537	$ 3.80

As of September 30, 2026, total unrecognized compensation expense related to restricted stock units was $3,840, which is being recognized over a remaining weighted average period of 1.4 years.

Performance-based Restricted Stock Units

During the year ended December 31, 2022 the Company granted 724,970 performance-based restricted stock units (“2022 PSUs”) under the 2020 Plan to employees with an aggregate grant fair value of $5,298. The performance period for the 2022 PSUs ran from February 1, 2022 through January 31, 2025 to achieve up to six defined performance metrics. The Company achieved two metrics which resulted in 50% of the grant date fair value being recognized as expense. Of the total 2022 PSUs granted, 25% vested on January 31, 2025, and 25% vested on January 31, 2026. The Company recorded compensation expense of $0 and $81 for the three months ended September 30, 2026 and 2025, respectively related to the 2022 PSUs. The Company recorded compensation expense of $27 and $278 for the nine months ended September 30, 2026 and 2025, respectively related to the 2022 PSUs.

During the year ended December 31, 2024, the Company granted 1,057,900 performance-based restricted stock units (“2024 PSUs”) under the 2020 Plan to employees with an aggregate grant date fair value of $4,401. The 2024 PSUs provide for a performance period from February 1, 2024 through January 31, 2027 to achieve up to four defined performance metrics. The percentage of 2024 PSUs eligible to vest will be determined based on the number of metrics achieved during the performance period and may range from 0% to 200%. As of September 30, 2026, two of the 2024 PSU metrics were deemed probable of achievement resulting in expense recognition of 75% of the 2024 PSU grant date value. Compensation expense is being recognized from the grant date through the final vest date of January 31, 2027. The Company recorded compensation expense of $278 for each of the three months ended September 30, 2026 and 2025 related to the 2024 PSUs. The Company recorded compensation expense of $823 for each of the nine months ended September 30, 2026 and 2025 related to the 2024 PSUs.

During the year ended December 31, 2025, the Company granted 1,045,600 performance-based restricted stock units (“2025 PSUs”) under the 2020 Plan to employees with an aggregate grant date fair value of $3,200. The 2025 PSUs provide for a performance period from February 1, 2025 through January 31, 2028 to achieve up to four defined performance metrics. The percentage of 2025 PSUs eligible to vest will be determined based on the number of metrics achieved during the performance period and may range from 0% to 200%. As of September 30, 2026, none of the 2025 PSU metrics were deemed probable of achievement. The Company recorded no compensation expense for the three and nine months ended September 30, 2026 and 2025 related to the 2025 PSUs.

During the nine months ended September 30, 2026, the Company granted 1,886,320 performance-based restricted stock units ("2026 PSUs") under the 2020 Plan to employees with an aggregate grant date fair value of $7,998. The 2026 PSUs provide for a performance period from February 1, 2026 through January 31, 2029 to achieve up to four defined performance metrics. The percentage of 2026 PSUs eligible to vest will be determined based on the number of metrics achieved during the performance period and may range from 0% to 200%. As of September 30, 2026, none of the 2026 PSU metrics were deemed probable of achievement. The Company recorded no compensation expense for the three and nine months ended September 30, 2026 related to the 2026 PSUs.

The following table summarizes the activity related to performance-based restricted stock units:

	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding at January 1, 2026	2,465,985	$ 4.13
Granted	1,886,320	$ 4.24
Released	(181,242)	$ 7.14
Cancelled	(181,243)	$ 7.14
Unvested at September 30, 2026	3,989,820	$ 3.91

As of September 30, 2026, total unrecognized compensation expense related to performance-based restricted stock units was $370, which is being recognized over a weighted average period of 1.6 years.

Employee Stock Purchase Plan

In October 2020, the Company's shareholders approved the Employee Stock Purchase Plan ("ESPP"), which became effective upon the closing of the Company's initial public offering in November 2020. The Company initially reserved a total of 1,187,000 shares of its Common Stock for issuance under the ESPP. The ESPP provides that the number of shares reserved and available for issuance under the ESPP will be increased on January 1 of each calendar year by 1% of the number of shares of Common Stock issued and outstanding on the immediately preceding December 31 or such lesser amount as specified by the board of directors. Through December 31, 2025, the number of shares of Common Stock available for future issuance under the ESPP had been increased by 2,511,861 shares. In January 2026, the number of shares of Common Stock available for future issuance under the ESPP was further increased by 781,267 shares.

The Company issued 26,111 and 26,138 shares for proceeds of $115 and $63 during the three months ended September 30, 2026 and 2025, respectively. The Company issued 80,077 and 80,434 shares for proceeds of $247 and $201 during the nine months ended September 30, 2026 and 2025, respectively.

Stock-based Compensation Expense

Stock-based compensation expense by award type included within the unaudited condensed consolidated statements of operations and comprehensive loss was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Stock options	$ 2,248	$ 2,752	$ 6,897	$ 10,825
Restricted stock units	914	1,394	2,752	4,165
Performance-based restricted stock units	278	359	850	1,101
Employee stock purchase plan	27	12	78	44
Total stock-based compensation expense	$ 3,467	$ 4,517	$ 10,577	$ 16,135

Stock-based compensation expense is classified as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Research and development expense	$ 1,685	$ 2,259	$ 5,370	$ 8,118
General and administrative expense	1,782	2,258	5,207	8,017
Total stock-based compensation expense	$ 3,467	$ 4,517	$ 10,577	$ 16,135

8. Net Loss Per Share

Basic and diluted earnings per share are calculated as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Net loss	$ (32,162)	$ (42,049)	$ (110,535)	$ (113,482)
Weighted-average common shares outstanding — basic and diluted	80,224,959	79,052,154	79,828,321	82,623,806
Net loss per share — basic and diluted	$ (0.40)	$ (0.53)	$ (1.38)	$ (1.37)

The following shares were excluded from the computation of the net loss per share for the three and nine months ended September 30, 2026 and 2025, respectively, due to the net loss during the respective period as their effect is antidilutive.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Stock options	21,787,692	22,842,960	21,787,692	22,842,960
Restricted stock units	1,552,537	2,247,064	1,552,537	2,247,064
Performance-based restricted stock units	3,989,820	2,465,985	3,989,820	2,465,985
Employee stock purchase plan	—	—	—	—

9. Leases

The Company has a non-cancelable operating lease agreement for its office space in Boston, Massachusetts at 225 Franklin Street ("225 Lease"). The 225 Lease commencement date was January 1, 2022 and the 225 Lease runs through December 31, 2026. The 225 Lease does not contain any options for renewal or extension.

Future minimum payments under the 225 Lease, the Company's only operating lease as of September 30, 2026 were $213.

For each of the three months ended September 30, 2026 and 2025, the Company recorded operating lease costs of $162 relating to its operating lease agreements. For each of the nine months ended September 30, 2026 and 2025, the Company recorded operating lease costs of $485 relating to its operating lease agreements.

10. Income Taxes

The Company recorded income tax expense of $38 and $196 for the three months ended September 30, 2026 and 2025, respectively. The Company recorded income tax expense of $112 and $606 for the nine months ended September 30, 2026 and 2025, respectively.

The Company maintained a full valuation allowance through September 30, 2026 due to uncertainty regarding its ability to utilize deferred tax assets.

11. Commitments and Contingencies

License Agreement

In December 2021, the Company entered into a license agreement ("Merck License Agreement") with MSD International GmbH, an affiliate of Merck & Co., Inc. ("Merck") for the development, manufacture and commercialization of ruzasvir. Ruzasvir is the NS5A inhibitor the Company is developing in combination with bemnifosbuvir for the treatment of HCV.

Pursuant to the terms of the Merck License Agreement, the Company obtained from Merck a worldwide exclusive (subject to certain reserved rights to conduct internal research) and sublicensable license under certain Merck patents and know-how to research, develop, manufacture, have manufactured, use, import, export, sell, offer for sale, and otherwise commercialize ruzasvir or products containing ruzasvir (each a "Product") for all therapeutic or prophylactic uses in humans.

In addition to a non-refundable upfront payment that the Company made in February 2022, the Company agreed to pay Merck milestone payments upon its achievement of certain development, regulatory and sales-based milestones. Additionally, the Company will pay Merck tiered royalties based on annual net sales of Products ranging from high single digits to mid-teens percentages. The Company's royalty payment obligations will continue until the later of (i) the expiration of the last to expire valid claim of a licensed Merck patent claiming such Product and (ii) a period of years after the first commercial sale of such Product in such country. The Company may terminate the Merck License Agreement for convenience upon prior written notice. The first milestone in the amount of $5,000 became due and payable and the related expense was recognized in April 2025 upon the initiation of the HCV Phase 3 clinical trial referred to as C-BEYOND. The next potential milestone under the Merck License Agreement, in the amount of $10,000, is payable upon the acceptance by the FDA of a NDA covering a product candidate including ruzasvir which the Company expects will be BEM/RZR for the treatment of HCV.

Contingent Consulting Fee

The Company has an agreement with a consultant that requires payment of a success fee calculated as a percentage of certain product sales, subject to a cumulative maximum payout of $5,000. This success payment is contingent upon the occurrence of future events and the timing and likelihood of such payment is neither probable nor estimable.

Indemnification

The Company enters into certain types of contracts that contingently require the Company to indemnify various parties against claims from third parties. These contracts primarily relate to (i) the Company's bylaws, under which the Company must indemnify directors and executive officers, and may indemnify other officers and employees, for liabilities arising out of their relationship with the Company, (ii) contracts under which the Company must indemnify directors and certain officers and consultants for liabilities arising out of their relationship with the Company, and (iii) procurement, service or license agreements under which the Company may be required to indemnify vendors, service providers or licensees for certain claims, including claims that may be brought against them arising from the Company's acts or omissions with respect to the Company's products, technology, intellectual property or services.

From time to time, the Company may receive indemnification claims under these contracts in the normal course of business. In the event that one or more of these matters were to result in a claim against the Company, an adverse outcome, including a judgment or settlement, may cause a material adverse effect on the Company's future business, operating results or financial condition. It is not possible to determine the maximum potential amount payable under these contracts since the Company has no history of prior indemnification claims and the unique facts and circumstances involved in each particular claim will be determinative.

12. Benefit Plan

The Company's defined contribution plan under Section 401(k) of the Internal Revenue Code ("401(k) Plan") covers substantially all employees who meet minimum age and service requirements. Under the terms of the 401(k) Plan, the Company records matching contributions up to 4% of the participant's eligible compensation. During the three months ended September 30, 2026 and 2025, the Company recognized expense of $133 and $75, respectively, relating to matching contributions to the 401(k) Plan. During the nine months ended September 30, 2026 and 2025, the Company recognized expense of $689 and $530, respectively, relating to matching contributions to the 401(k) Plan.

13. Related Party Transactions

During the year ended December 31, 2021, the Company entered into a consulting agreement with an entity controlled by one of its directors. The agreement provides for an annual retainer of $110. The Company recognized expense in the amount of $27 for each of the three months ended September 30, 2026 and 2025. The Company recognized expense in the amount of $81 for each of the nine months ended September 30, 2026 and 2025.

In May 2022, the Company entered into a consulting agreement with one of its directors. No expense related to this agreement was recognized during the three or nine months ended September 30, 2026 and 2025.

In June 2026, the Company entered into a consulting agreement with another one of its directors. The Company recognized expense of $25 and $33 during the three and nine months ended September 30, 2026.

14. Segment Information

The Company operates as one operating segment, focused on discovering, developing and commercializing antiviral therapeutics. The determination of a single business segment is consistent with the consolidated financial information regularly provided to the Company's Chief Executive Officer ("CEO") who is also the Chief Operating Decision Maker ("CODM"). As CODM, the CEO, uses consolidated, single-segment financial information for purposes of evaluating performance, making operating decisions, allocating resources, and planning and forecasting for future periods.

The CODM assesses performance and decides how to allocate resources based on consolidated net loss. This measure is used to monitor budget versus actual results to evaluate the performance of the segment.

The CODM reviews cash, cash equivalents and marketable securities as a measure of segment assets. As of September 30, 2026 and December 31, 2025, the Company's cash, cash equivalents and marketable securities were $191,199 and $301,830, respectively.

The following table illustrates information about significant segment expenses and segment operating loss for the three and nine months ended September 30, 2026 and 2025:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	**2025**	**2026**	**2025**
Research and development expense [1]				
HCV external costs [2]	$ 17,396	30,225	$ 64,659	$ 72,094
HEV external costs [2]	2,719	—	9,636	—
COVID-19 external costs [2]	—	113	—	1,269
Early stage discovery external costs [2]	—	776	—	1,372
Compensation and related expenses	4,480	4,094	14,051	14,550
Consulting and professional fees	440	435	1,509	1,522
Other research and development expenses	371	445	1,150	1,281
Total research and development expense	25,406	36,088	91,005	92,088
General and administrative [3]				
Compensation and related expenses	2,154	2,070	6,846	6,960
Consulting and professional fees	2,635	2,573	7,665	9,697
Other general and administrative	352	319	1,028	1,073
Total general and administrative	5,141	4,962	15,539	17,730
Stock-based compensation	3,467	4,517	10,577	16,135
Other segment items [4]	(1,852)	(3,518)	(6,586)	(12,471)
Net loss	$ (32,162)	$ (42,049)	$ (110,535)	$ (113,482)

[1]Research and development expense for the three months ended September 30, 2026 and 2025 excludes stock-based compensation of $1,685 and $2,259, respectively. Research and development expense for the nine months ended September 30, 2026 and 2025 excludes stock-based compensation of $5,370 and $8,118, respectively.

[2]External costs consist primarily of costs associated with preclinical, clinical and manufacturing related activities.

[3]General and administrative expense for the three months ended September 30, 2026 and 2025 excludes stock-based compensation of $1,781 and $2,258, respectively. General and administrative expense for the nine months ended September 30, 2026 and 2025 excludes stock-based compensation of $5,206 and $8,017, respectively.

[4]Other segment items include interest income and other, net and income tax expense.

15. Subsequent Events

On November 6, 2026 (the “Closing Date”), the Company entered into a loan and security agreement with Hercules Capital, Inc., as agent, and lenders party thereto (the “Loan and Security Agreement”), providing for term loans to the Company in the aggregate amount of up to $200,000. On the Closing Date, the Company borrowed $65,000 under the Loan and Security Agreement. Of the amount remaining under the facility, $30,000 is available to the Company at the discretion of the lenders and the remaining $105,000 is available upon the achievement by the Company of certain specified development, financing and commercial milestones within specified time periods.

All loans under the Loan and Security Agreement will mature on November 1, 2031. The loans bear interest at a floating rate equal to the greater of (i) the prime rate as reported in the Wall Street Journal plus 2.35%, and (ii) 9.35%. For the first 48 months, payment of interest only is required. The interest only period may be extended to maturity upon the Company’s achievement of a specified commercial milestone. The loans are secured by substantially all of the Company’s assets. Additionally, there are customary affirmative and restrictive covenants, representations and warranties and events of default included within the Loan and Security Agreement. Upon the occurrence of an event of default, the lenders may, among other things, accelerate the Company’s obligations under the Loan and Security Agreement. Upon an event of default relating to certain insolvency, liquidation, bankruptcy or similar events, all outstanding obligations will be automatically accelerated.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited condensed consolidated financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q, as well as our audited consolidated financial statements and related notes as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2025, filed with the Securities and Exchange Commission ("SEC") on March 5, 2026. This discussion contains forward-looking statements based upon current plans, expectations and beliefs involving risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth in Part II, Item 1A, "Risk Factors" and other factors set forth in other parts of this Quarterly Report on Form 10-Q.

Overview

We are a late-stage clinical biopharmaceutical company leveraging our deep understanding of antiviral drug development, medicinal chemistry, biochemistry and virology to discover, develop and commercialize novel, orally administered antivirals to treat serious viral diseases. Our current product candidate pipeline includes the fixed-dose combination ("FDC") regimen of bemnifosbuvir and ruzasvir ("BEM/RZR") which we believe has the potential to improve the current standard of care ("SOC") for the treatment of patients with hepatitis C virus ("HCV") infection and AT-587 which we believe has the potential to be the first direct-acting antiviral ("DAA") for the treatment of patients, particularly immunocompromised patients, with chronic hepatitis E virus ("HEV") infection.

HCV - Our Goal and our Program

The objective of our HCV development program is to improve upon the current SOC by offering BEM/RZR as a differentiated pan-genotypic protease inhibitor-free, short-duration regimen with a low risk of drug-drug interactions for patients infected with HCV, if successfully developed and approved. We believe that a novel, shorter duration, easily prescribable treatment will benefit today's HCV patient population, which is predominantly young (20-49 years old) and non-cirrhotic (80-90% of the US population), and would be a significant improvement to the current SOC.

Chronic HCV infection remains an ongoing public health crisis. If left untreated, HCV can progress to cirrhosis, end-stage liver disease and liver cancer, and it remains one of the leading causes of liver cancer in the US, Europe and Japan. According to the World Health Organization (cited July 28, 2026), approximately 50 million people worldwide are living with HCV, including up to 4 million people in the US, while new diagnoses continue to outpace annual cures. Additionally, many people living with HCV are also managing other chronic conditions, and roughly 80% take multiple concomitant medications for common comorbidities such as heartburn, heart arrhythmia, high blood pressure and gastroesophageal reflux disease ("GERD"), which may increase the potential for drug-drug interactions with currently approved therapies.

Presently, there are no short-course (i.e., eight week) nucleotide inhibitor-based, pan-genotypic HCV treatment regimens. Clinical and nonclinical results from studies we conducted prior to our Phase 3 program have shown that BEM/RZR has high antiviral potency and has been well tolerated. These studies have also shown that BEM/RZR has a low risk for drug-drug interactions with many commonly prescribed medications including proton pump inhibitors and offers the convenience of being able to be taken with or without food. This is a profile that we believe will offer a significant improvement to the current SOC, if approved.

The global HCV Phase 3 program we are conducting consists of two randomized, open label studies: C-BEYOND which has clinical trial sites in the United States ("US") and Canada, and C-FORWARD which has clinical trial sites in countries outside of North America. In these Phase 3 trials, we are comparing BEM/RZR to an active comparator, the fixed-dose combination regimen of sofosbuvir and velpatasvir ("SOF/VEL" marketed in the US under the brand Epclusa®), in patients with chronic HCV infection. We are conducting the Phase 3 program in geographically diverse regions in order to enroll patients with a broad array of HCV genotypes.

In July 2026, we announced positive topline results from C-BEYOND with BEM/RZR demonstrating statistical non-inferiority compared to SOF/VEL in the modified intent-to-treat ("mITT") population thereby achieving the trial's primary endpoint.

In the mITT analysis (n=905, cirrhotic and non-cirrhotic), BEM/RZR achieved a 93.9% sustained virologic response (SVR) rate vs. 94.8% for SOF/VEL at Week 24 from the start of treatment, encompassing SVR at 12 weeks post-treatment (the generally accepted definition of cure for HCV) in both arms. These results achieved the primary endpoint of statistical non-inferiority, with a 95% confidence interval for difference in SVR rates within the

prespecified 5% margin. The mITT analysis in patients without cirrhosis (n=721) showed BEM/RZR (8 weeks of treatment) achieved a 93.5% SVR rate vs. 94.6% for SOF/VEL (12 weeks of treatment). In patients with cirrhosis (12 weeks treatment in both arms) (n=184), BEM/RZR achieved a 95.4% SVR rate vs. 95.4% for SOF/VEL. In C-BEYOND, rates of virologic failure across all patient populations were low and comparable between treatment arms. Statistical non-inferiority was also met in secondary endpoints, including the per-protocol analysis.

BEM/RZR was administered as an 8-week regimen to patients without cirrhosis compared with the 12-week regimen of SOF/VEL, highlighting the potential of BEM/RZR to deliver robust antiviral efficacy with a shorter treatment duration. In the US, approximately 80-90% of people living with HCV do not have cirrhosis. Together with its potential advantages of a shorter treatment duration for most patients, low risk of drug-drug interactions and no food effect, the results from C-BEYOND further reinforce BEM/RZR's potential as a differentiated, best-in-class treatment option for people with HCV.

In C-BEYOND, BEM/RZR demonstrated robust SVR rates across HCV genotypes that predominate in North America. C-FORWARD, which is being conducted at approximately 120 sites in 17 countries outside North America, includes a broader range of HCV genotypes and is expected to provide additional efficacy data in genotypes more frequently found outside the US and Canada. In C-BEYOND, BEM/RZR was generally safe and well tolerated with no drug-related serious adverse events or drug related early treatment discontinuations. Safety was comparable between treatment arms.

In June 2026, we announced that we completed enrollment of more than 880 HCV patients in C-FORWARD. Currently, we anticipate to report the topline results from C-FORWARD in the first quarter of 2027. Pending successful results from C-FORWARD, we are targeting submission to the U.S. Food and Drug Administration ("FDA") of a New Drug Application ("NDA") for marketing approval in the second quarter of 2027.

In addition to our clinical development activities, we are executing a focused chemistry, manufacturing and controls ("CMC") strategy to manufacture BEM/RZR FDC tablets to fulfill NDA requirements and prepare us for potential launch.

Given the large number of patients currently infected with HCV and the incidence of newly reported chronic infections continuing to outpace rates of treatment, we expect that a substantial global market will exist for the foreseeable future. In 2025, global net sales of branded HCV therapeutics known in the US as Epclusa® (including the authorized generic copy of Epclusa®) and Mavyret® exceeded $2.5 billion with the US accounting for approximately 50% of these sales.

HEV – Our Goal and Our Program

We are developing AT-587 for the treatment of chronic HEV infection in immunocompromised patients. In this high-risk patient population, infection with HEV can rapidly progress to cirrhosis and other serious complications.

There are no DAAs currently available for the treatment of HEV. The most frequent interventions include reduction of immunosuppressive agents which, in solid organ transplant recipients, increases risk of transplant rejection, or off-label treatment with ribavirin which is indicated for treatment of other viruses but hindered by serious adverse events and limited HEV efficacy. The severity of disease in high-risk patients combined with the lack of approved HEV therapies is a substantial unmet medical need which we believe can be addressed if AT-587 is successfully developed.

AT-587 has demonstrated potent nanomolar antiviral activity against HEV *in vitro*. In single-dose *in vivo* nonclinical pharmacokinetic studies, high plasma concentrations of the surrogate to the active intracellular triphosphate metabolite were observed in all animal species tested. Results from *in vitro* toxicology, pharmacology and drug metabolism and pharmacokinetic studies indicate the potential for a favorable clinical profile for AT-587.

In July 2026, we initiated clinical development of AT-587 in a Phase 1 clinical trial which is designed to evaluate the safety, tolerability and pharmacokinetics of AT-587 in healthy volunteers. The single ascending dose phase of this study has been completed and we are now conducting the study's multiple ascending dose phase. As development advances in the Phase 1 clinical trial, we are also preparing for the initiation of a potential proof-of-concept study of AT-587 in 2027.

Developing a treatment for HEV, particularly a product candidate derived from our proprietary platform, is a potentially important and advantageous strategic expansion of our antiviral pipeline. If both product candidates

are successfully developed and approved, we will have a hepatology portfolio that we anticipate will improve upon the current SOC for HCV and introduce the first DAA for HEV.

Discovery efforts for other RNA virus infections

We have an extensive library of compounds that have been designed and generated by our medicinal chemists. Currently, we are evaluating select compounds derived from this library in *in vitro* and *in vivo* studies to assess the antiviral activity and other properties of such compounds against other RNA viral infections.

In all our discovery and preclinical efforts, we assess where there is a compelling market opportunity and then we aim to identify and advance only those candidates that we believe may have first- or best-in-class profiles with the potential to either become the SOC, or disrupt the existing SOC, and in each case, dramatically improve patient outcomes.

Financial Resources

We believe we are well capitalized to advance our current programs. We had $191.2 million in cash, cash equivalents and marketable securities at September 30, 2026. In November 2026, we entered into a loan and security agreement ("Loan and Security Agreement") with Hercules Capital, Inc. ("Hercules") providing for up to $200.0 million in term loans. On the closing date, we had access to and borrowed $65.0 million under the Loan and Security Agreement. For additional information, see "Liquidity and Capital Resources" below.

We do not have any products approved for sale and have not generated any product revenue since inception. We do not anticipate generating any revenue from product sales for the foreseeable future. Our ability to generate product revenue will depend on the successful development, regulatory approval and eventual commercialization of one or more of our product candidates. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through private or public equity, additional term loans under the Loan and Security Agreement (to the extent we meet the required conditions for remaining tranches), other debt financings, collaborative or other arrangements with third parties, or through other sources of financing. Adequate funding may not be available to us on acceptable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, scale back or discontinue the development and commercialization of our product candidates.

We remain focused on identifying initiatives, investments and opportunities to maximize stockholder value.

In an effort to enhance efficiency in the management of infrastructure expenses, in the first quarter of 2025, we reduced our workforce by approximately 25%. This workforce reduction is expected to result in aggregate cost savings of approximately $15.0 million through 2027.

Additionally, in April 2025, our Board authorized a program to repurchase shares of our common stock ("Common Stock"). Under this authorization, we returned capital to our stockholders while maintaining the capacity to complete the Phase 3 clinical development of BEM/RZR and execute on our other strategic business plans. Under the share repurchase program, which was fully completed in 2025, we expended $25.5 million (including transaction costs and excise taxes) in connection with the repurchase of 7,673,792 shares of our Common Stock.

Expecting that the results of our HCV Phase 3 clinical development program, if successful, will drive stockholder value and catalyze business development discussions, in November 2025, we concluded the formal engagement to explore strategic partnerships which we previously entered into with Evercore LLC, a global independent investment bank. As noted above, in July 2026, we reported topline results of C-BEYOND, our Phase 3 clinical trial, comparing our regimen of BEM/RZR against the regimen of SOF/VEL (marketed in the US under the brand Epclusa®). In C-BEYOND, BEM/RZR demonstrated statistical non-inferiority to SOF/VEL meeting both primary and secondary study endpoints. In addition to C-BEYOND, our HCV Phase 3 clinical development program also includes C-FORWARD, a second Phase 3 clinical trial. Patient enrollment in C-FORWARD was completed in June 2026 and we currently expect to report topline results from this Phase 3 clinical trial early in the first quarter of 2027. If C-FORWARD is successfully completed, we are targeting to submit an NDA to the FDA in the second quarter of 2027 seeking approval to market the regimen.

We remain open to consideration of strategic transactions and all other opportunities to drive stockholder value.

Merck License Agreement

In December 2021, we entered into a license agreement ("Merck License Agreement") with MSD International GmbH, an affiliate of Merck & Co., Inc. ("Merck") for the development, manufacture and commercialization of ruzasvir. Ruzasvir is the investigational NS5A inhibitor we are developing in combination with bemnifosbuvir for the treatment of HCV.

Pursuant to the terms of the Merck License Agreement, we obtained from Merck an exclusive (subject to certain reserved rights to conduct internal research), sublicensable, and worldwide license under certain Merck patents and know-how to research, develop, manufacture, have manufactured, use, import, export, sell, offer for sale, and otherwise commercialize ruzasvir or products containing ruzasvir (each a "Product") for all therapeutic or prophylactic uses in humans.

In addition to a non-refundable upfront payment that we made in February 2022, we agreed to pay Merck milestone payments upon our achievement of certain development, regulatory and sales-based milestones. Additionally, we will pay Merck tiered royalties based on annual net sales of Products ranging from high single digits to mid-teens percentages. Our royalty payment obligations will continue until the later of (i) the expiration of the last to expire valid claim of a licensed Merck patent claiming such Product and (ii) a period of years after the first commercial sale of such Product in such country. We may terminate the Merck License Agreement for convenience upon prior written notice. The first milestone in the amount of $5.0 million became due and payable in April 2025 when we enrolled our first patient in C-BEYOND, the Phase 3 clinical trial that we are currently conducting in the US and Canada evaluating BEM/RZR for the treatment of HCV. The Company recognized this milestone payment as research and development expense in the three months ended June 30, 2025. The next potential milestone, in the amount of $10.0 million, is payable upon acceptance by the FDA of a new drug application covering a product candidate including ruzasvir. If we successfully complete C-FORWARD, our Phase 3 clinical trial, and our HCV development program evaluating BEM/RZR, and we are able to complete and submit the NDA to the FDA on our current projected timeline, we anticipate that this next potential milestone may become due and payable during the three months ending September 30, 2027.

Financial Operations Overview

As of September 30, 2026, we had cash and investments of $191.2 million. Net cash used in operating activities was $112.3 million for the nine months ended September 30, 2026. In November 2026, upon entry into the Loan and Security Agreement, we had access to and borrowed an initial tranche of $65.0 million.

Based on our current plans, we anticipate our existing financial resources, including the initial borrowing of $65.0 million that we have drawn under the Loan and Security Agreement, will allow us to complete clinical Phase 3 development, prepare and submit an application to the FDA for marketing approval, engage in pre-launch activities, and if approved, initiate commercialization of BEM/RZR and to advance AT-587 for the treatment of HEV to late-stage clinical development.

We expect that our net cash used in operating activities will remain significant as we complete the clinical development of BEM/RZR for the treatment of HCV, seek regulatory approval (which among other things requires the manufacture of such product at commercial scale) and prepare for and, if approved, pursue commercialization activities; advance AT-587, our HEV product candidate through clinical development; acquire, discover, validate and develop additional product candidates; obtain, maintain, protect and enforce our intellectual property portfolio; and, if necessary, hire additional personnel. In addition, we may incur additional costs as we continue to operate as a public company. We believe that our available cash, including the $65.0 million that we have drawn under the Loan and Security Agreement, cash equivalents and marketable securities will be sufficient to fund our planned operations into mid-2028. We have based this estimate on assumptions that may prove to be wrong and we could exhaust our available capital resources sooner than we expect.

We do not have any products approved for sale and have not generated any product revenue since inception. We do not anticipate generating any revenue from product sales for the foreseeable future. Our ability to generate product revenue will depend on the successful development, regulatory approval and eventual commercialization of one or more of our product candidates. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through private or public equity, additional term loans under the Loan and Security Agreement (to the extent we meet the required conditions for remaining tranches), other debt financings, collaborative or other arrangements with third parties, or through other sources of financing. Adequate funding may not be available to us on acceptable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, scale back or discontinue the development and commercialization of our product candidates.

We plan to continue to use third-party service providers, including clinical research organizations ("CROs") to carry out our preclinical and clinical development, and contract manufacturing organizations ("CMOs") to manufacture and supply the materials used during the development of our product candidates. Additionally, we expect to rely on CMOs for the manufacture of commercial supply of any product candidate we may successfully develop.

As we continue to advance our programs, we expect to incur significant expenses over the next several years, as we:

- complete the Phase 3 clinical development of BEM/RZR for the treatment of HCV;
- complete non-clinical NDA enabling activities including those associated with the manufacture of BEM/RZR at commercial scale;
- seek marketing approval and prepare for potential commercialization of BEM/RZR for the treatment of HCV;
- advance the clinical development of AT-587 for the treatment of chronic HEV;
- continue discovery and preclinical activities to identify other potential product candidates for the treatment of diseases caused by other single stranded RNA viruses;
- acquire or in-license clinical stage drug candidates, form strategic alliances or establish collaborations with third parties;
- maintain, expand, protect and enforce our intellectual property portfolio;
- hire additional personnel, if necessary, to support our activities; and
- establish commercialization capabilities if we are successful in developing our product candidates.

Components of Results of Operations

Revenue

We do not have any products approved for sale and we have not generated any revenue in the periods presented.

If our product candidate development efforts are successful and result in commercialization, we may generate revenue in the future from product sales. Additionally, we may generate revenue from collaboration or license agreements that we may enter into with third parties.

Operating Expenses

Research and Development Expenses

Substantially all of our research and development expenses consist of expenses incurred in connection with the discovery and development of our product candidates. These expenses include external costs consisting of fees paid to third parties, including CROs and CMOs to conduct certain research and development activities on our behalf, and consulting costs, as well as internal costs consisting of payroll and personnel-related expenses, including salaries and bonuses, employee benefit costs and stock-based compensation expenses for our research and development employees and allocated overhead, including rent, equipment, depreciation, information technology costs and utilities attributable to our research and development personnel. We expense both internal and external research and development expenses as they are incurred. In circumstances where amounts have been paid in advance or in excess of costs incurred, we record a prepaid expense, which is expensed as services are performed or goods are delivered.

A significant portion of our research and development costs have been external costs, which we track by therapeutic area. We have not historically tracked our internal research and development expenses by therapeutic area as they are deployed across multiple programs.

The following table summarizes our external research and development expenses by indication and internal research and development expenses:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
	(in thousands)		(in thousands)	
HCV external costs	$ 17,396	30,225	$ 64,659	$ 72,094
HEV external costs	2,719	—	9,636	—
COVID-19 external costs	—	113	—	1,269
Early stage discovery external costs	—	776	—	1,372
Internal research and development costs	6,976	7,233	22,080	25,471
Total research and development costs	$ 27,091	$ 38,347	$ 96,375	$ 100,206

Substantially all of our resources are focused on the development of our product candidates. We expect our research and development expenses to vary quarter over quarter particularly as we complete our Phase 3 HCV clinical program, complete NDA associated activities and advance the clinical development of AT-587 for the treatment of HEV. Predicting the timing or cost to complete our clinical programs, validate our commercial manufacturing and supply processes and manufacture product at commercial scale is difficult and delays may occur because of many factors, including factors outside of our control. For example, if the FDA or other regulatory authorities were to require us to conduct clinical trials beyond those that we currently anticipate or the time to complete planned clinical trials is extended due to delays in enrollment or otherwise, we could be required to expend significant additional financial resources and time on the completion of clinical development. Furthermore, we are unable to predict with any certainty when our HCV and HEV product candidates or any other product candidate we may develop will, if ever, receive regulatory approval.

Early stage discovery activities include assessing the antiviral activity, pharmacokinetics, toxicity and other properties of select compounds derived from our nucleos(t)ide library in an effort to identify promising potential product candidates for the treatment of RNA viral infections for which there is no currently approved DAA or for which we believe the current SOC can be improved to address unmet medical needs.

General and Administrative Expenses

General and administrative expenses consist principally of payroll and personnel expenses, including salaries and bonuses, benefits and stock-based compensation expenses, professional fees for legal, consulting, accounting and tax services, business insurance, allocated overhead, including rent, equipment, depreciation, information technology costs and utilities, and other general operating expenses not otherwise classified as research and development expenses.

To the extent that we expand our organization or otherwise engage in increased activities associated with commercialization, including pre-launch activities prior to approval, we anticipate that our general and administrative expenses will increase. Additionally, our general and administrative expenses may increase, as a result of other increased personnel costs, other infrastructure expansions, increased consulting, legal and accounting services, costs associated with complying with Nasdaq and SEC requirements and increased investor relations costs.

Interest Income and Other, Net

Interest income and other, net, consists primarily of interest income earned on our cash and investments.

Income Taxes

Income taxes consists primarily of federal and state current income taxes.

Results of Operations

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

The following table summarizes our results of operations for the periods indicated:

	Three Months Ended September 30,		
	2026	2025	Change
	(in thousands)		
Operating expenses:			
Research and development	$ 27,091	$ 38,347	$ (11,256)
General and administrative	6,922	7,220	(298)
Total operating expenses	34,013	45,567	(11,554)
Loss from operations	(34,013)	(45,567)	11,554
Interest income and other, net	1,889	3,714	(1,825)
Loss before income taxes	(32,124)	(41,853)	9,729
Income tax expense	(38)	(196)	158
Net loss	$ (32,162)	$ (42,049)	$ 9,887

Research and Development Expenses

Research and development expenses decreased by $11.3 million from $38.3 million for the three months ended September 30, 2025 to $27.1 million for the three months ended September 30, 2026. The net decrease was primarily driven by a decrease in external spend for our HCV Phase 3 clinical development offset by an increase in external spend for HEV preclinical and clinical development activities. In addition, we had lower internal research and development expenses primarily related to lower stock-based compensation expense in the three months ended September 30, 2026.

General and Administrative Expenses

General and administrative expenses decreased by $0.3 million from $7.2 million for the three months ended September 30, 2025 to $6.9 million for the three months ended September 30, 2026. The net decrease was primarily related to lower stock-based compensation expense.

Interest Income and Other, Net

Interest income and other, net, decreased by $1.8 million for the three months ended September 30, 2026 compared to the three months ended September 30, 2025, primarily due to lower investment balances.

Income Taxes

Income tax expense was $0.1 and $0.2 million for the three months ended September 30, 2026 and 2025, respectively.

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

The following table summarizes our results of operations for the periods indicated:

	Nine Months Ended September 30,		
	2026	2025	Change
	(in thousands)		
Operating expenses:			
Research and development	$ 96,375	$ 100,206	$ (3,831)
General and administrative	20,745	25,747	(5,002)
Total operating expenses	117,120	125,953	(8,833)
Loss from operations	(117,120)	(125,953)	8,833
Interest income and other, net	6,697	13,077	(6,380)
Loss before income taxes	(110,423)	(112,876)	2,453
Income tax expense	(112)	(606)	494
Net loss and comprehensive loss	$ (110,535)	$ (113,482)	$ 2,947

Research and Development Expenses

Research and development expenses decreased by $3.8 million from $100.2 million for the nine months ended September 30, 2025 to $96.4 million for the nine months ended September 30, 2026. The net decrease was primarily driven by a decrease in external spend for our HCV Phase 3 clinical development offset by an increase in external spend for HEV preclinical and clinical development activities. In addition, we had lower internal research and development expenses primarily related to lower salaries and wages and lower stock-based compensation expense in the nine months ended September 30, 2026.

General and Administrative Expenses

General and administrative expenses decreased by $5.0 million from $25.7 million for the nine months ended September 30, 2025 to $20.7 million for the nine months ended September 30, 2026. The net decrease was primarily related to lower stock-based compensation expense and lower professional fees.

Interest Income and Other, Net

Interest income and other, net, decreased by $6.4 million for the nine months ended September 30, 2026 compared to the nine months ended September 30, 2025, primarily due to lower investment balances.

Income Taxes

Income tax expense was $0.1 and $0.6 million for the nine months ended September 30, 2026 and 2025, respectively.

Liquidity and Capital Resources

Sources of Liquidity

As of September 30, 2026, we had cash, cash equivalents and marketable securities of $191.2 million. We believe that our available cash and investments, inclusive of the $65.0 million we have drawn under the Loan and Security Agreement will be sufficient to fund our planned operations into mid-2028 including the completion of the Phase 3 program evaluating BEM/RZR for the treatment of HCV. We have based this estimate on assumptions that may prove to be wrong and we could exhaust our available capital resources sooner than we expect.

We are party to an amended and restated open market sales agreement ("Sales Agreement") with Jefferies LLC ("Jefferies"), pursuant to which we may from time to time offer and sell shares of our Common Stock for an aggregate offering price of up to $200.0 million, through or to Jefferies, acting as sales agent or principal. We have agreed to pay Jefferies a commission of up to 3.0% of the aggregate gross proceeds from each sale of shares, reimburse legal fees and disbursements and provide Jefferies with customary indemnification and contribution rights. As of September 30, 2026, no shares have been issued under the Sales Agreement. The shares will be offered and sold under the Company's shelf registration statement on Form S-3 declared effective by the SEC on November 19, 2024.

Loan and Security Agreement

On November 6, 2026 (the "Closing Date"), we entered into the Loan and Security Agreement with Hercules Capital, Inc., as agent, and the lenders party thereto, providing for term loans in an aggregate principal amount of up to $200.0 million, subject to the terms and conditions set forth therein.

The Loan and Security Agreement provides for senior secured term loans which mature on November 1, 2031 (the "Maturity Date"), for up to $200.0 million and consists of the following tranches (collectively, the "Term Loans"): (1) a Tranche 1 Term Loan of $65.0 million drawn on the Closing Date, (2) a Tranche 2 Term Loan of up to $35.0 million, (3) a Tranche 3 Term Loan up to the difference between $35.0 million and the amounts funded under Tranche 4, (4) a Tranche 4 Term Loan up to the difference between $70.0 million and the amounts funded under Tranche 3, and (5) a Tranche 5 Term Loan of up to $30.0 million. The Tranche 2 Term Loan is available subject to certain conditions, including the successful completion, prior to a specified date in the second half of 2027, of the Company's ongoing Phase 3 clinical trial, which is evaluating BEM/RZR for the treatment of hepatitis C virus infection. The Tranche 3 and Tranche 4 Term Loans are available subject to certain conditions, including the achievement of a financing milestone and certain milestones relating to the development and commercialization of BEM/RZR by specified dates. The Tranche 5 Term Loan is available in the sole discretion of the lenders.

All Term Loans will bear interest at a floating rate based upon an annual interest rate of the greater of (i) the prime rate as reported in The Wall Street Journal plus 2.35% and (ii) 9.35%, payable monthly in arrears. The Company is required to pay an initial upfront fee of $0.65 million and an upfront fee equal to 1.00% of any advance for Tranche 2 through Tranche 5. The Term Loans are interest-only for 48 months, extendable to maturity upon achievement of a commercial milestone. The Company may prepay the Term Loans in whole or in part prior to the maturity date, subject to certain prepayment fees. Upon any prepayment of the Term Loans, at maturity or upon acceleration, the Company is also required to pay an end of term charge.

The Loan and Security Agreement contains customary affirmative and restrictive covenants, representations and warranties and events of default. The Loan and Security Agreement contains financial covenants, including: (i) a minimum cash covenant, which is tested beginning on October 1, 2027, requiring the Company to maintain cash at all times in an amount greater than or equal to a specified percentage of the outstanding obligations under the Loan and Security Agreement; provided that the minimum cash covenant is not tested on any day when the Company meets a specified market capitalization requirement and (ii) a performance covenant that is tested beginning on the last day of the month that is six months after FDA approval of BEM/RZR, requiring the Company to meet specified minimum revenues from sales of BEM/RZR, or alternatively, meet a minimum cash covenant requiring the Company to maintain cash in an amount equal to at least 50% of outstanding obligations under the Loan and Security Agreement in addition to meeting a specified market capitalization requirement or maintain cash in an amount of at least 85% of outstanding obligations under the Loan and Security Agreement. Upon the occurrence of an event of default, the lenders may, among other things, accelerate the Company's obligations under the Loan and Security Agreement (including all obligations for principal, interest and any applicable prepayment charges and end of term charges); provided that upon an event of default relating to certain insolvency, liquidation, bankruptcy or similar events, all outstanding obligations will be automatically accelerated.

The Company's obligations under the Loan and Security Agreement are secured by substantially all of its assets, including its intellectual property. Certain of the Company's future subsidiaries may, from time to time after the Closing Date, join as co-borrowers or guarantors and be required to guarantee the Company's obligations under the Loan and Security Agreement and, in connection with such guarantee, pledge substantially all of their assets, including intellectual property, to secure such guarantee.

Future Funding Requirements

To date, we have not generated any product revenue. We do not expect to generate any product revenue unless and until we obtain regulatory approval of and commercialize any of our product candidates and we do not know when, or if, this will occur. We expect to continue to incur significant expenditures for the foreseeable future as we continue the development of, and seek regulatory approvals for, our product candidates, and prepare for and begin to commercialize any approved products. We are subject to all of the risks typically related to the development of new product candidates, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. Moreover, we expect to incur additional general and administrative costs, including selling costs, as we continue to operate as a public company and potentially expand our organization to support and otherwise initiate additional activities in preparation for potential commercialization of BEM/RZR.

We will continue to invest significant capital to develop our product candidates and fund operations for the foreseeable future. To fund such investment, we may seek to raise capital through public or private equity, additional term loans under the Loan and Security Agreement (to the extent we meet the required conditions for remaining tranches), or other debt financings, collaborative arrangements with third parties, or through other sources of financing. We anticipate that we may need to raise substantial additional capital, the requirements for which will depend on many factors, including:

- the scope, timing, rate of progress and costs of our Phase 3 program, including in particular the completion of our Phase 3 clinical trial, C-FORWARD, evaluating BEM/RZR for the treatment of HCV and our other drug discovery efforts, preclinical development activities, laboratory testing and clinical trials for other product candidates including AT-587 for the treatment of HEV;
- the scope and terms of strategic collaborations we enter into to strengthen our capabilities to commercialize BEM/RZR, if approved;
- the number and scope of additional clinical programs we decide to pursue;
- the cost, timing and outcome of preparing for and undergoing regulatory review of BEM/RZR for the treatment of HCV and any other product candidates;
- the scope and costs of development and commercial manufacturing activities;
- the cost and timing associated with commercializing BEM/RZR for the treatment of HCV and any other product candidates, if they receive marketing approval;
- the extent to which we acquire or in-license other product candidates and technologies;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- our ability to attract, hire and retain qualified personnel, including personnel to support the development of our product candidates and, if approved, the commercialization of our products;
- our maintenance and enhancement of operational, financial and management systems; and
- the costs associated with being a public company.

A change in the outcome of any of these or other variables with respect to any of our product candidates could significantly change the costs and timing associated with the development or potential commercialization of one or more of our product candidates. Furthermore, our operating plans may change in the future, and we will continue to require additional capital to meet operational needs and capital requirements associated with such operating plans. If we raise additional funds by issuing equity securities, our stockholders may experience dilution. The Loan and Security Agreement contains covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, make certain investments and engage in certain merger, consolidation or asset sale transactions. Any future debt financing may impose additional covenants and restrictions on us. Any future debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders.

Adequate funding may not be available to us on acceptable terms or at all. Our failure to raise capital as and when needed could have a negative impact on our financial condition and our ability to pursue our business strategies. If we are unable to raise additional funds when needed, we may be required to delay, reduce, or terminate some or all of our development programs, clinical trials and commercialization activities or we may also be required to sell or license to others rights to our product candidates in certain territories or indications that we would prefer to develop and commercialize ourselves. If we are required to enter into collaborations and other arrangements to supplement our funds, we may have to give up certain rights that limit our ability to develop and commercialize our product candidates or may have other terms that are not favorable to us or our stockholders, which could materially affect our business and financial condition.

Market volatility, inflation, interest rate fluctuations and other macroeconomic trends and geopolitical events, including civil or political unrest and terrorism, may have a significant impact on the availability of funding sources and the terms on which any funding may be available.

See *Part II, Item 1A,"Risk Factors"* for additional risks associated with our substantial capital requirements.

Summary Statements of Cash Flows

The following table sets forth the primary sources and uses of cash and cash equivalents for each of the periods presented below:

	Nine Months Ended September 30,	
	2026	**2025**
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ (112,349)	$ (103,808)
Investing activities	114,106	142,201
Financing activities	452	(25,745)
Net increase (decrease) in cash and cash equivalents	$ 2,209	$ 12,648

Cash Flows from Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2026 was $112.3 million. Cash used in operating activities was primarily due to a net loss of $110.5 million, accretion of premium and discounts on marketable securities of $1.5 million, a decrease in accounts payable and accrued expenses and other liabilities of $14.1 million, partially offset by decrease in prepaid and other assets of $3.1 million and stock-based compensation expense of $10.5 million.

Net cash used in operating activities for the nine months ended September 30, 2025 was $103.8 million. Cash used in operating activities was primarily due to a net loss of $113.5 million, accretion of premium and discounts on marketable securities of $4.1 million, increase in prepaid expenses and other assets of $4.5 million,
partially offset by stock-based compensation of $16.1 million and an increase in accounts payable and accrued expenses of $2.0 million.

Cash Flows from Investing Activities

Net cash provided by investing activities for the nine months ended September 30, 2026 was $114.1 million and consisted of sales and maturities of marketable securities of $234.4 million partially offset by purchases of marketable securities of $120.3 million.

Net cash provided by investing activities for the nine months ended September 30, 2025 was $142.2 million and consisted of sales and maturities of marketable securities of $380.3 million partially offset by purchases of marketable securities of $238.1 million.

Cash Flows from Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2026 was $0.5 million and consisted of $1.0 million in proceeds from the exercise of stock options and $0.2 million in proceeds from the issuance of our Common Stock under our employee stock purchase plan (“ESPP”) offset by $0.7 million used in connection with the net settlement of vested restricted stock units.

Net cash used in financing activities for the nine months ended September 30, 2025 was $25.7 million and consisted of stock repurchases of $25.5 million (including transaction costs and excise taxes) and $0.5 million used in connection with the net settlement of vested restricted stock units, partially offset by $0.3 million in proceeds from the issuance of our Common Stock under our ESPP and upon exercises of stock options.

Contractual Obligations and Commitments

During the nine months ended September 30, 2026, there were no material changes to our contractual obligations from those previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2025. In November 2026, we entered into the Loan and Security Agreement. For additional information, see “Liquidity and Capital Resources” above.

We enter into contracts in the normal course of business with CROs for preclinical and clinical studies and testing, CMOs for manufacture and supply of our clinical trial materials and otherwise as necessary to meet requirements for the submission of NDAs and other applications for marketing approval, and other third parties for other services and products used for operating purposes. These contracts do not contain any minimum purchase commitments and generally provide for termination following a certain period after notice, and therefore we

believe that our non-cancelable obligations under these agreements are not material. Payments due upon cancelation principally consist only of payments for services provided and expenses incurred up to the date of cancelation.

Critical Accounting Policies and Estimates

Our financial statements have been prepared in accordance with US generally accepted accounting principles ("GAAP"). The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported expenses incurred during the reporting periods. Our estimates are based on our 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. The effects of material revisions in estimates, if any, will be reflected in the consolidated financial statements prospectively from the date of change in estimates.

Our critical accounting policies are those policies that require the most significant judgments and estimates in the preparation of the financial statements. Management has determined that our most critical accounting policies are those relating to accrued research and development expenses and stock-based compensation.

Indemnification Agreements

We enter into standard indemnification arrangements in the ordinary course of business. Pursuant to these arrangements, we indemnify, hold harmless and agree to reimburse the indemnified parties for losses suffered or incurred by the indemnified party, including in connection with any trade secret, copyright, patent or other intellectual property infringement claim by any third party with respect to its technology. The term of these indemnification agreements is generally perpetual any time after the execution of the agreement. The maximum potential amount of future payments we could be required to make under these arrangements is not determinable. We have never incurred costs to defend lawsuits or settle claims related to these indemnification agreements. As a result, we believe the fair value of these agreements is minimal.

We have also agreed to indemnify our directors and officers for certain events or occurrences while the director or officer is, or was serving, at our request in such capacity. The indemnification period covers all pertinent events and occurrences during the director's or officer's service. The maximum potential amount of future payments we could be required to make under these indemnification agreements is not specified in the agreements; however, we have director and officer insurance coverage that is intended to reduce our exposure and enable us to recover a portion of any future amounts paid. We believe the estimated fair value of these indemnification agreements in excess of applicable insurance coverage is minimal.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Sensitivity

The market risk inherent in our financial instruments and in our financial position represents the potential loss arising from adverse changes in interest rates or exchange rates. As of September 30, 2026, we had cash, cash equivalents and marketable securities of $191.2 million, consisting of interest-bearing money market funds, US Treasury obligations, asset-backed securities, commercial paper and corporate bonds for which the fair value would be affected by changes in the general level of US interest rates. However, due to the short-term maturities and the low-risk profile of our cash equivalents, an immediate 10% relative change in interest rates would not have a material effect on the fair value of our cash equivalents or on our future interest income.

Borrowings we make under the Loan and Security Agreement, including the $65.0 million we borrowed in November 2026 when the agreement was entered into, bear interest at a floating rate, subject to a specified floor. A hypothetical 75 basis point increase in the prime rate published in the Wall Street Journal would increase our annual interest expense under the Loan and Security Agreement by approximately $0.5 million assuming the outstanding principal balance remained constant at $65.0 million for the full year. We currently believe that this impact would not be material to our financial condition or results of operations.

We do not believe that inflation, interest rate changes or foreign currency exchange rate fluctuations have had a significant impact on our results of operations for any periods presented herein.

Item 4. Controls and Procedures.

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated, as of the end of the period covered by this Quarterly Report on Form 10-Q, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")). Based on that evaluation, our principal executive officer and principal financial officer concluded that, as of September 30, 2026, our disclosure controls and procedures 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 (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended September 30, 2026 that have 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 subject to any material legal proceedings.

Item 1A. Risk Factors.

You should carefully consider the risks and uncertainties described below, as well as the other information in this Quarterly Report on Form 10-Q, including our unaudited condensed consolidated financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations." Our business, financial condition, results of operations or prospects could be materially and adversely affected if any of these risks occurs, and as a result, the market price of our common stock could decline and you could lose all or part of your investment. Our actual results could differ materially and adversely from those anticipated in these forward-looking statements as a result of certain factors, including those set forth below.

Risks Related to Our Financial Condition and Capital Requirements

We have a limited operating history and no history of successfully developing or commercializing any approved antiviral products, which may make it difficult to evaluate the success of our business to date and to assess the prospects for our future viability.

We are a clinical biopharmaceutical company in the late stages of development of our lead product candidate, the fixed-dose combination of bemnifosbuvir and ruzasvir ("BEM/RZR") for the treatment of hepatitis C virus ("HCV"). In addition to our HCV program, we have a clinical stage program evaluating AT-587 for the treatment of hepatitis E virus ("HEV"). Our operations to date have been limited to financing and staffing our company, developing our technology, and identifying and developing our product candidates. Our prospects must be considered in light of the uncertainties, risks, expenses and difficulties frequently encountered by biopharmaceutical companies in their early stages of operations. We have not yet demonstrated an ability to successfully develop, obtain marketing approval, manufacture a product on a commercial-scale, or conduct sales and marketing activities necessary for successful product commercialization, or have third parties to do these activities on our behalf. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing, obtaining marketing approval for and commercializing antiviral therapies.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown obstacles in developing or commercializing our products. For example in September 2024, we announced that the SUNRISE-3 Phase 3 clinical trial we conducted to evaluate bemnifosbuvir versus placebo for the treatment of COVID-19 did not meet the primary endpoint of a statistically significant reduction in all cause hospitalization or death through Day 29 in the monotherapy cohort of 2,221 high risk patients with mild to moderate COVID-19. This led us to discontinue efforts to develop bemnifosbuvir for the treatment of COVID-19.

If we successfully develop and obtain approval of any product candidate, we will need to transition from a company with a research and development focus to a company capable of executing commercial activities. We may not be successful in this transition.

As we continue to build our business, including completing Phase 3 clinical trials and preparing and potentially submitting applications seeking marketing approval for our HCV product candidate, we expect our financial condition and operating results may fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results included in this report or reports for any other particular prior quarterly or annual period as indications of future operating performance.

We have incurred significant operating expenses since inception and expect to incur significant additional operating expenses for the foreseeable future. We have no products that have generated any commercial revenue. We expect to incur operating losses in 2026 and for the foreseeable future.

We have incurred significant operating expenses since our inception. For the nine months ended September 30, 2026 and the year ended December 31, 2025, our operating expenses were $117.1 million and $180.9 million, respectively. As of September 30, 2026, we had an accumulated deficit of $633.1 million.

We have not commercialized any products and have never generated any revenue from product sales. We have devoted almost all of our financial resources to research and development, including our clinical trials and

preclinical development and manufacturing activities. We expect to continue to incur significant additional operating expenses and to incur operating losses for the foreseeable future as we seek to advance product candidates through clinical development, continue preclinical development, pursue research and development activities, discover or acquire and develop product candidates, complete preclinical studies and clinical trials, scale up and complete manufacturing and supply chain activities, seek regulatory approval and, if we receive regulatory approval, commercialize our products.

In order to obtain the FDA's or a foreign regulatory authority's approval to market any product candidate in the US or abroad, respectively, we must submit to the FDA a New Drug Application ("NDA") or similar application to the foreign regulatory authority demonstrating to the FDA's or foreign regulatory authority's satisfaction that the product candidate is safe and effective for its intended use(s). This demonstration requires significant research and extensive data from *in vitro* and *in vivo* laboratory experiments and animal tests, which are referred to as nonclinical or preclinical studies, as well as human tests, which are referred to as clinical trials. Additionally, extensive data related to the chemistry and physical characteristics of the product candidate, the intended packaging of the commercial product, the processes to be used for consistently manufacturing the product candidate in commercial quantities in accordance with certified Good Manufacturing Practices ("GMP") and the results of stability studies to establish shelf life of the product must also be included in the NDA and similar foreign regulatory applications.

Furthermore, the costs of advancing product candidates into each succeeding clinical development phase tend to increase substantially over time. For example, the costs of our HCV Phase 3 development program are substantially greater than the costs we incurred in our HCV Phase 2 development program. These increased Phase 3 costs are attributable to a number of factors including a significantly increased number of patients enrolled in the Phase 3 program and costs associated with the use of an active comparator in the Phase 3 program which was not a part of the Phase 2 program. Because of the numerous risks and uncertainties associated with the development of our product candidates, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to begin generating revenue from the commercialization of products or again achieve profitability.

Further, we expect we will continue to incur substantial operating expenses if or as we:

- continue to discover and develop additional product candidates;
- successfully complete clinical trials and seek regulatory approval for BEM/RZR for the treatment of HCV, AT-587 for the treatment of HEV or other product candidates, if any;
- establish long-term manufacturing and supply chain capacity, including US domestic manufacturing capacity, sufficient to provide long term commercial quantities of any product candidates for which we may obtain marketing approval, if any;
- manufacture product in quantities sufficient to support product launch and commercialization, if approved;
- establish a sales, marketing and distribution infrastructure and internal systems to commercialize any products for which we may obtain regulatory approval, if any, in geographies in which we plan to commercialize our products ourselves or with collaborators;
- maintain, expand, protect and enforce our intellectual property portfolio;
- hire additional staff, including clinical, scientific, technical, regulatory, operational, financial, commercial and support personnel, to execute our business plan and support our product candidate discovery, development and potential future commercialization efforts;
- more extensively utilize external vendors for support with respect to research, development, manufacturing, commercialization, regulatory, pharmacovigilance and other functions;
- acquire or in-license commercial products or additional product candidates and technologies;
- make milestone, royalty or other payments under the Merck License Agreement with respect to the development and commercialization of ruzasvir in combination with bemnifosbuvir for the treatment of HCV;
- make upfront, milestone, royalty or other payments in connection with any future in-license agreements relating to other product candidates; and

- incur continuing and increasing legal, accounting and other expenses in operating our business as a public company.

Furthermore, our ability to successfully develop, commercialize and license any products and generate product revenue is subject to substantial additional risks and uncertainties. Our HCV and HEV product candidates and any future product candidates we may discover, license or otherwise acquire, will require regulatory approval in not less than one jurisdiction, the securing of manufacturing supply, capacity, distribution channels and expertise, the use of external vendors, the building of or other access to a commercial organization, substantial investment and significant marketing efforts before we generate any revenue from product sales. Additionally, our HCV and HEV product candidates and any future product candidates require additional preclinical and clinical development. As a result, we expect to continue to use cash for operating activities and incur operating expenses and operating losses for the foreseeable future. The use of cash and incurrence of operating expenses and operating losses has had, and we expect will continue to have, an adverse effect on our working capital.

The amount of future expenses or losses and our ability to achieve or maintain profitability in future years, if ever, are uncertain. We have no products that have generated any commercial revenue, do not expect to generate revenues from the commercial sale of products in the near term, and might never generate revenues from the sale of products. Our ability to generate product revenue and maintain profitability will depend on, among other things, successful completion of the development of our HCV and HEV product candidates and other product candidates, if any; obtaining necessary regulatory approvals from the FDA and foreign regulatory authorities; establishing manufacturing and sales capabilities; successfully manufacturing commercial scale quantities of products, market acceptance of our products, if approved, and establishing marketing infrastructure or otherwise arranging to commercialize our product candidates for which we obtain approval; and raising sufficient funds to finance our activities. We might not succeed at any of these undertakings. If we are unsuccessful at some or all of these undertakings in the future, our business, prospects, and results of operations may be materially adversely affected.

Our loan and security agreement with Hercules Capital, Inc. ("Hercules") contains operating and financial covenants that may restrict our business and financing activities, is secured by substantially all of our assets, including our intellectual property, and we may be required to repay our outstanding indebtedness earlier than we expect, any of which could have a material adverse effect on our business.

In November 2026, we entered into a loan and security agreement (the "Loan and Security Agreement") with Hercules, as agent and the lenders party thereto, which provides for term loans in an aggregate principal amount of up to $200.0 million, of which $65.0 million was funded at closing. The term loans bear interest at floating rates based on the prime rate, subject to specified floors, payable monthly in arrears, and mature on November 5, 2031. Increases in the prime rate would increase our debt service obligations, and servicing our indebtedness will require a substantial amount of cash and will reduce the funds available for our operations. In addition, of the amounts not funded at closing, $105.0 million is available only upon the achievement of specified milestones and $30.0 million is available only in lenders' sole discretion. Accordingly, we may never have access to the full amount of the facility, and we cannot be certain that the milestones will be achieved or that lenders will elect to make discretionary amounts available to us.

The Loan and Security Agreement contains customary affirmative and restrictive covenants that, among other things, limit our ability to transfer or dispose of assets, merge with other companies or consummate certain changes of control, make investments, incur additional indebtedness and liens and enter into new businesses. We therefore may not be able to engage in any of the foregoing transactions unless we obtain the consent of Hercules or terminate the Loan and Security Agreement, which may limit our operating flexibility. The Loan and Security Agreement also contains a minimum cash covenant that will require us to maintain cash equal to a specified percentage of our outstanding obligations under the Loan and Security Agreement unless we meet a specified market capitalization. Additionally, the Loan and Security Agreement also contains a performance covenant that will require us, if BEM/RZR is approved for marketing in the US, to satisfy at least one of (1) a combination of a market capitalization test and a minimum cash test, (2) a minimum cash test, or (3) a net product revenue test. Because the applicability of the minimum cash covenant, and our ability to satisfy the market capitalization prong of the performance covenant, depend in part on our market capitalization, a decline in the trading price of our common stock, which may occur for reasons unrelated to our business or results of operations, could cause the minimum cash covenant to apply, or make the performance covenant more difficult to satisfy, at times when they otherwise would not. These covenants could restrict our ability to operate our business and pursue our business strategies, and we may not be able to comply with these covenants in the future. If the

minimum cash covenant becomes applicable, a portion of our cash will effectively be unavailable to fund our operations, and any failure to comply with the covenants in the Loan and Security Agreement could result in an event of default.

Our obligations under the Loan and Security Agreement are secured by a security interest in substantially all of our assets, including our intellectual property, and certain of our future subsidiaries, if any, may be required to join as co-borrowers or guarantors and guarantee our obligations and pledge substantially all of their assets, including intellectual property, to secure such guarantees. Upon the occurrence of an event of default, Hercules may accelerate all of our outstanding obligations, including principal, interest and any applicable prepayment charges and end of term charges, and our obligations will be automatically accelerated upon certain insolvency, liquidation, bankruptcy or similar events. If our obligations are accelerated, we may not have sufficient cash to repay them, and Hercules could foreclose on the collateral, including intellectual property that is critical to our business. Any voluntary prepayment of the term loans is also subject to prepayment and end of term fees, which could make it more costly for us to refinance the facility. In addition, because our assets, including our intellectual property, are pledged to Hercules, our ability to obtain additional debt or other secured financing may be limited, and any future financing may be more difficult or costly to obtain.

We may require substantial additional financing, which may not be available on acceptable terms, or at all. A failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts.

Since inception, we have incurred substantial operating expenses. We expect to incur substantial expenses in connection with our current and planned business activities, particularly completing the late stage development of BEM/RZR, the manufacture of drug supply, the preparation and submission of an NDA and other similar applications seeking marketing approval and engaging in pre-launch activities, including establishing directly or with third parties, sales, marketing, internal systems and distribution infrastructure to commercialize our HCV product candidate, if approved. Additionally, we anticipate to incur substantial expenses in connection with the development of AT-587 for the treatment of HEV, and in connection with the discovery, license or other acquisition and potential development of other product candidates, if any. Further, if we successfully develop and receive regulatory approval to market BEM/RZR for the treatment of HCV or any other product candidates, we expect we will incur substantial expenses in connection with the commercialization of such product candidates.

If our cash, cash equivalents and marketable securities are not sufficient to fund our future operations, we will need additional capital to fund these activities, which we may raise through equity offerings, additional term loans under the Loan and Security Agreement (to the extent we meet the required terms for remaining tranches), other debt financings, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or other sources. Additional sources of financing might not be available on favorable terms, if at all.

If we raise additional funds by issuing equity securities, our stockholders will suffer dilution, and the terms of any financing may adversely affect the rights of our stockholders. In addition, as a condition to providing additional funds to us, future investors may demand, and may be granted, rights superior to those of existing stockholders. Debt financing, such as our Loan and Security Agreement, or other financing, if available, is likely to involve restrictive covenants limiting our flexibility in conducting future business activities, and, in the event of insolvency, debt holders would be repaid before holders of our equity securities received any distribution of our corporate assets. For additional information regarding restrictive covenants in our Loan and Security Agreement, see Part I, Item 2, “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources”.

If we do not succeed in raising additional funds on acceptable terms, we might be delayed or unable to initiate or complete planned clinical trials or seek regulatory approvals for our product candidates from the FDA, or any foreign regulatory authorities, be delayed or unable to initiate and complete activities, including pre-launch activities and other activities related to commercialization of product candidates, if any, for which we receive marketing approval or forced to discontinue product development or commercialization efforts. In addition, attempting to secure additional financing could divert the time and attention of our management from day-to-day activities and may harm our product candidate development and commercialization efforts.

The timing and amount of our future capital requirements will depend on many factors, including but not limited to:

- the scope, progress, results and costs of our preclinical studies and clinical trials, in particular the completion of our Phase 3 development of BEM/RZR for the treatment of HCV;

- the timing of and costs associated with the development of AT-587 for the treatment of HEV and the discovery, license or acquisition of a product candidate for the treatment of other diseases resulting from infection with single stranded RNA viruses;
- the timing of, and the costs involved in, obtaining marketing approvals for our current and future product candidates in regions where we choose to commercialize any products including for example, our anticipated submission to the FDA of an NDA for marketing approval of our HCV product candidate BEM/RZR;
- the number of future product candidates and potential additional indications that we may pursue and their development requirements;
- the stability, scale, yield and cost of manufacturing our product candidates for clinical trials, in preparation for regulatory approval and in preparation for commercialization;
- the scope, costs and timing of establishing commercialization capabilities related to the potential US commercialization, if approved, of BEM/RZR or any other product candidate;
- the costs of manufacturing and commercialization activities for any approved product candidate to the extent such costs are not the responsibility of any future collaborators, including the costs and timing of manufacturing commercial supply at a scale to meet demand and the costs of conducting product sales, marketing and distribution activities in connection with the commercialization of any such product candidates;
- revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval;
- the costs, timing and changes in pharmaceutical pricing and reimbursement infrastructure resulting from, among other things, the enactment of the Inflation Reduction Act ("IRA") and other legislation, regulations, executive orders and other initiatives and policies that may be subsequently enacted;
- our ability to compete with other therapies in the indications we target;
- the extent to which we in-license or acquire rights to products, product candidates or technologies in addition to ruzasvir;
- growth of our headcount and associated costs if and as we establish a commercial infrastructure;
- the costs of preparing, filing and prosecuting patent applications and maintaining and protecting our intellectual property rights, including enforcing and defending intellectual property-related claims; and
- the continued costs of operating as a public company.

Excluding the Loan and Security Agreement which provides for the draw of additional term loans subject to the satisfaction of certain terms and conditions which we have not yet satisfied, we do not currently have any committed external source of funds or other support and we cannot be certain that additional funding will be available on acceptable terms, if needed.

Our ability to access potential sources of future liquidity and raise funds will depend upon financial, economic and geopolitical conditions and other factors, many of which are beyond our control. These external factors, including rates of interest and inflation, will also impact and may increase substantially costs we incur in connection with any potential fundraising. If we are unable to raise additional capital in sufficient amounts, on terms acceptable to us, or on a timely basis, we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidates or other research and development initiatives.

We may engage in strategic collaborations or other transactions that could disrupt our business, cause dilution to our stockholders, reduce our financial resources, and subject us to other risks.

In the future, we may enter into strategic collaborations or other transactions. While we remain open to consideration of a broad range of strategic alternatives, including strategic partnerships, acquisition, merger, or other business combination, sale of assets or other strategic transactions, we believe that it is most likely that actionable alternatives may be available after we receive the results from our currently ongoing HCV Phase 3 development program. In July 2026, we announced positive topline results from C-BEYOND, our Phase 3 clinical trial conducted in the US and Canada. In June 2026, we announced that we had completed enrollment of

patients in C-FORWARD, our Phase 3 clinical trial being conducted outside the US and Canada. Currently, we anticipate to report topline results from C-FORWARD in the first quarter of 2027.

There is no assurance we will conclude any specific transaction or outcome. If we do identify suitable collaboration candidates or strategic partners, we may not be able to complete such collaborations or other strategic transactions timely or on favorable terms, or at all. Any collaborations or other strategic transactions may not strengthen our competitive position, and these transactions may be viewed negatively by stock research analysts or investors, and we may never realize the anticipated benefits of such transactions. We may decide to issue our common stock or other equity securities to a strategic partner or collaborator which would reduce the percentage ownership of our existing stockholders. In addition, we may not be able to successfully integrate with any collaborator or strategic partner in an effective, timely and non-disruptive manner. Collaborations or other strategic transactions may also divert management attention from day-to-day responsibilities, lead to a loss of key personnel, increase our expenses and reduce our cash and investments available for operations and other uses. We cannot predict the number, timing or size of future collaborations or strategic partnerships or the effect that any such transactions might have on our operating results.

We have not generated any revenue from product sales and may not be able to achieve profitability.

We incurred a net loss of $110.5 million for the nine months ended September 30, 2026. Our ability to achieve and sustain future profitability depends upon our ability to generate revenue from product sales. We have not generated product revenue and we do not expect to generate product revenue unless or until we successfully complete clinical development and obtain regulatory approval of, and then successfully commercialize, at least one of our product candidates. Our HCV and HEV product candidates and future product candidates, if any, require additional preclinical and clinical development, regulatory review and approval, substantial investment in and access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenue from product sales. Currently, we do not anticipate generating revenue from product sales in the near term. Our ability to generate revenue depends on a number of factors, including, but not limited to:

- timely completion of our clinical trials, including C-FORWARD, our HCV Phase 3 clinical trial evaluating BEM/RZR for the treatment of HCV, and the clinical trials of AT-587 for the treatment of HEV, as well as our preclinical studies and other clinical trials, each of which may be significantly slower or more costly than we currently anticipate and will depend substantially upon the performance of third-party contractors;
- our ability to complete additional investigational drug application (“IND”) enabling studies and successfully submit INDs, clinical trial application (“CTAs”) or comparable applications to allow us to initiate clinical trials for other product candidates;
- whether we are required by the FDA or similar foreign regulatory authorities to conduct additional clinical trials or other studies beyond those planned to support the approval and commercialization of our HCV and HEV product candidates or any future product candidates;
- our ability to demonstrate to the satisfaction of the FDA or similar foreign regulatory authorities the safety and efficacy of our HCV and HEV product candidates or any future product candidates;
- the prevalence, duration and severity of potential side effects or other safety issues experienced with our HCV and HEV product candidates or future product candidates, if any;
- the timely receipt of necessary marketing approvals from the FDA, European Medicines Agency ("EMA") and other foreign regulatory authorities;
- the availability, actual and perceived advantages and relative cost, convenience, safety and efficacy of our HCV and HEV product candidates or other product candidates we may be able to commercialize, compared to other commercially available therapies for the targeted indications, or, in the case of HEV other interventions, as well as the accuracy and sufficiency of clinical evidence supporting any such advantages of our product candidates;
- the willingness of physicians, operators of clinics and patients to conduct or participate in clinical trials evaluating our product candidates and, if successfully developed, to utilize or adopt our HCV and HEV product candidates or any future product candidates, if approved as antiviral therapies;
- our ability and the ability of third parties with whom we contract to manufacture adequate clinical and commercial supplies of our HCV and HEV product candidates or future product candidates, remain in

good standing with regulatory authorities and develop, validate and maintain commercially viable manufacturing processes that are compliant with current good manufacturing practices ("cGMP") or similar requirements outside the US;

- our ability to establish a commercial infrastructure and commercialization strategy and thereafter to successfully commercialize our HCV and HEV product candidates or any future product candidates, in the US and internationally, if approved for marketing, reimbursement, sale and distribution in such countries and territories, whether alone or in collaboration with others; and
- our ability to establish, maintain, protect and enforce intellectual property rights in and to our HCV and HEV product candidates or any future product candidates.

Many of the factors listed above are beyond our control, and could cause us to experience significant delays, incur substantially greater expenses than anticipated or prevent us from obtaining regulatory approvals or commercializing our product candidates. Even if we are able to commercialize our product candidates, we may not be able to achieve and maintain profitability after generating product sales or meet outside expectations for our profitability. If we are unable to achieve or sustain profitability or to meet outside expectations for our profitability, the value of our common stock will be materially adversely affected. In addition, if we are unable to generate sufficient revenue through the sale of any products, we may be unable to meet our interest and debt payment obligations under the terms of the Loan and Security and Agreement, which would result in an event of default which could jeopardize our ability to continue operations.

We maintain our cash at financial institutions, often in balances that exceed federally insured limits.

The majority of our cash is held in accounts at US banking institutions. Cash held in depository accounts may exceed the Federal Deposit Insurance Corporation ("FDIC") standard deposit insurance limit of $250,000. If such banking institutions were to fail, such as Silicon Valley Bank when the FDIC took control in March 2023, we could lose all or a portion of those amounts held in excess of such insured amounts. In the future, our access to our cash in amounts adequate to finance our operations could be significantly impaired if the financial institutions with which we have arrangements encounter liquidity constraints or failures. Any future limitation on timely access to our funds or any material loss that we may experience in the future could have a material adverse effect on our financial condition and could materially impact our ability to pay our operating expenses or make other payments.

Our ability to use our net operating loss carryforwards and other tax attributes to offset taxable income may be subject to certain limitations.

As of December 31, 2025, we had US federal and state net operating loss carryforwards ("NOLs"), of $202.8 million and $219.3 million, respectively.

In general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended ("Code"), a corporation that undergoes an "ownership change," which is generally defined as a greater than 50% change by value in its equity ownership over a three-year period, is subject to limitations on its ability to utilize its pre-change NOLs and its research and development credit carryforwards to offset future taxable income. Our NOLs and research and development credit carryforwards may be subject to limitations arising from previous ownership changes, and if we undergo an ownership change, our ability to utilize NOLs (to the extent not previously utilized) and research and development credit carryforwards could be further limited by Sections 382 and 383 of the Code.

For the years ended December 31, 2025 and 2024, we have completed a Section 382 study, the results of which indicated that no ownership shift occurred during such respective period. However, this conclusion could be challenged by tax authorities. In addition, future changes in our stock ownership, some of which might be beyond our control, could result in an ownership change under Sections 382 and 383 of the Code. For these reasons, we may not be able to utilize existing NOLs or research and development credit carryforwards or net operating losses and research and development credits that may be generated in the future.

We may delay, suspend or terminate the development of a product candidate at any time if we believe the perceived market or commercial opportunity does not justify further investment or for other strategic business, financial or other reasons, which could materially harm our business and adversely affect our stock price.

Even if the results of preclinical studies and clinical trials that we have conducted or may conduct in the future may support further development of one or more of our product candidates, we may delay, suspend or terminate the future development of a product candidate at any time for strategic, business, financial or other reasons,

including the determination or belief that the emerging profile of the product candidate is such that it may not receive regulatory approvals in key markets, gain meaningful market acceptance, otherwise provide any competitive advantages in its intended indication or market or generate a significant return to stockholders. For example, in September 2024, after the SUNRISE-3 Phase 3 clinical trial failed to reach its primary endpoint, we discontinued the development of bemnifosbuvir for the treatment of COVID-19. Any similar delays, suspensions or terminations of other clinical programs or product candidates, particularly our HCV product candidate, could materially harm our business, results of operations or financial condition.

Risks Related to the Discovery, Development, Preclinical and Clinical Testing, Manufacturing and Regulatory Approval of Our Product Candidates

Our business is highly dependent on the success of our lead product candidate, BEM/RZR for the treatment of HCV, which requires significant additional clinical testing, principally including successful completion of the C-FORWARD Phase 3 clinical trial, before we can seek regulatory approval and potentially launch commercial sales. If this product candidate fails in clinical development, does not receive regulatory approval or is not successfully commercialized, or is significantly delayed in doing so, our business will be harmed.

A substantial portion of our business and future success depends on our ability to develop, obtain regulatory approval for and successfully commercialize BEM/RZR for the treatment of HCV. We currently have no products that are approved for commercial sale and have not successfully completed the development of any of our product candidates, and we may never be able to develop marketable products.

During the near term, we expect to devote substantial efforts and financial resources to complete the Phase 3 clinical development of BEM/RZR for the treatment of HCV, manage clinical, medical affairs and manufacturing activities, seek and obtain regulatory approvals in multiple jurisdictions, secure additional sources of manufacturing supply and capacity, build or otherwise access a commercial organization, and engage in significant pre-launch efforts.

We cannot be certain that C-FORWARD, our Phase 3 clinical trial evaluating BEM/RZR for the treatment of HCV, or any clinical trial evaluating AT-587 for the treatment of HEV will be successful. Additionally, we cannot be certain that BEM/RZR for the treatment of HCV, AT-587 for the treatment of HEV or future product candidates, if any, we may subsequently develop will receive regulatory approval or be successfully commercialized even if we receive regulatory approval. Further, our development of any product candidate may be delayed or suspended, which may affect our ability to successfully commercialize such product candidate. Additionally, our ability to successfully commercialize a product will also be dependent upon our ability to timely manufacture at commercial scale the quantities of product that will satisfy market demand.

Even if we receive approval to market our HCV product candidate, our HEV product candidate or any other product candidate, we cannot be certain that such product candidate will be as or more effective than commercially available alternatives, successfully commercialized or widely accepted in the marketplace. There are currently approved and well established oral antiviral HCV products against which we would be required to compete if BEM/RZR is approved for the treatment of HCV.

We cannot be certain that, if approved, the safety and efficacy profile of BEM/RZR will be consistent with the results observed in clinical trials. If we are not able to successfully complete the clinical development of the BEM/RZR for the treatment of HCV, if the required regulatory approvals for this product candidate are not obtained, if there are significant delays in completing the development or obtaining approval of this product candidate or in supplying commercial quantities of BEM/RZR or any other product, if approved, on an uninterrupted basis, or if we are otherwise not commercially successful, our business, financial condition and results of operations may be materially harmed.

The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, expensive, time-consuming, and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates, we will be unable to generate product revenue and our business will be seriously harmed.

We are not permitted to commercialize, market, promote or sell any product candidate in the US without obtaining marketing approval from the FDA. Foreign regulatory authorities impose similar requirements. The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable, typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the type,

complexity and novelty of the product candidates involved and the disease or condition for which the product candidate is intended.

In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development, and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application.

Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. Approval by any one regulatory authority does not ensure approval by any other regulatory authority.

We have not submitted an NDA for, or obtained regulatory approval of, any product candidate. We must complete additional clinical and preclinical studies to demonstrate the safety and efficacy of our product candidates in humans to the satisfaction of the regulatory authorities before we will be able to obtain these approvals, and it is possible that none of our product candidates will ever obtain regulatory approval. Applications for our product candidates could fail to receive regulatory approval for many reasons, including but not limited to the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design, implementation or interpretation of results of our clinical trials;
- the FDA or comparable foreign regulatory authorities may determine that our product candidates are not safe and effective, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use of our products;
- the population studied in the clinical program may not be sufficiently broad or representative to assure efficacy and safety in the full population for which we seek approval;
- we may be unable to demonstrate to the FDA or comparable foreign regulatory authorities that a product candidate's clinical and other benefits outweigh its safety risks;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the US or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications, or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

If the results of C-FORWARD, our HCV Phase 3 clinical trial, are unfavorable or we are otherwise not able to successfully complete our HCV development program, we may fail to obtain regulatory approval to market our HCV product candidate, which may seriously harm our business. Unfavorable results from clinical trials evaluating AT-587 or other product candidates, if any, that we may clinically develop, may result in us being unable to obtain regulatory approval for such product candidate. Further, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may impose significant limitations in the form of narrow indications, warnings, or a Risk Evaluation and Mitigation Strategy ("REMS") or similar risk management measures. Regulatory authorities may not approve the price we intend to charge for products we may develop, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could seriously harm our business.

Clinical development, including enrollment and retention of patients in clinical trials, is an expensive, lengthy and uncertain process. We may encounter substantial delays and costs in our clinical trials or may not be able to conduct or complete our clinical trials on the timelines we expect, if at all.

Before obtaining marketing approval from the FDA or other comparable foreign regulatory authorities for the sale of our product candidates, we must complete preclinical development and extensive clinical trials to demonstrate the safety and efficacy of our product candidates. Clinical testing is expensive, time-consuming and subject to uncertainty. A failure of one or more clinical trials can occur at any stage of the process, such as the failure in September 2024 of bemnifosbuvir to meet the primary endpoint in the COVID-19 Phase 3 SUNRISE-3 clinical

trial. The outcome of preclinical studies and early-stage clinical trials may not be predictive of the success of later clinical trials. Moreover, preclinical and clinical data, particularly the analysis of exploratory endpoints and analysis of data derived from patient subgroups, including in the case of HCV, patients infected with varying viral genotypes, are often susceptible to varying interpretations, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and varying stages of clinical trials have nonetheless failed to obtain marketing approval of their drugs.

We cannot guarantee that any of our planned or ongoing clinical trials will be initiated or conducted as planned or completed on schedule, if at all. We also cannot be sure that submission of any future IND or similar application for any future product candidate will result in the FDA or other regulatory authority, as applicable, allowing future clinical trials to begin in a timely manner, if at all. Moreover, even for trials that begin or have begun, issues may arise that could cause regulatory authorities to suspend or terminate such clinical trials.

Events that may prevent successful or timely initiation or completion of clinical trials include but are not limited to:

- inability to generate sufficient preclinical, toxicology, or other *in vivo* or *in vitro* data to support the initiation or continuation of clinical trials;
- delays in reaching a consensus with regulatory authorities on study design or implementation of the clinical trials;
- delays or failure in obtaining regulatory allowance to commence or amend a clinical trial;
- delays in reaching agreement on acceptable terms with prospective contract research organizations (“CROs”) and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among CROs and clinical trial sites;
- delays in identifying, recruiting and training suitable clinical investigators;
- delays in obtaining required institutional review board or ethics committee approval or positive opinion at each clinical trial site;
- delays in recruiting, screening and enrolling a suitable number and diversity of patients to participate in our clinical trials;
- subjects enrolled in our clinical trials or clinical sites deviating from the clinical trial protocol or dropping out of a trial;
- delays in manufacturing, testing, releasing, validating or importing/exporting sufficient stable quantities of our product candidates for use in clinical trials or the inability to do any of the foregoing;
- insufficient or inadequate supply or quality of product candidates or other materials necessary for use in clinical trials, or delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for clinical trials;
- imposition of a temporary or permanent clinical hold by regulatory authorities for a number of reasons, including after review of an IND or amendment or equivalent foreign application or amendment; as a result of a new safety finding that presents unreasonable risk to clinical trial participants; or a negative finding from an inspection of our clinical trial operations or study sites;
- developments on trials conducted by competitors for related technology that raises FDA or foreign regulatory authority concerns about risk to patients of the technology broadly;
- developments during the course of a clinical trial that cause the FDA, a foreign regulatory authority or the clinical trial data safety monitoring board (“DSMB”) to find that the investigational protocol or plan is clearly deficient to meet its stated objectives;
- difficulty collaborating with patient groups and investigators;
- failure by our CROs, other third parties or us to adhere to clinical trial protocols; failure to perform in accordance with the FDA’s or any other regulatory authority’s good clinical practices (“GCPs”), or applicable regulatory guidelines in other countries;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits, or occurrence of adverse events in trial of the same class of agents conducted by other companies;

- changes to the clinical trial protocols;
- delays caused by patients withdrawing from clinical trials or failing to return for post-treatment follow-up;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols or otherwise impact the conduct of the clinical trial;
- changes in the standard of care or rate of event occurrence upon which a clinical development plan was based, which may require discontinuation of current trials or new or additional trials;
- selection of clinical endpoints that require prolonged periods of observation or analyses of resulting data;
- the cost of clinical trials of our product candidates being greater than we anticipate;
- clinical trials of our product candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us to conduct additional clinical trials or abandon development of such product candidates;
- transfer of manufacturing processes to larger-scale facilities operated by a contract manufacturing organization ("CMO") and delays or failure by our CMOs or us to make any necessary changes to such manufacturing process; and
- third parties being unwilling or unable to satisfy their contractual obligations to us.

Any inability to successfully complete C-FORWARD, our Phase 3 clinical trial evaluating BEM/RZR for the treatment of HCV or the completion of our first-in-human Phase 1 and additional planned clinical trials we may initiate for AT-587, our HEV product candidate, could result in additional costs to us or impair our ability to seek approval for our HCV and HEV product candidate and ultimately generate revenue from product sales.

In addition, if we make manufacturing or formulation changes to our product candidates, we may be required to or we may elect to conduct additional studies to bridge our modified product candidates to earlier versions. Clinical trial delays could also shorten any periods during which any approved products have patent protection and may allow our competitors to further strengthen the market position of their current products or bring new products to market before we do, which could impair our ability to successfully commercialize our product candidates and may seriously harm our business.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the DSMB for such trial, or by the FDA or any other regulatory authority, or if the institutional review boards of the institutions at which such trials are being conducted suspend or terminate the participation of the clinical investigators and sites subject to their review. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Further, conducting clinical trials in foreign countries for our HCV and HEV product candidates or other product candidates, if any, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries. For example, clinical trial sites in Ukraine are expected to participate in our HCV pediatric study and are participating in and have enrolled patients in C-FORWARD, our HCV Phase 3 clinical trial. To the extent that these patients in Ukraine are not able to complete the study or there is a loss of data related to those patients as a result of the ongoing conflict in that area or otherwise, there may be a delay in completing the studies or an adverse impact on the results from the studies.

Delays in the completion of any clinical trial of our product candidates will increase our costs, slow down our product candidate development and approval process and delay or potentially jeopardize our ability to commence product sales and generate product revenue. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Any delays to our clinical trials that occur as a result could shorten any period during which

we may have the exclusive right to commercialize our product candidates and our competitors may be able to further strengthen the market position of their current products or bring new or additional products to market before we do, which could significantly reduce the commercial viability of our product candidates. Any of these occurrences may harm our business, financial condition and prospects significantly.

In addition, the FDA's and other regulatory authorities' policies with respect to clinical trials being conducted outside North America may change and additional government regulations may be enacted. For instance, with very limited exception for certain EU countries and certain clinical trials, the regulatory landscape related to clinical trials in the EU recently evolved. The EU CTR which was adopted in April 2014 and repealed the EU Clinical Trials Directive, became applicable on January 31, 2022. While the EU Clinical Trials Directive required a separate CTA to be submitted in each member state in which the clinical trial takes place, to both the competent national health authority and an independent ethics committee, the CTR introduced a centralized process and only requires the submission of a single application for multi-center trials. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed. With very limited exception for certain EU countries and certain clinical trials including our first-in-human clinical trial of AT-587, all CTAs and clinical trials conducted in the EU (including those which are ongoing) are subject to the provisions of the CTR. Even though the CTAs we submitted in connection with the conduct of our HCV Phase 3 clinical trial in the EU were prepared in compliance with the CTR requirements, we have limited experience submitting applications under the CTR. If we or our third-party service providers, such as CROs, encounter difficulties or are unable to comply with the CTR requirements our developments plans would be adversely impacted.

In April 2025, the UK government adopted the Medicines for Human Use (Clinical Trials) Amendment Regulations. The amendment, which took effect from April 2026, aims to provide a more flexible regime to make it easier to conduct clinical trials in the UK, increase the transparency of clinical trials conducted in the UK and make clinical trials more patient centered.

If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may also be impacted.

We are developing certain of our product candidates in combination with other therapies, which exposes us to additional risks.

Combination therapies are commonly used for the treatment of viral infections. Developing combination therapies exposes us to additional clinical risks, such as the requirement that we demonstrate the safety and efficacy of each active component of any combination regimen we may develop.

For the treatment of HCV, we are currently developing bemnifosbuvir in combination with ruzasvir, a product candidate that has not yet been approved for marketing by the FDA or similar foreign regulatory authorities.

If the FDA or similar foreign regulatory authorities do not approve the combination agents or revoke the approval thereof, or if safety, efficacy, manufacturing, or supply issues arise with the drugs we choose to evaluate in combination with our product candidates, we may be unable to obtain approval of or market our product candidates for combination therapy regimens.

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

Our product candidates may be associated with serious adverse events ("SAEs"), undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, limit their commercial potential or result in significant negative consequences.

Adverse events or other undesirable side effects caused by our product candidates could cause us, our collaborators, any DSMB for a trial, or regulatory authorities to interrupt, delay or halt clinical trials and could result

in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authorities.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not the product candidate being studied caused these conditions. It is possible that as we test our product candidates in larger, longer and more extensive clinical trials, or as use of these product candidates becomes more widespread if they receive regulatory approval, illnesses, injuries, discomforts and other adverse events that were observed in previous trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by patients. Many times, side effects are only detectable after investigational products are tested in large-scale clinical trials or, in some cases, after they are made available to patients on a commercial scale following approval.

If any SAEs occur, clinical trials or commercial distribution of any product we successfully develop could be suspended or terminated, and our business could be seriously harmed. Treatment-related side effects could also affect patient recruitment and the ability of enrolled patients to complete the trial or result in potential liability claims. Regulatory authorities could order us to cease further development of, deny approval of, or require us to cease selling any product candidate or product for any or all targeted indications. If we are required to delay, suspend or terminate any clinical trial or commercialization efforts, the commercial prospects of such product candidate or product may be harmed, and our ability to generate revenues from such product may be delayed or eliminated. Additionally, if one or more of our product candidates receives marketing approval and we or others later identify undesirable side effects or adverse events caused by such products, a number of potentially significant negative consequences could result, including but not limited to:

- regulatory authorities may suspend, limit or withdraw approvals of such product, or seek an injunction against its manufacture or distribution;
- regulatory authorities may require additional warnings on the label, including “boxed” warnings, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- we may be required to change the way the product is administered or conduct additional clinical trials or post-approval studies;
- we may be required to create a REMS or similar risk management measures which could include a medication guide outlining the risks of such side effects for distribution to patients;
- we may be subject to fines, injunctions or the imposition of criminal penalties;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could seriously harm our business, financial condition and results of operations.

If we encounter difficulties enrolling and retaining enrolled patients in our clinical trials and having patients comply with the clinical trial protocol, our clinical development activities could be delayed or otherwise adversely affected.

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain adherent to the protocol and in the trial until its conclusion. A delay in the completion of the study would also delay our ability to seek regulatory approval to commercialize the product candidate which is being evaluated in the clinical trial.

Enrollment of patients and timely completion of our clinical trials depends on many factors, including but not limited to:

- the patient eligibility criteria defined in the protocol;
- the size of the target disease population and rates of diagnostic testing among the target disease population;
- the size of the patient population required for analysis of the trial’s primary endpoints;
- the proximity of patients to trial sites;

- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any products that may be approved for the indications we are investigating;
- our ability to obtain and maintain patient consents;
- the risk that patients enrolled in clinical trials will drop out of the trials before trial completion;
- the risk that patients enrolled in the clinical trial will fail to adhere to the protocol; and
- other factors outside of our control, such as political unrest, war, terrorism and the occurrence of a global health crisis such as COVID-19 which, among other things, created substantial burdens on healthcare providers who were required to prioritize immediate critical patient care over clinical research.

In addition, our clinical trials may compete with other clinical trials sponsored by third parties, including potential competitors, that are in the same or substantially similar therapeutic areas as our product candidates, and this competition may reduce the number and types of patients available to us because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, it is possible that we will conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of our ongoing and planned clinical trials, which could prevent completion or commencement of these trials and adversely affect our ability to advance the development of our product candidates.

Patients failing to adhere to the protocol, whether as a result of failing to take the drug as directed or otherwise, may adversely impact the clinical trial results if the lack of adherence or other failure to follow the protocol contributes to or results in the patient failing to meet the clinical trial primary endpoint.

A Fast Track designation by the FDA may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that our product candidates will receive marketing approval.

If a product candidate is intended for the treatment of a serious or life-threatening condition and the product candidate demonstrates the potential to address unmet medical needs for such condition, the product candidate sponsor may apply for Fast Track designation. The sponsor of a product candidate that has received Fast Track designation may have opportunities for more frequent interactions with the FDA review team during product development and, once an NDA is submitted, the NDA may be eligible for priority review. An NDA for a Fast Track designated product candidate may also be eligible for rolling review, where the FDA may consider review of sections of the NDA on a rolling basis before the complete NDA is submitted.

The FDA has broad discretion whether or not to grant Fast Track designation to any particular product candidate. As a result, we may seek such Fast Track designation for our product candidates, but cannot assure you that the FDA would decide to grant it. Even if a Fast Track designation has been received, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. Many product candidates that have received Fast Track designation have nevertheless failed to obtain approval.

We currently conduct clinical trials, and may in the future choose to conduct additional clinical trials, of our product candidates in sites outside the US, and the FDA may not accept data from trials conducted in foreign locations.

We currently conduct, and expect in the future to conduct, clinical trials outside the US for our product candidates. The acceptance of study data from clinical trials conducted outside the US or another jurisdiction by the FDA or comparable foreign regulatory authorities may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the US, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are

applicable to the US population and US medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to good clinical practice ("GCP") regulations; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, if the study was not otherwise subject to an IND, the FDA will not accept the data as support for an application for marketing approval unless the study was conducted in accordance with GCP requirements and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the US or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in current or future product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction.

In addition, there are risks inherent in conducting clinical trials in multiple jurisdictions, inside and outside of the US, such as:

- regulatory and administrative requirements of the jurisdiction where the trial is conducted that could burden or limit our ability to conduct our clinical trials;
- foreign exchange fluctuations;
- manufacturing, customs, shipment and storage requirements for clinical trial materials and supplies as well as shipment and storage of biological samples;
- cultural differences in medical practice and clinical research; and
- the risk that the patient populations in such trials are not considered representative as compared to the patient population in the target markets where approval is being sought.

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

From time to time, we may publicly disclose preliminary or top-line data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data. Similar to all preliminary and then-available data, these results and related findings and conclusions are subject to change as additional data becomes available or following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. Consequently, the top-line or preliminary data that we report may differ from final results reported from the same studies, or different conclusions or considerations may qualify such preliminary or topline data, once additional data have been received and fully evaluated. Top-line and preliminary data also remain subject to audit and verification procedures that may result in the final results being materially different from the preliminary or topline data we previously published. As a result, top-line and preliminary data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may subsequently complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available or as patients from our clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final results could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general.

In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or

otherwise appropriate information to include in our disclosure. If the interim, top-line, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

We may not be successful in our efforts to identify and successfully develop additional product candidates.

Part of our strategy involves identifying novel product candidates.

Our efforts to discover additional product candidates may fail to yield product candidates for clinical development for a number of reasons, including those discussed in these risk factors and also:

- we may not be able to assemble sufficient resources to acquire or discover additional product candidates;
- competitors may develop alternatives that render our potential product candidates obsolete or less attractive;
- potential product candidates we develop may nevertheless be covered by third-parties' patent or other intellectual property or exclusive rights;
- potential product candidates may, in further study, be shown to have harmful side effects, toxicities or other characteristics that indicate that they are unlikely to be products that will receive marketing approval or achieve market acceptance, if approved;
- potential product candidates may not be effective in treating their targeted diseases or symptoms;
- the market for a potential product candidate may change so that the continued development of that product candidate is no longer reasonable;
- a potential product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; or
- the regulatory pathway for a potential product candidate is highly complex and difficult to navigate successfully or economically.

If we are unable to identify and successfully develop and commercialize additional suitable product candidates, this would adversely impact our business strategy and our financial position.

We may focus on potential product candidates that may prove to be unsuccessful and we may have to forego opportunities to develop other product candidates that may prove to be more successful.

We may choose to focus our efforts and resources on one or more potential product candidates that ultimately prove to be unsuccessful as was the case with the failure of bemnifosbuvir to meet the primary endpoint in the COVID-19 Phase 3 SUNRISE-3 clinical trial. Further, we may license or purchase a marketed product that does not meet our financial expectations. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases that may later prove to have greater commercial potential.

Furthermore, we have limited financial and personnel resources and are placing significant focus on the development of our lead product candidate, BEM/RZR for the treatment of HCV, and the development of AT-587 for the treatment of HEV and as such, we may forgo or delay pursuit of opportunities with other future product candidates that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and other future product candidates for specific indications may not yield any commercially viable future product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to such product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such future product candidates.

We may attempt to secure FDA approval of certain product candidates through the use of the accelerated approval pathway or similar expedited approval pathways outside the US. If we are unable to obtain such approval, we may be required to conduct additional preclinical studies or clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive accelerated approval from the FDA or similar expedited approval by foreign regulatory authorities, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA or foreign regulatory authorities may seek to withdraw accelerated approval or similar conditional approval.

We are developing our product candidates for the treatment of serious conditions and therefore may decide to seek approval of such product candidates under the FDA's accelerated approval pathway. A product candidate may be eligible for accelerated approval if it is designed to treat a serious or life-threatening disease or condition and generally provides a meaningful advantage over available therapies, upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit.

The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, confirmatory studies to verify and describe the drug's clinical benefit. If the sponsor fails to conduct such studies in a timely manner, or if such confirmatory studies fail to verify the drug's predicted clinical benefit, the FDA may withdraw its approval of the drug on an expedited basis. Additionally, as a part of the Food and Drug Omnibus Reform Act of 2022, the FDA obtained statutory authority to mitigate potential risks to patients from continued marketing of ineffective drugs previously granted accelerated approval. Under these provisions, the FDA may require a sponsor of a product seeking accelerated approval to have a confirmatory trial underway prior to such approval being granted.

In the EU, a "conditional" MA may be granted in cases where all the required safety and efficacy data are not yet available. The conditional MA is subject to conditions to be fulfilled for generating the missing data or ensuring increased safety measures. It is valid for one year and has to be renewed annually until fulfillment of all the conditions. Once the pending studies are provided, it can become a "standard" MA. However, if the conditions are not fulfilled within the timeframe set by the EMA, the MA ceases to be renewed. Furthermore, MA may also be granted "under exceptional circumstances" when the applicant can show that it is unable to provide comprehensive data on the efficacy and safety under normal conditions of use even after the product has been authorized and subject to specific procedures being introduced. This may arise in particular when the intended indications are very rare and, in the present state of scientific knowledge, it is not possible to provide comprehensive information, or when generating data may be contrary to generally accepted ethical principles. This MA is close to the conditional MA as it is reserved for medicinal products to be approved for severe diseases or unmet medical needs and the applicant does not hold the complete data set legally required for the grant of a MA. However, unlike the conditional MA, the applicant does not have to provide the missing data and will never have to. Although the MA "under exceptional circumstances" is granted definitively, the risk-benefit balance of the medicinal product is reviewed annually, and the MA is withdrawn in case the risk-benefit ratio is no longer favorable.

The competent regulatory authorities in the EU have broad discretion whether to grant such a conditional marketing authorization or marketing authorization under exceptional circumstances, and, even if such assessment or authorization is granted, we may not experience a faster development process, review or authorization compared to conventional procedures. Moreover, the removal or threat of removal of such marketing authorizations may create uncertainty or delay in the clinical development of our product candidates and threaten the commercialization prospects of our products and product candidates, if approved. Such an occurrence could materially impact our business, financial condition and results of operations.

If we decide to submit an NDA seeking accelerated approval or receive an expedited regulatory designation for our product candidates, there can be no assurance that such submission or application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. Failure to obtain

accelerated approval or any other form of expedited development, review or approval for a product candidate would result in a longer time period prior to commercialization of such product candidate, if any, and could increase the cost of development of such product candidate, which could harm our competitive position in the marketplace.

Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain and may prevent us or any future collaboration partners from obtaining approvals for the commercialization of any product candidate we develop.

Any product candidates we may develop and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory authorities in the US and by comparable authorities in other countries. Any product candidates we develop may not be effective, may be only moderately effective, or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate in a given jurisdiction. We have not received approval to market any product candidates from regulatory authorities in any jurisdiction. It is possible that neither the HCV product candidate or the HEV product candidate we are developing or other product candidates, if any, that we may seek to develop in the future, will ever obtain regulatory approval. We, as a company, have no experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party CROs, suppliers, vendors or regulatory consultants to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority.

The process of obtaining marketing approvals, both in the US and abroad, is expensive, may take many years if numerous clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application**.** For instance, the EU pharmaceutical legislation has been undergoing a complete review process. The European Commission's proposed changes would affect the duration of regulatory data protection and market protection, including for orphan medicinal products, revising the eligibility for expedited pathways, etc. The changes have not yet been formally adopted. The proposed changes are not expected to enter into application before 2028 and may have a significant impact on the pharmaceutical industry and our business in the long term.

The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

If we experience delays in obtaining approval or if we fail to obtain approval of any product candidates we may develop, the commercial prospects for those product candidates may be harmed, and our ability to generate product revenue will be materially impaired.

Even if we obtain FDA approval of any of our product candidates, we may never obtain approval or commercialize such products outside of the US, which would limit our ability to realize their full market potential.

In order to market any products outside of the US, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approvals could result in significant delays, difficulties and costs for us and may require additional preclinical studies or clinical trials which would be costly and time-consuming. Regulatory requirements

can vary widely from country to country and could delay or prevent the introduction of our products in those countries. Satisfying these and other regulatory requirements is costly, time-consuming, uncertain and subject to unanticipated delays. In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and as an organization we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, our ability to realize the full market potential of our products will be harmed.

Even if a current or future product candidate receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

If any current or future product candidate we develop receives marketing approval, whether as a single agent or in combination with other therapies, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. For example, current approved oral antiviral products are well established in the medical community for the treatment of HCV and doctors and other prescribers may continue to rely on these therapies.

If the product candidates we develop do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of any product candidate, if approved for commercial sale, will depend on a number of factors, including but not limited to:

- the continued longevity of any market for which we develop a product;
- efficacy and potential advantages, including convenience, duration of treatment and ease of administration, of our product compared to alternative treatments;
- the prevalence and severity of any side effects associated with our product relative to any alternative treatment;
- the willingness of the target patient population to try new therapies and of physicians and other healthcare providers to prescribe these therapies;
- the strength and effectiveness of sales, marketing and distribution support;
- the cost to patients of our treatment regimens in relation to alternative treatments; and
- the ability to obtain sufficient adequate reimbursement from third-parties as well as the impact of any agreements among any competitor and any third party payor limiting access to our product.

If the market opportunities for our product candidates are smaller than we believe they are or any approval we obtain is based on a narrower definition of the patient population, our business may suffer.

We currently focus on the discovery and development of product candidates for the treatment of serious viral diseases. Our eligible patient population, pricing estimates and available coverage and reimbursement may differ significantly from the actual market addressable by our product candidates. Our estimates of the number of people who have these diseases, the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, and the market demand for our product candidates are based on our beliefs and analyses. These estimates have been derived from a variety of sources, including the scientific literature, current third-party data regarding prescriptions dispensed, and market research, and may prove to be incorrect. The number of patients may turn out to be lower than expected. Likewise, the potentially addressable patient population for our product candidates may be limited or may not be receptive to treatment with our product candidates, and new patients may become increasingly difficult to identify or access. Additionally, the availability of superior or competitive therapies from our competitors could negatively impact or eliminate market demand for our product candidates. If the market opportunities for our product candidates are smaller than we estimate, it could have an adverse effect on our business, financial condition, results of operations and prospects.

Disruptions at the FDA and foreign regulatory authorities caused by funding shortages, staffing limitations or policy changes could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA and foreign regulatory authorities to review or approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's or foreign regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's or foreign regulatory authorities' ability to perform routine functions. Average review times at the FDA and foreign regulatory authorities have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, the US government has shut down and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. Additionally, government efficiency initiatives, including initiatives and programs recently undertaken in the US, have resulted in significant changes to senior FDA personnel which may affect the ability of the agency to process our regulatory submissions which may adversely impact our ability to timely complete critical activities associated with the development of our HCV product candidate or the FDA's review of any NDA we may submit.

If a prolonged government shutdown occurs, or funding shortages, staffing limitations prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities on a timely basis, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Our insurance policies are expensive and protect us only from some business risks, which leaves us exposed to significant uninsured liabilities.

Though we have insurance coverage for clinical trial product liability, we do not carry insurance for all categories of risk that our business may encounter. Some of the additional policies we currently maintain include general liability, property, auto, workers' compensation, cybersecurity, umbrella, and directors' and officers' insurance.

As a part of the clinical trial regulatory submission process, in many countries, we are required to provide local insurance coverage covering claims that persons associated with the clinical trial may assert if they are or believe they are injured as a result of participation in the clinical trial or contact with the investigational product candidate being studied in the clinical trial. These local insurance policies can be time consuming to obtain which may delay the anticipated start of a clinical trial in a particular country. Additionally, these local insurance policies may not cover all the claims an injured party may assert and may be insufficient to cover the losses associated with our defense of the claim and any judgment against us that may result.

Any additional product liability insurance coverage we acquire in the future may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and in the future we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If we obtain marketing approval for any of our product candidates, we intend to acquire insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments are for claims not covered by or are in amounts that exceed our insurance coverage, could adversely affect our results of operations and business, including preventing or limiting the development and commercialization of any product candidates we develop. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury from biological or hazardous waste, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended.

Operating as a public company has in the past and may in the future make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits or coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our board of directors, our board committees or as executive officers. We do not know if we will be able to maintain existing insurance with adequate levels of

coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash and cash equivalents position and results of operations.

Our business and operations may suffer in the event of information technology system failures, cyberattacks, or deficiencies, which could materially affect our results.

Our information technology systems, as well as those of our CROs and other contractors and consultants, are vulnerable to attack, failure and damage from computer viruses and other malware (e.g., ransomware), unauthorized access or other cybersecurity attacks, malfeasance by external or internal parties, human error (e.g., social engineering, phishing), natural disasters (including hurricanes), terrorism, war, fire and telecommunication or electrical failures. In the ordinary course of our business, we directly or indirectly collect, store and transmit sensitive data, including intellectual property, confidential information, preclinical and clinical trial data, proprietary business information, personal data and personally identifiable health information of our clinical trial subjects and employees, in our data centers and on our networks, or on those of third parties. The secure processing, maintenance and transmission of this information is critical to our operations.

Despite security measures that we and our critical third parties (e.g., service providers and collaborators) implement, our information technology systems may be vulnerable to attacks by hackers or internal bad actors, or breached due to human error, a technical vulnerability, malfeasance or other disruptions. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, level of persistence, intensity and sophistication of attempted attacks and intrusions from around the world have increased. We also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. We may not be able to anticipate all types of security threats, nor may we be able to implement preventive measures effective against all such security threats. The techniques used by cybercriminals change frequently, may not be recognized until launched and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations or hostile foreign governments or agencies. Because of this, we may also experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques, including artificial intelligence (“AI”), that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence.

Additionally, integration of AI in our or any third party’s operations, products or services is expected to pose new or unknown cybersecurity risks and challenges. We cannot assure you that our data protection efforts and our investment in information technology will prevent significant breakdowns, data leakages or breaches in our systems or those of our CROs and other contractors and consultants or that any such significant breakdowns, data leakages or breaches will be timely discovered, disclosed (if applicable) and remediated.

We and certain of our service providers are from time to time subject to cyberattacks and security incidents. While we do not believe that we have experienced any significant system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product candidate development programs. For example, the loss of data from completed, ongoing or planned preclinical studies or clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability, the further development of our product candidates could be delayed and the cost of such further product candidate development could be increased. There can be no assurance that our cybersecurity risk management program and processes, including our policies, controls or procedures, will be fully implemented, complied with or effective in protecting our information technology systems and confidential information.

If a security breach or other incident were to result in the unauthorized access to or unauthorized use, disclosure, release or other processing of personal information, it may be necessary to notify individuals, governmental authorities, supervisory bodies, the media and other parties pursuant to privacy and security laws. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information and significant regulatory penalties, and such an event could disrupt our operations, damage our reputation and cause a loss of confidence in us and our ability to conduct clinical trials, which could adversely affect our reputation and delay and increase the cost of our clinical development of our product candidates. Further, our insurance coverage may not be sufficient to cover the financial, legal, business or reputational losses that may result from an interruption or breach of our systems.

Risks Related to Healthcare Laws and Other Legal Compliance Matters

We are subject to extensive and costly government regulation.

Our product candidates will be subject to extensive and rigorous domestic government regulation, including regulation and oversight by the FDA, the US Centers for Medicare & Medicaid Services ("CMS"), other divisions of US Department of Health & Human Services ("HHS"), the US Department of Justice, state and local governments, and their respective equivalents outside of the US. The FDA regulates the research, development, preclinical and clinical testing, manufacture, safety, effectiveness, record-keeping, reporting, labeling, packaging, storage, approval, advertising, promotion, sale, distribution, import and export of pharmaceutical products. If our products are marketed abroad, they will also be subject to extensive regulation by foreign governments, whether or not they have obtained FDA approval. Such foreign regulation may be equally or more demanding than corresponding US regulation.

Government regulation substantially increases the cost and risk of researching, developing, manufacturing and, if approved, selling our products. The regulatory review and approval process, which includes preclinical testing and clinical trials of each product candidate, is lengthy, expensive and uncertain. We must obtain and maintain regulatory authorization to conduct clinical trials. We must obtain regulatory approval for each product we intend to market, and the manufacturing facilities used for the products must be inspected and meet legal requirements. Securing regulatory approval requires the submission of extensive preclinical and clinical data and other supporting information for each proposed therapeutic indication in order to establish the product's safety and efficacy, potency and purity, for each intended use. The development and approval process takes many years, requires substantial resources, and may never lead to the approval of a product.

Even if we are able to obtain regulatory approval for a particular product, the approval may limit the indicated medical uses for the product, may otherwise limit our ability to promote, sell and distribute the product, may require that we conduct costly post-marketing surveillance, and/or may require that we conduct ongoing post-marketing studies. Material changes to an approved product, such as, for example, manufacturing changes or revised labeling, may require further regulatory review and approval. Once obtained, any approvals may 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 consultants, CMOs, CROs or other vendors, fail to comply with applicable regulatory requirements at any stage during the regulatory process, such noncompliance could result in, among other things, delays in the approval of applications or supplements to approved applications; refusal of a regulatory authority, including the FDA, to review pending market approval applications or supplements to approved applications; warning letters; fines; import and/or export restrictions; product recalls or seizures; injunctions; total or partial suspension of production; civil penalties; withdrawals of previously approved marketing applications or licenses; recommendations by the FDA or other regulatory authorities against governmental contracts; and/or criminal prosecutions.

Moreover, our operations are broadly subject to an evolving regulatory environment. New and changing laws, regulations, executive orders and enforcement priorities can also create uncertainty about how such laws and regulations will be interpreted and applied, which may increase our costs or otherwise adversely impact our business and results of operations.

Enacted and future legislation and policies may increase the difficulty and cost for us to commercialize our product candidates and could adversely affect our business.

In the US, the EU and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities involving any product candidates for which we obtain marketing approval, impact pricing and reimbursement and impact our ability to sell any such products profitably. In particular, there have been and continue to be a number of initiatives at the US federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare, including initiatives with the express purpose of eradicating HCV in the US. In addition, new regulations and interpretations of existing healthcare statutes and regulations are frequently adopted. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we may receive for our product. New and changing laws and regulations may also create uncertainty about how such laws and regulations will be interpreted and applied. If we are found to have violated laws and regulations, it could materially adversely affect our business, results of operations and financial condition.

In March 2010, the Patient Protection and Affordable Care Act ("ACA"), was enacted, which substantially changed the way healthcare is financed in the US by both governmental and private insurers. Among the provisions of the ACA, those of greatest importance to the pharmaceutical and biotechnology industries include the following:

- an annual, non-deductible fee payable by any entity that manufactures or imports certain branded prescription drugs and biologic agents (other than those designated as orphan drugs), which is apportioned among these entities according to their market share in certain government healthcare programs;
- increases and changes in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- extension of a manufacturer's Medicaid rebate liability to covered outpatient drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- a Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and
- establishment of the Center for Medicare and Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial, Congressional and executive challenges to certain aspects of the ACA. On June 17, 2021, the US Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA.

In addition, other legislative changes have been proposed and adopted in the US since the ACA was enacted. Most recently, the One Big Beautiful Bill Act (the "OBBBA"), which was enacted in July 2025, imposes significant reductions in the funding of the Medicaid program. Such reductions in Medicaid funding are expected to decrease the number of persons enrolled in Medicaid and reduce the services covered by Medicaid, which could adversely affect demand for any products for which we receive approval. The OBBBA also modified federal income tax rules relating to the expensing of research and development costs, certain other capital expenditures and certain business interest expense. There can be no assurance that the OBBBA and any resulting administrative guidance would not adversely affect us and the tax consequences to an investor.

In August 2011, the Budget Control Act of 2011 imposed aggregate reductions of Medicare payments to providers, effective April 1, 2013, which, due to subsequent legislative amendments, will stay in effect through 2032. Further, on March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminated the statutory Medicaid drug rebate cap, beginning January 1, 2024. The rebate was previously capped at 100% of a drug's average manufacturer price.

Moreover, payment methodologies may be subject to other changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as outcomes-based reimbursement. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several US executive orders and other executive branch initiatives, Congressional inquiries and proposed and enacted federal legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, and review the relationship between pricing and manufacturer patient programs.

Additionally, on August 16, 2022, the IRA was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation; and replaces the Part D coverage gap discount program with a new discounting program (which began in 2025). The IRA permits the HHS Secretary to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. CMS has published the negotiated prices for the initial ten drugs, which went into effect in 2026, and the subsequent 15 drugs, which will first be effective in 2027. Each year thereafter, more Part B and Part D products will become subject to the HHS price negotiation program, although the program is currently subject to legal challenges. HHS has issued and will continue to issue guidance

implementing the IRA. While the impact of the IRA on us and the pharmaceutical industry cannot yet be fully determined, it is likely to be significant.

The Trump administration is pursuing a two-fold strategy to reduce drug costs in the US. While it is unclear whether and how the Trump administration proposals will be implemented, the Trump administration policies are likely to have a negative impact on the pharmaceutical industry and on our ability to receive adequate revenues for our product candidates, if approved. On the one hand, President Trump has threatened to impose significant tariffs on pharmaceutical manufacturers that do not adopt pricing policies such as most favored nation pricing, which would tie the price for drugs in the US to the lowest price in a group of other countries. In response, multiple manufacturers have reportedly entered into confidential pricing agreements with the federal government. On the other hand, the Trump administration is pursuing traditional regulatory pathways to impose drug pricing policies and published two proposed regulations in December 2025, referred to as Globe and Guard. The final Globe regulation was published in September 2026 and implements a mandatory payment model under which manufacturers of eligible Medicare Part B drugs will be required to pay rebates to the US federal government on a portion of the units of their drugs that are reimbursed by Medicare, with the rebate amount based on most favored nation pricing, although the program is currently subject to legal challenges. The proposed Guard regulations would impose a similar mandatory payment model covering Medicare Part D drugs. We anticipate that each of BEM/RZR for the treatment of HCV and AT-587 for the treatment of HEV, if approved and covered by Medicare, would be classified as Medicare Part D drugs. While the impact of the final Globe and proposed Guard regulations, if finalized, cannot yet be determined, it is likely to be significant. Pharmaceutical pricing and marketing has long been the subject of considerable discussion in Congress and among policymakers, and it is possible that Congress could enact additional laws that negatively affect the pharmaceutical industry.

We expect that additional US federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the US federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Individual states in the US have also increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure, drug price reporting and other transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Some states have enacted legislation creating so-called prescription drug affordability boards, which ultimately may attempt to impose price limits on certain drugs in these states. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, states and other regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. The states of Louisiana and Washington used bidding procedures in 2019 and more recently Minnesota did so in 2021 to secure contracts with suppliers of HCV antiviral therapeutics for certain populations including those covered by Medicare and those in correctional institutions. Other states are currently engaged in similar discussions, and similar programs are being proposed by US federal government legislators. The existing and future state, regional and individual hospital programs, and if enacted, any future federal program, could reduce the ultimate demand for our product candidates or put pressure on our product pricing.

In the EU, similar political, economic and regulatory developments may affect our ability to profitably commercialize our product candidates, if approved. In addition to continuing pressure on prices and cost containment measures, legislative developments at the EU or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the EU, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than EU, law and policy. National governments and health service providers have different priorities and approaches to the delivery of healthcare and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing EU and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize our product candidates, if approved.

In markets outside of the US and the EU, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

Enacted and future legislation and policies may increase the difficulty and cost for us to obtain marketing approval of our product candidates and could adversely affect our business.

In the US, legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA's regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the US, the EU or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability.

Even if we obtain regulatory approval for a product candidate, our products will remain subject to regulatory scrutiny and post-marketing requirements.

Any regulatory approvals that we may receive for our product candidates will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of the product candidate, may contain significant limitations related to use restrictions for groups specified by, among other things, age or medical condition, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements. For example, the FDA may require a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if any of our product candidates is approved, it will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies and submission of safety, efficacy, and other post-market information, including both federal and state requirements in the US and requirements of comparable foreign regulatory authorities. Manufacturers and manufacturers' facilities are required to comply with extensive FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP and similar regulations. As such, we and our CMOs will be subject to continual review and inspections to assess compliance with cGMP and similar requirements and adherence to commitments made in any approved marketing application. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

If the FDA or another regulatory authority discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, such regulatory authorities may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory authority or enforcement authority may, among other things:

- issue warning letters;
- impose civil or criminal penalties;
- suspend or withdraw regulatory approval;
- suspend any of our clinical trials;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our CMO's facilities; or
- seize or detain products, or require a product recall.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory

requirements may adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if any regulatory approval is withdrawn, our business will be seriously harmed.

Moreover, the policies of the FDA and of other regulatory authorities may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the US or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action, and we may not achieve or sustain profitability.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

If any of our product candidates are approved and we are found to have improperly promoted off-label uses of those products, we may become subject to significant liability. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as our product candidates, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If we receive marketing approval for a product candidate, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability. The US federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

Our business operations and current and future relationships with clinical trial investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties.

Our business operations and current and future arrangements with clinical trial investigators, other healthcare professionals, consultants, third-party payors, patient organizations and customers, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, and if approved, market, sell and distribute our product candidates. Such laws include but are not limited to:

- the US federal Anti-Kickback Statute, which makes it illegal for any person to knowingly and willfully solicit, offer, receive, pay or provide any remuneration (including any kickback, bribe or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under US federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the US federal civil and criminal false claims laws, including the civil False Claims Act ("FCA"), which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the US federal government, claims for payment or approval that are false, fictitious or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the US federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The government may deem manufacturers to have "caused" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. Companies that submit claims directly to payors may also be liable under the FCA for the direct submission of such claims. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery. When an entity is determined to have violated the FCA, the government may impose civil fines and penalties for

each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;

- the US federal civil monetary penalties laws, which impose civil fines for, among other things, the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception applies;
- the US federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and its implementing regulations, which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the US federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- the US federal Physician Payments Sunshine Act and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the government information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants and certified nurse midwives), and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members;
- US federal price reporting laws, which require manufacturers to calculate and report complex pricing metrics to government programs, where reported prices may be used in the calculation of reimbursement and/or discounts on approved products;
- US federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- analogous US state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the US federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; and state and local laws that require the registration of pharmaceutical sales representatives; and
- similar healthcare laws and regulations in the EU and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices, including our relationships with physicians and other healthcare providers, some of whom are compensated in the form of stock or stock options for services provided to us and may be in the position to influence the ordering of or use of our product candidates, if approved, may not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties,

including civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment, which could affect our ability to operate our business. Further, defending against any such actions can be costly, time-consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

We are subject to governmental regulation and other legal obligations, particularly related to privacy, data protection and information security, and we are subject to consumer protection laws that regulate our marketing practices and prohibit unfair or deceptive acts or practices. Our actual or perceived failure to comply with such obligations could harm our business.

We are subject to diverse laws and regulations relating to data privacy and security. New privacy rules are being enacted in the US and globally, and existing ones are being updated and strengthened. For example, the California Consumer Privacy Act, as amended by the California Privacy Rights Act (collectively, the “CCPA”), requires covered businesses that process the personal information of California residents to, among other things: (i) provide certain disclosures to California residents regarding the business’s collection, use, and disclosure of their personal information; (ii) receive and respond to requests from California residents to access, delete, and correct their personal information, or to opt out of certain disclosures of their personal information; and (iii) enter into specific contractual provisions with service providers that process California resident personal information on the business’s behalf. Additional compliance investment and potential business process changes may be required. Similar laws have passed in other states, and are continuing to be proposed at the state and federal level, reflecting a trend toward more stringent privacy legislation in the US. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging. Any liability from failure to comply with the requirements of applicable data privacy and data protection laws could adversely affect our financial condition.

Complying with these numerous, complex and often changing regulations is expensive and difficult, and failure to comply with any privacy laws or data security laws or any security incident or breach involving the misappropriation, loss or other unauthorized processing, use or disclosure of sensitive or confidential patient, consumer or other personal information, whether by us, one of our CROs or business associates or another third-party, could adversely affect our business, our operations abroad, financial condition and results of operations. Such adverse effects may include, but are not limited to: investigation costs; material fines and penalties; compensatory, special, punitive and statutory damages; litigation; consent orders regarding our privacy and security practices; requirements that we provide notices, credit monitoring services and/or credit restoration services or other relevant services to impacted individuals; adverse actions against our licenses to do business; reputational damage; and injunctive relief.

Our operations abroad, including the clinical trials we conduct outside the US, may also be subject to scrutiny or attention from data protection authorities. For example, the EU General Data Protection Regulation ("GDPR") went into effect in May 2018, and imposes strict requirements for processing the personal data of individuals within the EEA or in the context of our activities in the EEA. The GDPR and related implementing laws in individual EU member states govern the collection and use of health data and other personal data in the EU including the personal data processed by companies outside the EU in connection with the offering of goods or services to individuals in the EU or the monitoring of their behavior (including in the context of clinical trials). We and other companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. In addition to the foregoing, a breach of the GDPR could result in regulatory investigations, reputational damage, orders to cease / change our processing of our data, enforcement notices, and/ or assessment notices (for a compulsory audit). We and other companies may also face civil claims including representative actions and other class action type litigation (where individuals have suffered harm), potentially amounting to significant compensation or damages liabilities, as well as associated costs, diversion of internal resources, and reputational harm.

Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the US, and the efficacy

and longevity of current transfer mechanisms between the EEA, and the US remains uncertain. On July 10, 2023, the European Commission adopted its Adequacy Decision in relation to the new EU-US Data Privacy Framework ("DPF"), rendering the DPF effective as a GDPR transfer mechanism to US entities self-certified under the DPF. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the standard contractual clauses cannot be used, and/or start taking enforcement action, we could incur additional costs, and may be subject to complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we conduct our business, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

In addition, since January 1, 2021, after the end of the transition period following the UK's departure from the EU, we are also subject to the UK data protection regime (the UK GDPR and UK Data Protection Act 2018), which imposes separate but similar obligations to those under the GDPR and comparable penalties, including fines of up to £17.5 million or 4% of a noncompliant company's global annual revenue for the preceding financial year, whichever is greater. On October 12, 2023, the UK Extension to the DPF came into effect (as approved by the UK Government), as a data transfer mechanism from the UK to US entities self-certified under the DPF. As we continue to expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business.

We cannot assure you that our CROs or other third-party service providers with access to our or our suppliers', trial patients', investigators and clinical site employees' personally identifiable and other sensitive or confidential information in relation to which we are responsible will not breach contractual obligations imposed by us, or that they will not experience data security breaches or attempts thereof, which could have a corresponding effect on our business, including putting us in breach of our obligations under privacy laws and regulations and/or which could in turn adversely affect our business, results of operations and financial condition. We cannot assure you that our contractual measures and our own privacy and security-related safeguards will protect us from the risks associated with the third-party processing, use, storage and transmission of such information. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We face potential liability related to the privacy of health information we obtain from clinical trials sponsored by us.

Most healthcare providers in the US, including research institutions from which we obtain patient health information, are subject to privacy and security regulations promulgated under HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act. We do not believe that we are currently acting as a covered entity or business associate under HIPAA and thus are not directly subject to its requirements or penalties. However, any person may be prosecuted under HIPAA's criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information. Even when HIPAA does not apply, according to the Federal Trade Commission ("FTC"), failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of the Federal Trade Commission Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards.

We, our CROs and third-party service providers receive and maintain sensitive information, including health-related information, that we receive throughout the clinical trial process and in the course of our research collaborations. As such, we may also be subject to state laws, requiring notification of affected individuals and state regulators in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA. Our clinical trial programs and other activities outside the US may implicate international data protection laws, including the UK GDPR, GDPR and legislation of the EU member states implementing it. In addition, the EU imposes obligations on the use of data generated from clinical trials and enables European patients to have the opportunity to access their personal data processed in the context of clinical trials.

Our activities outside the US impose additional compliance requirements and generate additional risks of enforcement for noncompliance. Failure by our CROs and other third-party contractors to comply with the strict

rules on the transfer of personal data outside of the EU into the US may result in the imposition of criminal and administrative sanctions on such collaborators, which could adversely affect our business. Furthermore, certain health privacy laws, data breach notification laws, consumer protection laws and genetic testing laws may apply directly to our operations and/or those of our collaborators and may impose restrictions on our collection, use and dissemination of individuals' health information.

Moreover, patients from whom we or our collaborators obtain health information, as well as the providers who share this information with us, may have statutory or contractual rights that limit our ability to use and disclose the information. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

If we or third-party CMOs, CROs or other contractors or consultants fail to comply with applicable federal, state or foreign regulatory privacy requirements, we could be subject to a range of regulatory actions that could affect our or our contractors' ability to develop and commercialize our product candidates and could harm or prevent sales of any affected products that we are able to commercialize, or could substantially increase the costs and expenses of developing, commercializing and marketing our products. Any threatened or actual government enforcement action could also generate adverse publicity and require that we devote substantial resources that could otherwise be used in other aspects of our business. Increasing use of social media could give rise to liability, breaches of data security or reputational damage. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Our business may be affected by the evolving regulatory framework relating to the use of AI.

We are increasing our use of AI tools and technology throughout our business. The regulatory framework for AI is rapidly evolving as many federal, state, and foreign government bodies and agencies have introduced or are currently considering additional laws and regulations. Additionally, existing laws and regulations may be interpreted in ways that would affect our use of AI.

It is possible that new laws and regulations will be adopted in the US and in other non-US jurisdictions, or that existing laws and regulations, including competition and antitrust laws, may be interpreted in ways that would limit our ability to use AI for our business. The cost of compliance with such laws, regulations, or decisions and/or guidance interpreting existing laws could be significant and would increase our operating expenses (such as by imposing additional reporting obligations regarding our use of AI. Such an increase in operating expenses, as well as any actual or perceived failure to comply with such laws and regulations, could adversely affect our business, financial condition and results of operations.

We are subject to environmental, health and safety laws and regulations, and we may become exposed to liability and substantial expenses in connection with environmental compliance or remediation activities.

Our operations, including our development, testing and manufacturing activities, are subject to numerous environmental, health and safety laws and regulations. These laws and regulations govern, among other things, the controlled use, handling, release and disposal of and the maintenance of a registry for, hazardous materials and biological materials, such as chemical solvents, human cells, carcinogenic compounds, mutagenic compounds and compounds that have a toxic effect on reproduction, laboratory procedures and exposure to blood-borne pathogens. If we fail to comply with such laws and regulations, we could be subject to fines or other sanctions. Moreover, certain environmental laws may impose liability without regard to fault or legality of the action at the time of its occurrence.

As with other companies engaged in activities similar to ours, we face a risk of environmental liability inherent in our current and historical activities, including liability relating to releases of or exposure to hazardous or biological materials. Environmental, health and safety laws and regulations are becoming more stringent. We may be required to incur substantial expenses in connection with future environmental compliance or remediation activities, in which case, the production efforts of our third-party manufacturers or our development efforts may be interrupted or delayed.

We and our employees are increasingly utilizing social media tools as a means of communication both internally and externally.

Despite our efforts to monitor evolving social media communication guidelines and comply with applicable rules, there is risk that the use of social media by us or our employees to communicate about our product candidates or

business may cause us to be found in violation of applicable requirements. In addition, our employees may knowingly or inadvertently make use of social media in ways that may not comply with applicable laws and regulations, our policies and other legal or contractual requirements, which may give rise to regulatory enforcement action, liability, lead to the loss of trade secrets or other intellectual property or result in public exposure of personal information of our employees, clinical trial patients, customers and others. Furthermore, negative posts or comments about us or our product candidates in social media could seriously damage our reputation, brand image and goodwill. Any of these events could have a material adverse effect on our business, prospects, operating results and financial condition and could adversely affect the price of our common stock.

Risks Related to Commercialization

Developments by competitors may render our products or technologies obsolete or non-competitive or may reduce the size of our markets.

Our industry is characterized by extensive research and development efforts, rapid developments in technologies, intense competition and a strong emphasis on proprietary products. We expect our product candidates to face intense competition with existing products and increasing competition as new products enter the relevant markets and advanced technologies become available.

We face potential competition from many different sources, including pharmaceutical, biotechnology and specialty pharmaceutical companies. Academic research institutions, governmental agencies and public and private institutions are also potential sources of competitive products and technologies. Our competitors may have or may develop superior technologies or approaches, which may provide them with competitive advantages. Many of these competitors have products already approved or in development in the therapeutic categories that we are targeting with our product candidates. Either alone or together with their collaborative partners, many of these competitors operate larger research and development programs and have substantially greater financial resources and access to larger pools of capital, including in some cases US government funding, than we do.

Additionally, many of these competitors have greater experience in:

- developing product candidates;
- undertaking preclinical testing and clinical trials;
- obtaining NDA approval by the FDA and comparable approvals of product candidates from foreign regulatory authorities;
- formulating and manufacturing products; and
- launching, marketing and selling products.

If these competitors access the marketplace before we do with effective vaccines or safer, more effective, or less expensive therapeutics, our product candidates, if approved for commercialization, may not be profitable to sell or worthwhile to continue to develop. Technology in the pharmaceutical industry has undergone rapid and significant change, and we expect that it will continue to do so.

In the biopharmaceutical industry, AI is being increasingly used by companies and entities with which we compete. We are increasing our use of AI but other entities may be more advanced in their deployment and use of AI which may enhance such other entities' business operations particularly their discovery efforts and the integration of operational efficiencies in the preclinical and clinical development of product candidates. If we are unable to use AI as effectively as our competitors, we could experience competitive disadvantages.

Any compounds, products or processes that we develop may become obsolete or uneconomical before we recover any expenses incurred in connection with their development. The success of our product candidates will depend upon factors such as product efficacy, safety, reliability, availability, timing, scope of regulatory approval, acceptance and price, among other things. Other important factors to our success include speed in developing product candidates, completing clinical development and laboratory testing, obtaining regulatory approvals and manufacturing and selling commercial quantities of potential products.

For the treatment of HCV, we will face significant competition from approved and authorized oral treatments. The approved HCV drugs are well-established products and are widely-accepted by physicians, patients and third-party payors. For other diseases that we may target, we may face competition from drugs approved for treatment of such diseases as well as other treatments in development.

Our HCV product candidate, if approved, is expected to compete directly or indirectly with existing, currently commercialized products. For example, if we successfully develop and receive marketing approval for our HCV product candidate, we anticipate that we will face competition from currently approved oral antiviral HCV products that are well established and widely accepted by physicians, patients and third-party payors, including products marketed and sold by Gilead Sciences, Inc. ("Gilead Sciences"), Asegua Therapeutics LLC, a wholly owned subsidiary of Gilead Sciences, Inc. and AbbVie Inc. ("AbbVie"). Even if approved and commercialized, our HCV product candidate may fail to achieve market acceptance with hospitals, physicians, patients or third-party payors. Hospitals, physicians, patients or third-party payors may conclude that our product is less safe or effective or otherwise less attractive than existing drugs. If our HCV product candidate or other future product candidates, if any, do not receive market acceptance for any reason, our revenue potential would be diminished, which would materially adversely affect our ability to become profitable. Other product candidates, if any, may also compete with existing products in a similar manner.

Many of our competitors have substantially greater capital resources, access to larger pools of capital, robust product candidate pipelines, established presence in the market, deep and broad commercial infrastructures and greater expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and reimbursement and marketing approved products than we do. As a result, our competitors may be able to maintain market share or achieve product commercialization or patent or other intellectual property protection earlier than we can. For example, in each of May 2023 and October 2024, the US Patent and Trademark Office ("USPTO") granted Gilead Sciences patents in the US that include claims which purportedly covers our compound bemnifosbuvir. While we believe the claims in these patents are invalid and unenforceable and will expire not later than June 15, 2028, if Gilead Sciences asserts either of these patents in an infringement suit, we may not be successful in convincing a trial court that the claims are invalid and unenforceable. In that circumstance, if we were selling or offering to sell BEM/RZR prior to the expiration of these Gilead Sciences patents, we would need to obtain a license from Gilead Sciences covering the then remaining term of the patents, which may not be available on reasonable terms, if at all. If such a license is required and we are unable to agree on license terms, a court may impose license terms, which could result in significant cost for the period we may be commercializing the product prior to the expiration of the patents held by Gilead Sciences.

Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified clinical, regulatory, scientific, sales, marketing and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any products that we may develop or that would render any products that we may develop obsolete or noncompetitive, which would have a material adverse effect on our business and operations.

The successful commercialization of our product candidates will depend in part on the extent to which governmental authorities and health insurers establish coverage, adequate reimbursement levels and pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate product revenue.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. Our ability to successfully commercialize our product candidates will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. The availability of coverage and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford treatments.

Third-party payors increasingly are challenging prices charged for pharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs and biologics when an equivalent generic drug, biosimilar or a less expensive therapy is available. It is possible that a third-party payor may consider our product candidates as substitutable and only offer to reimburse patients for the less expensive product. Even if we show improved efficacy, shorter duration or improved convenience of administration with our product candidates, pricing of existing third-party therapeutics may limit the amount we will be able to charge for our product candidates. Payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in our product candidates. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates and may not be able to obtain a satisfactory financial return on our product candidates.

In the US, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologics will be covered and reimbursed. The Medicare program is increasingly used as a model for how private and other governmental payors develop their coverage and reimbursement policies for new drugs. However, no uniform policy for coverage and reimbursement for products exists among third-party payors in the US. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to meet specified annual timelines set by certain payors for formulary inclusion decisions, in addition to providing scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Some third-party payors may require pre-approval of coverage for new or innovative drug therapies before they will reimburse healthcare providers who use such therapies. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases on short notice, and we believe that changes in these rules and regulations are likely. We cannot predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

Outside the US, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in the EU and other jurisdictions have and will continue to put pressure on the pricing and usage of our product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the US, the reimbursement for our product candidates may be reduced compared with the US and may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and third-party payors in the US and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. For example, the future value of the US HCV market may be impacted by payors obtaining additional discounts from manufacturers and by payor contracting dynamics. Medicaid agencies in certain individual states have enacted HCV treatment subscription models where manufacturers provide unrestricted access to their antiviral medication for a capitated total price and the Medicaid agencies in other states may in the future enact such HCV treatment subscription models. Contract duration and restrictions of such agreements could impact the ability of the non-awarded HCV oral antivirals to compete. In addition, future US government sponsored HCV eradication initiatives, including federal programs similar to state HCV treatment subscription programs, could impact the HCV market opportunity. While future US government sponsored HCV programs could significantly expand the number of HCV infected patients being treated, it also could negatively impact market value and access to many HCV oral antivirals including products such as ours.

We expect to experience pricing pressures in connection with the sale of our product candidates due to the presence of approved, and in the case of HCV, authorized generic, products already in many marketplaces, the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional changes resulting from legislative actions, including the IRA and other governmental initiatives. The downward pressure on healthcare costs in general, particularly prescription drugs and biologics and other treatments, has become intense. As a result, increasingly high barriers are being erected to the entry of new products.

If we are unable to establish sales, marketing and distribution capabilities either on our own or in collaboration with third parties, we may not be successful in commercializing any of our product candidates, if approved, and we may not be able to generate any product revenue.

We have limited personnel and limited infrastructure for the sales, marketing or distribution of products, and no experience as a company in commercializing a product candidate. The cost of building and maintaining such an organization may exceed the cost-effectiveness of doing so.

Currently, we anticipate to establish our own commercial organization for the purpose of commercializing in the US our HCV product candidate, if approved. Outside the US, we anticipate to rely on one or more collaborators to commercialize our HCV product candidate, if approved. We do not currently have any commercialization arrangements in place with any collaborator or other third parties either within or outside the US and we may be unable to enter into acceptable arrangements to do so.

There are significant expenses and risks involved with building our own sales, marketing and distribution capabilities, including our ability to hire, retain and appropriately incentivize qualified individuals, generate sufficient sales leads, provide adequate training for sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities could delay the product launch, and adversely impact the commercialization of our product candidates, if approved. Additionally, if the commercial launch of our product candidates for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our product candidates on our own include but are not limited to:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe our future products;
- our inability to equip medical and sales personnel with effective materials, including medical and sales literature to help them educate physicians and other healthcare providers regarding applicable diseases and our future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- our inability to develop or obtain sufficient operational functions to support our commercial activities; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

In those territories where we engage a collaborator to commercialize our products in whole or in part our sales will depend on the collaborator’s strategic interest in the product and such collaborator’s ability to successfully commercialize the product.

If we are unable to build our own sales force or access a collaborative relationship for the commercialization of any of our product candidates, we may be forced to delay the potential commercialization of our product candidates or reduce the scope of our sales or marketing activities for such product candidates. If we elect to increase our expenditures to fund additional commercialization activities ourselves, we will need to obtain additional capital, which may not be available to us on acceptable terms, or at all. We could enter into arrangements with collaborative partners at an earlier stage than otherwise would be ideal and we may be required to relinquish rights to any of our product candidates or otherwise agree to terms unfavorable to us, any of which may have an adverse effect on our business, operating results and prospects.

If we are unable to establish adequate sales, marketing and distribution capabilities, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates and may not become profitable and may incur significant additional losses. We will be competing with many companies, including large pharmaceutical companies, and specifically Gilead Sciences and AbbVie in HCV, that have extensive and well-funded marketing and sales operations. Without a robust internal team or the support of

third-parties to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

In addition, even if we do establish adequate sales, marketing and distribution capabilities, the progress of general industry trends with respect to pricing models, supply chains and delivery mechanisms, among other things, could deviate from our expectations. If these or other industry trends change in a manner which we do not anticipate or for which we are not prepared, we may not be successful in commercializing our product candidates or become profitable.

Our future growth may depend, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future profitability may depend, in part, on our ability to commercialize our product candidates in foreign markets. Currently, we anticipate to rely on third party collaborators for such foreign market commercialization. We are evaluating potential collaborations and opportunities for the commercialization of our product candidates in foreign markets but currently we do not have any collaboration agreements or arrangements in place. Neither we or any third party with which we may collaborate is permitted to market or promote any of our product candidates before regulatory approval of such product candidate is received from the applicable regulatory authority in that foreign market, and such regulatory approval for any of our product candidates may never result. To obtain regulatory approvals in countries outside the US, it will be necessary to comply with numerous and varying regulatory requirements of such countries regarding the safety and efficacy of our product candidates and governing, among other things, clinical trials and commercial sales, pricing and distribution of our product candidates, and we cannot predict success in these jurisdictions. If we obtain approval of our product candidates and ultimately commercialize such product in foreign markets, we would be subject to additional risks and uncertainties, including but not limited to:

- our customers' ability to obtain reimbursement for our product candidates in foreign markets;
- our inability to directly control commercial activities of any third parties upon which we are relying;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- import or export licensing requirements;
- our ability, or the ability of our collaborators, to supply our products on a timely and large-scale basis in local markets;
- longer lead times for shipping which may necessitate local manufacture of our products;
- language barriers for technical training and the need for language translations;
- reduced protection of patent and other intellectual property rights in some foreign countries;
- the existence of additional potentially relevant third-party intellectual property rights;
- longer accounts receivable collection times;
- foreign currency exchange rate fluctuations; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

Foreign sales of any product for which we obtain approval could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs.

If any of our product candidates are approved for commercialization outside the US, we currently anticipate to selectively partner with third parties to market such product in the territories in which approval has been obtained. In connection with the marketing of a product outside the US, we expect that we will be subject to additional risks related to international pharmaceutical operations, including but not limited to:

- different regulatory requirements for drug approvals and rules governing drug commercialization in foreign countries;
- reduced protection for patent and other intellectual property rights;

- foreign reimbursement, pricing and insurance regimes;
- potential noncompliance with the US Foreign Corrupt Practices Act, the U.K. Bribery Act 2010 and similar anti-bribery and anticorruption laws in other jurisdictions; and
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad.

As an organization, we have no prior experience in these areas. In addition, we may need to comply with complex regulatory, tax, labor and other legal requirements imposed by both the EU and many of the individual member states in the EU as well as in other global territories. Many US-based biotechnology and biopharmaceutical companies have found the process of marketing products outside of North America to be very challenging.

Certain legal and political risks are also inherent in foreign operations without regard to whether these activities are conducted by us or by a collaborator. There is a risk that foreign governments may nationalize private enterprises in certain countries where any collaborator with which we are collaborating may operate. In certain countries or regions, terrorist activities and the response to such activities may threaten our operations or the operations of any collaborator to a greater degree than in the US. Social and cultural norms in certain countries may not support compliance with our corporate policies, including those that require compliance with substantive laws and regulations. Also, changes in general economic and political conditions in countries where we may operate are a risk to our financial performance and future growth.

Additionally, the need to identify financially and commercially strong partners for commercialization outside the US who will comply with the high manufacturing and legal and regulatory compliance standards we require is a risk to our financial performance. As we operate our business globally, our success will depend, in part, on our ability to anticipate and effectively manage these and other related risks. There can be no assurance that the consequences of these and other factors relating to our international operations will not have an adverse effect on our business, financial condition or results of operations.

In many countries outside the US, particularly in the EU, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a drug. To obtain reimbursement or pricing approval in some countries, we may be required to conduct clinical trials that compare the cost-effectiveness of our product candidates to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

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

Currently, we face an inherent risk of product liability claims as a result of the testing of our product candidates and we will face product liability risks if we, or a collaborator, commercialize any of our product candidates that are approved. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. On occasion, large judgments have been awarded in class action lawsuits based on products that had unanticipated adverse effects. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs, which may not be covered by insurance. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- injury and impairment of our business reputation and significant negative media attention;
- withdrawal of participants from our clinical trials;
- initiation of investigations by regulators;
- significant costs to defend the claims and related litigation;
- distraction of management’s attention from our primary business;
- substantial monetary awards to patients or other claimants;
- inability to commercialize a product candidate;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- exhaustion of any available insurance and our capital resources;

- decreased demand for a product candidate, if approved for commercial sale; and
- loss of revenue.

Failure to obtain or retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with commercial collaborators. To date, we have not sought and do not yet have any experience securing product liability insurance for a product that is being commercialized. Currently, we have clinical trial insurance to cover the use of our product candidates in the clinical trials we are conducting. However, these insurance policies have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future commercial collaborators entitle us to indemnification against product liability claims and associated losses, such indemnification may not be available or adequate should any claim or loss arise.

Risks Related to Manufacturing and our Dependence on Third Parties

We rely and expect to continue to rely on third parties for the manufacture of materials for our research programs, preclinical studies and clinical trials and, if approved, commercialization. We do not currently have long-term contracts with any of these parties. This reliance on third parties increases the risk that we will not have sufficient quantities of such materials or any product candidates that we may develop and, if approved, commercialize, or that such supply will not be available to us at an acceptable cost, which could delay, prevent, or impair our development or commercialization efforts.

We rely and expect to continue to rely on third parties for the manufacture of materials for our clinical trials, research activities and preclinical development. We expect to rely on third parties for commercial manufacture if any of our product candidates receive marketing approval. We do not currently have long-term agreements with any of the third-party manufacturers we currently use to provide preclinical and clinical trial materials, and we purchase any required materials on a purchase order basis. Certain of these manufacturers are critical to our production and the loss of these manufacturers, or an inability to obtain quantities at an acceptable cost or quality, could delay, prevent or impair our ability to timely conduct preclinical studies or clinical trials or seek regulatory approval and would materially and adversely affect our development and commercialization efforts.

We may be unable to maintain or establish required agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including but not limited to:

- the failure of the third-party to manufacture our product candidates according to our schedule, or at all, including if our third-party contractors give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them as a result of accidents, fire, loss of personnel, business decisions at or by the third-party manufacturer or otherwise;
- the reduction or termination of production or deliveries by suppliers, or the raising of prices or renegotiation of terms;
- the termination or nonrenewal of arrangements or agreements by our third-party contractors at a time that is costly or inconvenient for us;
- the breach by the third-party contractors of our agreements with them;
- the failure of third-party contractors to comply with applicable regulatory requirements;
- the failure of the third-party to manufacture our product candidates according to our specifications;
- the mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or placebo not being properly identified;
- improper handling of clinical supplies, whether during transit or otherwise, impacting the quality of such clinical supplies leading to loss of GMP status and the resulting inability to use such clinical supplies in clinical trials which may result in clinical interruptions and delays in the commencement of planned clinical trials;

- clinical supplies not being delivered to clinical sites on time, leading to delays in the commencement of planned clinical trials or interruptions in ongoing clinical trials, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales; and
- the misappropriation or unauthorized disclosure of our intellectual property or other proprietary information, including our trade secrets and know-how.

Any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or changes in global, political, regulatory and economic conditions affecting US trade, manufacturing, development or investment, could result in additional restrictions on our ability to manufacture materials for our research programs, preclinical studies, clinical trials and our manufacture of product for commercialization, if approved, or significantly increase our costs. In recent years, the US has instituted or proposed changes in trade policies that include the negotiation or termination of trade agreements, the imposition of higher tariffs on imports into the US, economic sanctions on individuals, corporations or countries, and other government regulations affecting trade between the US and other countries, in particular China, Mexico, Canada and the EU. A number of other nations have proposed or instituted similar measures directed at trade with the US in response. As a result of these developments, there may be greater restrictions and economic disincentives on international trade that could adversely affect our business. Various tariffs enacted by the US federal government in 2025 have been subject to successful legal challenge leading to some tariffs being refunded, but the extent to which the US federal government may attempt to impose new or similar tariffs under alternative statutory mechanisms remains unclear. For example, recently the administration imposed new tariffs under Section 301 of the Trade Act of 1974. As additional trade-related policies are instituted, we may need to modify our business operations to comply and adapt to such developments, which may be time-consuming and expensive.

For ruzasvir, we have a sole supplier located in China for our active pharmaceutical ingredient, and for both ruzasvir and bemnifosbuvir, all suppliers of the regulatory starting materials for the respective manufacturing processes are located in China. We expect to continue to use such third-party manufacturers including for the manufacture of commercial supply, if approved. Any disruption in production or inability of our manufacturers in China to produce adequate quantities to meet our needs, including as a result of a natural disaster, public health crises, trade disruptions, or changes in the US trade policies, could impair our ability to operate our business on a day-to-day basis and adversely impact our ability to continue the research and development of our product candidates and, if approved, to commercialize our products. Tariffs on certain Chinese origin goods may impact the cost of manufactured materials we import from China for our research programs, preclinical studies and clinical trials and for commercialization of products, if any, that may be approved. Additionally, the indirect impact of inflationary pressure on costs throughout the supply chain may result in higher input costs, which could have a material adverse effect on our business, prospects, results of operations and cash flows.

We do not have complete control over all aspects of the manufacturing process of, and are dependent on, our contract manufacturing partners for compliance with cGMP regulations and similar regulatory requirements for manufacturing both active drug substances and finished drug products. Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the US. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA and other applicable regulatory authorities, they will not be able to secure and/or maintain authorization for their manufacturing facilities. In addition, we do not have control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not authorize these facilities for the manufacture of our product candidates or if it withdraws any such authorization in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain marketing approval for or, if approved, market our products. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates or drugs and harm our business and results of operations.

Our third-party manufacturers may be unable to successfully scale up manufacturing of our product candidates in sufficient quality and quantity in a timely manner, if at all, which may impair the clinical advancement and commercialization of our product candidates.

In order to conduct clinical trials of our product candidates and commercialize any approved product, our manufacturers need to manufacture them in large quantities. However, they may be unable to successfully increase the manufacturing capacity for any of our product candidates or products in a timely or cost-effective

manner, or at all. In addition, quality issues may arise during scale-up activities. If we, or any manufacturers are unable to successfully scale up the manufacture of our product candidates in sufficient quality and quantity in a timely manner, the development, testing and clinical trials of these product candidates may be delayed or infeasible, and regulatory approval or commercial launch and sustained commercialization of any resulting products may be delayed or not obtained, which could significantly harm our business. Supply sources could be interrupted from time to time and, if interrupted, would disrupt our manufacturers' ability to manufacture our product candidates at the scale required. If we are unable to meet the clinical or commercial supply need for our product candidates, or to do so on commercially reasonable terms, we may not be able to develop our product candidates and commercialize our products successfully.

We do not have multiple sources of supply for all of the components used in our product candidates, nor long-term supply contracts, and certain of our suppliers are critical to our production. If we were to lose a critical supplier, it could have a material adverse effect on our ability to complete the development of our product candidates and our efforts to manufacture products for commercialization, if approved. If we obtain regulatory approval and seek to commercialize any approved product we will need to expand the number of manufacturers supplying components of such approved product.

We do not have multiple sources of supply for all of the components used in the manufacture of bemnifosbuvir or ruzasvir. For ruzasvir, we have a sole supplier located in China for our active pharmaceutical ingredient, and for both ruzasvir and bemnifosbuvir, all suppliers of the regulatory starting materials for the respective manufacturing processes are located in China. We do not have long-term supply agreements with any of our component suppliers. We may not be able to establish additional sources of supply for our product candidates, or may be unable to do so in a timely manner or on acceptable terms. Manufacturing suppliers are subject to cGMP and comparable foreign quality standards and requirements covering manufacturing, testing, quality control and record keeping relating to our product candidates and subject to ongoing inspections by applicable regulatory authorities. Manufacturing suppliers are also subject to local, state and federal regulations and licensing requirements. Failure by any of our suppliers to comply with all applicable regulations and requirements may result in long delays and interruptions in supply.

The number of suppliers of the components of our product candidates is limited. In the event it is necessary or desirable to acquire supplies from alternative suppliers, we might not be able to obtain them in a timely manner or on commercially reasonable terms, if at all. It could also require significant time and expense to redesign our manufacturing processes to work with another manufacturer and redesign of processes can trigger the need for conducting additional clinical studies such as comparability or bridging studies. Additionally, certain of our suppliers are critical to our production, and the loss of these suppliers to one of our competitors or otherwise would materially and adversely affect our development and commercialization efforts.

As part of any application for marketing approval, regulatory authorities generally conduct inspections that must be satisfactory prior to the approval of the product. Failure of manufacturing suppliers to successfully complete these regulatory inspections could result in delays or prevent the approval of our product candidates. In addition, if supply from the supplier of an approved product is interrupted, there could be a significant disruption in commercial supply. An alternative vendor would need to be qualified through an NDA amendment or supplement, which could result in further delay. The FDA or other regulatory authorities outside of the US may also require additional studies if a new supplier is relied upon for commercial production. Switching vendors may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

If we are unable to obtain the supplies we need at a reasonable price or on a timely basis, it could have a material adverse effect on our ability to complete the development of our product candidates or, if we obtain regulatory approval for our product candidates, to commercialize them.

We rely on third parties to conduct our preclinical studies and clinical trials. Any failure by a third-party to conduct the clinical trials according to GCPs and in a timely manner may delay or prevent our ability to seek or obtain regulatory approval for or commercialize our product candidates.

We are dependent on third parties to conduct critical aspects of the Phase 3 and other clinical development activities for our HCV product candidate, BEM/RZR. We are also dependent on third parties to conduct the clinical development of AT-587, our HEV product candidate. Specifically, we have used and relied on, and intend to continue to use and rely on, medical institutions, clinical investigators, CROs and consultants to conduct our clinical trials in accordance with our clinical protocols and regulatory requirements. These CROs, investigators and other third parties play a significant role in the conduct and timing of these trials and subsequent collection and analysis of data. While we have agreements governing the activities of our third-party contractors, we have

limited influence over their actual performance. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs and other third parties does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for all of our product candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs or trial sites fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials or research activities complies with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP or similar regulations outside the US. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory review process.

Any third parties conducting our clinical trials or preclinical studies are not and will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot guarantee that any such CROs, investigators or other third parties will devote adequate time and resources to such trials or perform as contractually required. If any of these third parties fail to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, or otherwise performs in a substandard manner, our clinical trials may be extended, delayed or terminated. In addition, many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities that could harm our competitive position.

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive monetary or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA or foreign regulatory authorities conclude that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned, and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of any NDA or similar applications we submit to the FDA or foreign regulatory authorities. Any such delay or rejection could prevent us from commercializing our product candidates.

Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs and substantially all our clinical trial sites have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination.

If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties or do so on commercially reasonable terms. Switching or adding additional CROs, investigators and other third parties involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which could materially impact our ability to meet our desired clinical development and regulatory submission timelines. Though we carefully manage our relationships with our CROs, investigators and other third parties, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We currently expect that we may collaborate with third parties in connection with the commercialization of our product candidates, if approved. We may not succeed in establishing and maintaining collaborative relationships, which may significantly limit our ability to develop and commercialize our product candidates successfully, if at all.

For commercialization of any of our product candidates that may be approved, our current strategy includes the potential establishment of collaborative relationships with third parties. As a result of entering into collaborative arrangements with third parties, we would become dependent on the amount and timing of resources that our collaborators dedicate to the development or potential commercialization of any product candidates we may seek to develop or commercialize with them. Our ability to generate product revenue from any collaborations will depend on our collaborators' abilities to successfully perform the functions assigned to them. We cannot predict the success of any collaboration that we enter into.

Collaborations involving our product candidates involve many risks, including:

- collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not properly obtain, maintain, enforce or defend intellectual property or proprietary rights relating to our product candidates or may use our proprietary information inappropriately or in such a way as to expose us to potential litigation or other intellectual property-related proceedings, including proceedings challenging the scope, ownership, validity and enforceability of our intellectual property;
- collaborators may own or co-own intellectual property rights covering our product candidates that result from our collaboration with them, and in such cases, we may not have the exclusive right to commercialize such intellectual property or such product candidates;
- disputes may arise with respect to the ownership of intellectual property developed pursuant to collaborations;
- we may need the cooperation of our collaborators to enforce or defend any intellectual property we contribute to or that arises out of our collaborations, which may not be provided to us;
- collaborators may infringe, misappropriate or otherwise violate the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborators may terminate the collaboration, and, as a result, we may not be able to develop a product candidate or we will have to use our own clinical resources and capital to continue development of the product candidates;
- collaborators may decide not to pursue development and commercialization of any product candidates we develop or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus or available funding or external factors, such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive;
- collaborators with marketing and distribution rights to one or more product candidates may not commit sufficient resources to the marketing and distribution of such product candidates;
- we may lose certain valuable rights under circumstances identified in our collaborations, including if we undergo a change of control;
- collaborators may undergo a change of control and the new owners may decide to take the collaboration in a direction that is not in our best interest;
- collaborators may become party to a business combination transaction and the continued pursuit and emphasis on our development or commercialization program by the resulting entity under our existing collaboration could be delayed, diminished or terminated;
- collaborators may become bankrupt, which may significantly delay our research or development programs, or may cause us to lose access to valuable technology, devices, materials, know-how or intellectual property of the collaborator relating to our product candidates;
- key personnel at our collaborators may leave, which could negatively impact our ability to productively work with our collaborators;
- collaborations may require us to incur short- and long-term expenditures, issue securities that dilute our stockholders, or disrupt our management and business;

- collaborations may be terminated which may result in a need for additional capital to pursue further development or commercialization or result in delays in development or commercialization of the applicable product candidates; and
- collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all.

We may face significant competition in seeking appropriate collaborations. Business combinations among biopharmaceutical and pharmaceutical companies have resulted in a reduced number of potential collaborators. In addition, the negotiation process is time-consuming and complex, and we may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate or delay its potential commercialization or reduce the scope of any sales, marketing or distribution activities, or increase our expenditures and undertake development, manufacture or commercialization activities at our own expense. If we elect to increase our expenditures to fund development, manufacture or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop product candidates or bring them to market and generate product revenue.

If we enter into collaborations to develop, manufacture and potentially commercialize any product candidates, we may not be able to realize the benefit of such transactions if we or our collaborator elect not to exercise the rights granted under the agreement or if we or our collaborator are unable to successfully integrate a product candidate into existing operations. In addition, if our agreement with any of our collaborators terminates, our access to technology and intellectual property licensed to us by that collaborator may be restricted or terminate entirely, which may delay our continued development of our product candidates utilizing the collaborator's technology or intellectual property or require us to stop development of those product candidates completely. For example, if the license agreement with Merck was terminated, we would be required to discontinue the development, manufacture and commercialization of our lead product candidate, which is the fixed-dose combination of ruzasvir and bemnifosbuvir, unless we could enter into another agreement with Merck potentially on terms less favorable to us. We may also find it more difficult to find a suitable replacement collaborator or attract new collaborators, and our development programs may be delayed or the perception of us in the business and financial communities could be adversely affected. Any collaborator may also be subject to many of the risks relating to product development, regulatory approval, and commercialization described in this "Risk Factors" section, and any negative impact on our collaborators may adversely affect us.

Data provided by collaborators and others upon which we rely that have not been independently verified could turn out to be false, misleading or incomplete.

We rely on third-party vendors, such as CROs, CMOs, investigators, scientists and other service providers to provide us with significant data and other information related to our programs, preclinical studies or clinical trials and our business. If such third parties provide inaccurate, misleading or incomplete data, our business, prospects and results of operations could be materially adversely affected.

Our employees and independent contractors, including principal investigators, CROs, consultants, vendors and any third parties we may engage in connection with research, development, regulatory, manufacturing, quality assurance and other pharmaceutical functions and commercialization may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.

Misconduct by our employees and independent contractors, including principal investigators, CROs, consultants, vendors and any third parties we may engage in connection with research, development, regulatory, manufacturing, quality assurance and other pharmaceutical functions and commercialization, could include intentional, reckless or negligent conduct or unauthorized activities that violate: (i) the laws and regulations of the FDA, and other similar regulatory authorities, including those laws that require the reporting of true, complete and accurate information to such authorities; (ii) manufacturing standards; (iii) data privacy, security, anti-corruption, fraud and abuse and other healthcare laws and regulations; or (iv) laws that require the reporting of true, complete and accurate financial information and data. Specifically, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws could also involve the improper use or

misrepresentation of information obtained in the course of preclinical studies or clinical trials, creation of fraudulent data in preclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to 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 have a significant impact on our business and results of operations, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid, other US federal healthcare programs or healthcare programs in other jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, individual imprisonment, other sanctions, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations.

If our CMOs and CROs use hazardous materials in a manner that causes injury or violates applicable law, we may be liable for damages.

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical materials by our CMOs and medical and biological materials by our CROs. Our CMOs and CROs are subject to federal, state and local laws and regulations in the US and in the countries in which they operate governing the use, manufacture, storage, handling and disposal of hazardous materials. Although we believe that our CMOs' and CROs' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from chemical, medical, biological or other potentially hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. Generally, we do not have any insurance for liabilities arising from the improper handling of chemical, medical, biological or other potentially hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

Risks Related to Intellectual Property

If we are unable to obtain, maintain, enforce and adequately protect our intellectual property rights with respect to our technology and product candidates, or if the scope of the patent or other intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully develop and commercialize our technology and product candidates may be adversely affected.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect our intellectual property and prevent others from duplicating AT-511 (the free base of bemnifosbuvir), bemnifosbuvir and our in-licensed compound ruzasvir and their use or manufacture, or any of our other pipeline product candidates and any future product candidates. Our success depends in large part on our ability to obtain and maintain patent protection in the US and other countries with respect to such product candidates.

The patent prosecution process is expensive, time-consuming, and complex, and we may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patents or patent applications at a reasonable cost or in a timely manner. Although we enter into confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, CROs, consultants, scientific advisors and other contractors, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the US and other jurisdictions are typically not published until 18 months after filing, and some remain so until issued. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file any patent application related to an invention or product candidate. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced.

The strength of patents in the pharmaceutical field involves complex legal, factual and scientific questions and can be uncertain. It is possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. The patent applications that we own may fail to result in issued patents with claims that cover our product candidates in the US or in other foreign countries. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue and even if such patents cover our product candidates, third parties may challenge the inventorship, ownership, validity, enforceability or scope of such patents, which may result in such patents being narrowed or invalidated, or being held unenforceable. Our pending and future patent applications may not result in patents being issued which protect our technology or product candidates or which effectively prevent others from commercializing competitive technologies and product candidates. Additionally, any US provisional patent application that we file is not eligible to become an issued patent until, among other things, we file a non-provisional patent application within 12 months of filing the related provisional patent application. If we do not timely file any non-provisional patent application, we may lose our priority date with respect to the provisional patent application and any patent protection on the inventions disclosed in the provisional patent application.

Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates or prevent others from designing around our claims. In addition, no assurances can be given that third parties will not create similar or alternative products or methods that achieve similar results without infringing upon our patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

If the patent applications we hold with respect to our programs or product candidates fail to issue, if the breadth or strength of protection of our current or future issued patents is threatened, or if they fail to provide meaningful exclusivity for our product candidates, it could dissuade companies from collaborating with us to develop product candidates, or threaten our ability to commercialize our current or future product candidates. Several patent applications covering our HCV product candidate have been filed recently by us. We cannot offer any assurances about which, if any, will result in issued patents, the breadth of any such patents or whether any issued patents will be found invalid or unenforceable or will be threatened by third parties. Any successful opposition to these patents or any other patents owned by us could deprive us of rights necessary for the successful commercialization of any product candidates that we may develop.

The issuance of a patent is not conclusive as to its inventorship, ownership, scope, validity or enforceability, and our patents may be challenged in courts or patent offices in the US and abroad. In addition, the issuance of a patent does not give us the right to practice the patented invention, as third parties may have blocking patents that could prevent us from marketing our product candidate, if approved, or practicing our own patented technology.

Wide-ranging patent reform legislation in the US, including the Leahy-Smith America Invents Act of 2011 (“Leahy-Smith Act”), may increase the uncertainty of the strength or enforceability of our intellectual property and the cost to defend it. The Leahy-Smith Act reforms included a number of significant changes to US patent law, including provisions that affect the way patent applications are prosecuted and also affect patent litigation. Under the Leahy-Smith Act, the US transitioned from a “first-to-invent” to a “first-to-file” system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. This will require us to be prompt going forward during the time from invention to filing of a patent application and to be diligent in filing patent applications, but circumstances could prevent us from promptly filing or prosecuting patent applications on our inventions. The Leahy-Smith Act also enlarged the scope of disclosures that qualify as prior art. Furthermore, if a third-party filed a patent application before effectiveness of applicable provisions of the Leahy-Smith Act, on March 16, 2013, an interference proceeding in the US can be initiated by a third-party to determine if it was the first to invent any of the subject matter covered by the claims of our patent applications. We may also be subject to a third-party preissuance submission of prior art to the USPTO.

The Leahy-Smith Act created for the first time new procedures to challenge issued patents in the US, including post-grant review, inter partes review and derivation proceedings, which are adversarial proceedings conducted at the USPTO, which some third parties have been using to cause the cancellation of selected or all claims of issued patents of competitors. For a patent with a priority date of March 16, 2013 or later, which all of our patent filings have, a petition for post-grant review can be filed by a third-party in a nine-month window from issuance of the patent. A petition for inter partes review can be filed immediately following the issuance of a patent if the patent was filed prior to March 16, 2013. A petition for inter partes review can be filed after the nine-month period for filing a post-grant review petition has expired for a patent with a priority date of March 16, 2013 or later. Post-grant review proceedings can be brought on any ground of challenge, whereas inter partes review proceedings

can only be brought to raise a challenge based on published prior art. These adversarial actions at the USPTO include review of patent claims without the presumption of validity afforded to US patents in lawsuits in US federal courts. The USPTO issued a final rule effective November 13, 2018 announcing that it will now use the same claim construction standard currently used in the US federal courts to interpret patent claims in USPTO proceedings, which is the plain and ordinary meaning of words used. If any of our patents are challenged by a third-party in such a USPTO proceeding, there is no guarantee that we will be successful in defending the patent, which would result in a loss of the challenged patent right to us, including loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us.

As a result of all of the foregoing, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Third-party claims of intellectual property infringement, misappropriation or other violation may result in substantial costs or prevent or delay our development and commercialization efforts.

Our commercial success depends in part on our avoiding actual and allegations of infringement, misappropriation or other violation of the patents and other proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the US, involving patent and other intellectual property rights in the pharmaceutical industry, including patent infringement lawsuits, interferences, oppositions, re-examination, and post-grant and inter partes review proceedings before the USPTO and similar proceedings in foreign jurisdictions, such as oppositions before the European Patent Office (“EPO”). Numerous US and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are pursuing development candidates. As the pharmaceutical industry expands and more patents are issued, and as third parties become more aware of our product pipeline, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

For example, in March 2021, fourteen years after its priority date, Gilead Sciences first presented a patent claim to the USPTO that purports to cover bemnifosbuvir. On May 9, 2023, the USPTO issued US Patent No. 11,642,361 (“ ‘361 patent”) with an amended claim (“Claim”) to Gilead Sciences that purports to cover bemnifosbuvir. We believe that the ‘361 patent, if valid and enforceable, will expire on June 15, 2028. On August 7, 2023, we filed a Post Grant Review Petition with the USPTO Patent Trial and Appeal Board (“PTAB”), challenging the issuance of the Claim to Gilead, on the basis that the Claim is not supported by the written description of the ‘361 patent and that the ‘361 patent does not have an enabling disclosure for the Claim. In February 2024, the PTAB denied to exercise its discretion to institute the post grant proceeding. This denial does not stop us from making the same or similar arguments, or additional arguments, nor from bringing the same or new evidence of invalidity or unenforceability in court if Gilead Sciences files an infringement suit. However, while we believe this Claim is invalid and unenforceable, a trial court or an appellate court may disagree and uphold the Claim of the '361 patent, which would require us, prior to commercialization of a product candidate containing bemnifosbuvir to obtain a license from Gilead Sciences to the ‘361 patent. Such a license may not be available on reasonable terms or at all. If a license is required and we are unable to obtain such license, commercialization of approved product candidates, if any, containing bemnifosbuvir may not be able to continue without infringement which could result in significant cost during the period we commercialize any such product prior to the expiration of the ‘361 patent.

On October 22, 2024, seventeen years after its priority date, the USPTO issued US Pat. No. 12,121,529 (“ '529 patent”) to Gilead Sciences with claims that again purport to cover bemnifosbuvir. We believe that the '529 patent will expire on March 21, 2028. While we believe these claims are also invalid and unenforceable, a trial court or an appellate court may disagree and uphold one or more claims of the '529 patent, which would require us to obtain a license from Gilead Sciences to the '529 patent prior to commercialization of a bemnifosbuvir product candidate. Such a license may not be available on reasonable terms or at all. If a license is required and we are unable to obtain such license, commercialization of approved product candidates, if any, containing bemnifosbuvir may not be able to continue without infringement which could result in significant cost during the period we commercialize any such product prior to the expiration of the '529 patent.

Third party claimants may have substantially greater resources than we do and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to composition of matter, drug delivery, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. We cannot guarantee that our technologies, products, compositions and their uses do not or will not infringe, misappropriate or otherwise violate third-party patent or other intellectual property rights. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Pending patent applications that have been published can, or subject to certain limitations, later present claims in a manner that could cover our product candidates or the use of our product candidates. After issuance, the scope of patent claims remains subject to construction as determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history.

Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our product candidates. To challenge the validity of a US patent, we would need to initiate an action either in federal court or at the PTAB. Alternatively, a challenge to validity of a US patent could be brought by us in defense to an allegation of infringement by a third party. An action brought before the PTAB must be timely submitted within nine months of the issuance of the patent we are seeking to challenge unless based on published prior art. In either a PTAB or federal court proceeding, there is no assurance that the PTAB or a court of competent jurisdiction would invalidate the claims of any such US patent or, if a PTAB decision is appealed, that a federal court would uphold a PTAB determination of invalidity. If any third-party patents were held by a court of competent jurisdiction to cover the composition of matter of any of our product candidates, the manufacturing process of any of our product candidates or the method of use for any of our product candidates, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtain a license under the applicable patents, which may not be available at all or on commercially reasonable terms, or until such patents expire.

Litigation and contested proceedings can be expensive and time-consuming, and our adversaries in these proceedings may have the ability to dedicate greater resources to prosecuting these legal actions than we can. The risks of being involved in such litigation and proceedings may increase if and as our product candidates near commercialization. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of the merit of such claims. We may not be aware of all intellectual property rights potentially relating to our technology and product candidates and their uses, or we may incorrectly conclude that third-party intellectual property is invalid or that our activities and product candidates do not infringe, misappropriate or otherwise violate such intellectual property. Thus, we do not know with certainty that our technology and product candidates, or our development and commercialization thereof, do not and will not infringe, misappropriate or otherwise violate any third-party's intellectual property.

Parties making claims against us may seek to obtain injunctive or other equitable relief, which could if granted effectively block our ability to further develop and commercialize one or more of our product candidates and/or harm our reputation and financial results. Defense of these claims, regardless of their merit, could involve substantial litigation expense and could be a substantial diversion of management and employee resources from our business. In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products, in the case of claims concerning registered trademarks, rename our product candidates, or obtain one or more licenses from third parties, which may require substantial time and monetary expenditure, and which might be impossible or technically infeasible. Furthermore, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us; alternatively or additionally it might include terms that impede or destroy our ability to compete successfully in the commercial marketplace. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

A number of companies and universities file and obtain patents in the same area as our product candidates, and these patent filings could be asserted against us, which may affect our business, and if successful, could lead to expensive litigation, affect the profitability of our products and/or prohibit the sale of a product or its use.

Bemnifosbuvir, the product candidate we are developing in combination with ruzasvir for the treatment of HCV, and AT-587, the product candidate we are developing for the treatment of HEV, are each nucleotide prodrugs and other product candidates we may develop, may also be or include nucleotide prodrugs, or nucleotide phosphoramidates. A number of companies and universities have patent applications and issued patents in this general area, including for viral indications, such as, for example, Gilead Pharmasset, LLC; Gilead Sciences; Merck & Co.; Bristol Myers Squibb; F. Hoffmann-La-Roche Ltd.; University of Cardiff; University College Cardiff Consultants; NuCana, plc; Janssen Pharmaceutical Companies; Medivir AB; and others. If any of these companies or universities, or others, assert that a patent it holds is infringed by any of our product candidates or their use or manufacture, we may be drawn into expensive litigation, which may affect our business, take the time of and distract the attention of our employees, and if the litigation is successful, could affect the profitability of our products or prohibit their sale.

For example, we note that sixteen years after its priority date, Gilead Sciences obtained the '361 patent that includes a Claim that purportedly covers bemnifosbuvir. We believe that the '361 patent will expire on June 15, 2028. We requested the PTAB Board to institute a post grant review of this patent and it declined to exercise its discretion to do so. This denial does not stop us from making the same or similar arguments, or additional arguments, nor from bringing the same or new evidence of invalidity or unenforceability in court if Gilead files an infringement suit. While we believe this Claim is invalid and unenforceable, a trial court or an appellate court may disagree and uphold the Claim of the '361 patent, which would require us, prior to commercialization of a bemnifosbuvir product candidate to obtain a license from Gilead Sciences to the '361 patent for the time period that we are commercializing a product candidate, if any, containing bemnifosbuvir prior to expiration of the '361 patent or pay a court ordered royalty or other damages which could result in significant cost.

Additionally, on October 22, 2024, seventeen years after its priority date, Gilead Sciences obtained US '529 patent with claims that also purport to cover bemnifosbuvir. We believe that the '529 patent will expire on March 21, 2028. While we believe these claims are also invalid and unenforceable, a trial court or an appellate court may disagree and uphold one or more claims of the '529 patent, which would require us to obtain a license from Gilead Sciences to the '529 patent for the time period that we are commercializing a product candidate, if any, containing bemnifosbuvir prior to the expiration of the '529 patent or pay a court ordered royalty or other damages which could result in significant cost.

Our products are subject to The Drug Price Competition and Patent Term Restoration Act of 1984, as amended (also referred to as the Hatch-Waxman Act), in the US, that can increase the risk of litigation with generic companies trying to sell our products, and may cause us to lose patent protection.

Because our clinical candidates are pharmaceutical molecules reviewed by the Center for Drug Evaluation and Research of the FDA, after commercialization they will be subject in the US to the patent litigation process of the Hatch-Waxman Act, as currently amended, which allows a generic company to submit an Abbreviated New Drug Application ("ANDA") to the FDA to obtain approval to sell our drug using bioequivalence data only. Under the Hatch-Waxman Act, we will have the opportunity to list our patents that cover our drug product or its method of use in the FDA's compendium of "Approved Drug Products with Therapeutic Equivalence Evaluation," sometimes referred to as the FDA's Orange Book.

Currently, in the US, the FDA may grant five years of exclusivity for new chemical entities ("NCEs") for which most or all of our products may qualify. An NCE is a drug that contains no active moiety that has been approved by the FDA in any other NDA. A generic company can submit an ANDA to the FDA four years after approval of our product. The submission of an ANDA by a generic company is considered a technical act of patent infringement. The generic company can certify that it will wait until the natural expiration date of our listed patents to sell a generic version of our product or can certify that one or more of our listed patents are invalid, unenforceable or not infringed. If the latter, we will have 45 days to bring a patent infringement lawsuit against the generic company. This will initiate a challenge to one or more of our Orange Book-listed patents based on arguments from the generic company that our listed patents are invalid, unenforceable or not infringed. Under the Hatch-Waxman Act, if a lawsuit is brought, the FDA is prevented from issuing a final approval on the generic drug until 30 months from the date the litigation is started, or a final decision of a court holding that our asserted patent claims are invalid, unenforceable or not infringed. If we do not properly list our relevant patents in the Orange

Book, do not timely file a lawsuit in response to a certification from a generic company under an ANDA, or if we do not prevail in the resulting patent litigation, we can lose our proprietary protection, and our product can rapidly become generic. Further, even if we do correctly list our relevant patents in the Orange Book, bring a lawsuit in a timely manner and prevail in that lawsuit, the generic litigation may be at a very significant cost to us of attorneys' fees and employee time and distraction over a long period. Further, it is common for more than one generic company to try to sell an innovator drug at the same time, and so we may be faced with the cost and distraction of multiple lawsuits. We may also determine it is necessary to settle the lawsuit in a manner that allows the generic company to enter our market prior to the expiration of our patent or otherwise in a manner that adversely affects the strength, validity or enforceability of our patent.

A number of pharmaceutical companies have been the subject of intense review by the FTC or a corresponding agency in another country based on how they have conducted or settled drug patent litigation, and certain reviews have led to an allegation of an antitrust violation, sometimes resulting in a fine or loss of rights. We cannot be sure that we would also not be subject to such a review or that the result of the review would be favorable to us, which could result in a fine or penalty.

The FTC has brought a number of lawsuits in federal court in the past few years to challenge Hatch-Waxman Act ANDA litigation settlements between innovator companies and generic companies as anti-competitive. As an example, the FTC has taken an aggressive position that anything of value is a payment, whether money is paid or not. Under its approach, if an innovator as part of a patent settlement agrees not to launch or delay launch of an authorized generic during the 180-day period granted to the first generic company to challenge an Orange Book-listed patent covering an innovator drug, or negotiates a delay in entry without payment, the FTC may consider it an unacceptable reverse payment. The pharmaceutical industry argues that such agreements are rational business decisions to dismiss risk and are immune from antitrust attack if the terms of the settlement are within the scope of the exclusionary potential of the patent. In 2013, the US Supreme Court, in a five-to-three decision in FTC v. Actavis, Inc., rejected both the pharmaceutical industry's and FTC's arguments with regard to so-called reverse payments, and held that whether a "reverse payment" settlement involving the exchange of consideration for a delay in entry is subject to an anticompetitive analysis depends on five considerations: (a) the potential for genuine adverse effects on competition; (b) the justification of payment; (c) the patentee's ability to bring about anticompetitive harm; (d) whether the size of the payment is a workable surrogate for the patent's weakness; and (e) that antitrust liability for large unjustified payments does not prevent litigating parties from settling their lawsuits, for example, by allowing the generic to enter the market before the patent expires without the patentee paying the generic. Furthermore, whether a reverse payment is justified depends upon its size, its scale in relation to the patentee's anticipated future litigation costs, its independence from other services for which it might represent payment, as was the case in Actavis, and the lack of any other convincing justification. The Court held that reverse payment settlements can potentially violate antitrust laws and are subject to the standard antitrust rule-of-reason analysis, with the burden of proving that an agreement is unlawful on the FTC, leaving to lower courts the structuring of such rule of reason analysis. If we are faced with drug patent litigation, including Hatch-Waxman Act litigation with a generic company, we could be faced with such an FTC challenge based on that activity, including how or whether we settle the case, and even if we strongly disagree with the FTC's position, we could face a significant expense or penalty.

Patent terms may be inadequate to protect our competitive position on our products for an adequate amount of time.

The term of any individual patent depends on applicable law in the country where the patent is granted. In the US, provided all maintenance fees are timely paid, a patent generally has a term of 20 years from its application filing date or earliest claimed non-provisional filing date. Extensions may be available under certain circumstances, but the life of a patent and, correspondingly, the protection it affords is limited. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. For patents that are eligible for extension of patent term, we expect to seek extensions of patent terms in the US and, if available, in other countries, however there can be no assurance that we will be granted any patent term extension we seek, or that any such patent term extension will provide us with any competitive advantage.

The Hatch-Waxman Act in the US provides for the opportunity to seek a patent term extension on one selected patent for each of our products, and the length of that patent term extension, if at all, is subject to review and approval by the USPTO and the FDA.

In the US, the Hatch-Waxman Act permits one patent term extension of up to five years beyond the normal expiration of one patent per product, which if a method of treatment patent, is limited to the approved indication (or any additional indications approved during the period of extension). The length of the patent term extension is typically calculated as one half of the clinical trial period plus the entire period of time during the review of the NDA by the FDA, minus any time of delay by us during these periods. There is also a limit on the patent term extension to a term that is no greater than fourteen years from drug approval. Therefore, if we select and are granted a patent term extension on a recently filed and issued patent, we may not receive the full benefit of a possible patent term extension, if at all. We might also not be granted a patent term extension at all, because of, for example, failure to apply within the applicable period, failure to apply prior to the expiration of relevant patents or otherwise failure to satisfy any of the numerous applicable requirements. Moreover, the applicable authorities, including the FDA and the USPTO in the US, and any equivalent regulatory authorities in other countries, may not agree with our assessment of whether such extensions are available, may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to obtain approval of competing products following our patent expiration by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case if our patent covering the product has expired or been held invalid by a court of final jurisdiction. If this were to occur, it could have a material adverse effect on our ability to generate product revenue.

In 1997, as part of the Food & Drug Administration Modernization Act, ("FDAMA"), Congress enacted a law that provides incentives to drug manufacturers who conduct studies of drugs in children. The law, which provides six months of exclusivity in return for conducting pediatric studies, is referred to as the pediatric exclusivity provision. If clinical studies are carried out by us that comply with the FDAMA, we may receive an additional six-month term added to our regulatory data exclusivity period and our patent term extension period, if received, on our product. However, if we choose not to carry out pediatric studies that comply with the FDAMA, or are not accepted by the FDA for this purpose, we would not receive this additional six-month exclusivity extension to our data exclusivity or our patent term extension.

In Europe, supplementary protection certificates are available to extend a patent term up to five years to compensate for patent term lost during regulatory review, and can be extended for an additional six months if data from clinical trials is obtained in accordance with an agreed-upon pediatric investigation plan. Although all countries in Europe must provide supplementary protection certificates, there is no unified legislation among European countries and so supplementary protection certificates must be applied for and granted on a country-by-country basis. This can lead to a substantial cost to apply for and receive these certificates, which may vary among countries or not be provided at all.

If we are unable to obtain licenses from third parties on commercially reasonable terms or at all, or fail to comply with our obligations under such agreements, our business could be harmed.

It may be necessary for us to use the patented or other proprietary technology of third parties to commercialize our products, in which case we would be required to obtain a license from these third parties. If we are unable to license such technology, or if we are forced to license such technology on unfavorable terms, our business could be materially harmed. If we are unable to obtain a necessary license, we may be unable to develop or commercialize the affected product candidates, which could materially harm our business and the third parties owning or otherwise controlling such intellectual property rights could seek either an injunction prohibiting our sales or an obligation on our part to pay royalties and/or other forms of compensation. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us.

If we are unable to obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may be required to expend significant time and resources to redesign our technology, product candidates or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we

may be unable to develop or commercialize the affected technology and product candidates, which could harm our business, financial condition, results of operations and prospects significantly.

Additionally, if we fail to comply with our obligations under any future license agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market, or may be forced to cease developing, manufacturing or marketing, any product that is covered by these agreements or may face other penalties under such agreements. Such an occurrence could materially adversely affect the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements, or restrictions on our ability to freely assign or sublicense our rights under such agreements when it is in the interest of our business to do so, may result in our having to negotiate new or reinstated agreements with less favorable terms, cause us to lose our rights under these agreements, including our rights to important intellectual property or technology, or impede, or delay or prohibit the further development or commercialization of one or more product candidates that rely on such agreements.

Litigation and adversarial proceedings are expensive, time-consuming and if unsuccessful, can adversely affect our ability to sell our products when commercialized.

Competitors and other third parties may infringe, misappropriate or otherwise violate our or our future licensors' patents, trademarks, copyrights or other intellectual property. As a result, we may need to file infringement, misappropriation or other intellectual property-related claims against third parties. To counter infringement or other unauthorized use, we may be required to file claims on a country-by-country basis, which can be expensive and time-consuming and divert the time and attention of our management and scientific personnel. There can be no assurance that we will have sufficient financial or other resources to file and pursue such claims, which often last for years before they are concluded.

Any claims we assert against third parties could also provoke these parties to assert counterclaims against us alleging that we infringe, misappropriate or otherwise violate their intellectual property. In addition, in a patent infringement proceeding, such parties could counterclaim that the patents we have asserted are invalid or unenforceable, or both. In patent litigation in the US, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may institute such claims before administrative bodies in the US or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, inter partes review, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). The outcome following legal assertions of invalidity and unenforceability is unpredictable.

In any such proceeding, a court may decide that a patent of ours, or a patent that we in-license, is not valid, is unenforceable and/or is not infringed, or may construe such patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, interpreted narrowly or held unenforceable in whole or in part, could put our patent applications at risk of not issuing, and could limit our ability to assert those patents against those parties or other competitors and curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks, which could materially harm our business and negatively affect our position in the marketplace.

Even if we establish infringement, misappropriation or other violation of our intellectual property, the court may decide not to grant an injunction against further such activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Our composition of matter patent filing on bemnifosbuvir has now been granted in over 70 countries including the US, Europe, China, Japan, Korea, Australia, Brazil, Eurasia, Canada, Israel, New Zealand, South Africa, Russia and Mexico, and is pending in certain other countries and regions.

Our patent on AT-511 or its pharmaceutically acceptable salt, which includes bemnifosbuvir, has been granted in over 70 countries including the US, Europe, China, Japan, Korea, Australia, Eurasia, Canada, Israel, Singapore, Malaysia, Indonesia, Georgia, Russia, Ukraine, Colombia and Mexico, and is also pending in certain other countries and regions.

On November 4, 2025, the USPTO issued US Patent No. 12,458,656 that covers our method for treating HCV using the combination of bemnifosbuvir and ruzasvir. The expected year of expiration for this patent family, if valid and enforceable, is 2042, without regard to adjustments of term that may be available in the US or other national laws. Similar applications are pending in other countries.

On July 21, 2026, the USPTO issued US Patent No. 12,686,697 that covers our morphic form of bemnifosbuvir. The patent was granted with 429 days of patent term adjustment. The expiration date of the patent is March 31, 2043.

We also solely own a patent application covering the FDC of bemnifosbuvir and ruzasvir, which has now been allowed by the USPTO and expected to issue in Q4 2026. The expected year of expiration for patents, if any, issuing from this application, if valid and enforceable, is 2046, without regard to any adjustments of term that may be available under US or other national law.

We may not be aware of patent claims that are currently or may in the future be pending that affect our business by the competitors working in this area. Patent applications are typically published between six and eighteen months from filing, and the presentation of new claims in already pending applications can sometimes not be visible to the public, including to us, for a period of time, or if publicly available, not yet seen by us. We cannot provide any assurance that a third-party practicing in the general area of our technology will not present a patent claim that covers one or more of our products or their methods of use or manufacture at any time. If that does occur, we may have to take steps to try to invalidate such patent or application, and we may either choose not to or may not be successful in such attempt. A license to the patent or application may not be available on commercially reasonable terms or at all.

On April 12, 2022, we received notification of a Pre-Grant Opposition from the Controller General of Patents, Designs, and Trademarks at the Indian Patent Office. The Opposition was filed by Sankalp Rehabilitation Trust and challenged our pending patent claims to AT-511 or a pharmaceutically acceptable salt thereof. In February 2023, we responded to this Pre-Grant Opposition. Over three years later, on July 7, 2026, Sankalp Rehabilitation Trust filed a purported rejoinder to our response with an affidavit of a scientist. On July 23, 2026, Sankalp Rehabilitation Trust withdrew the affidavit of the scientist on the scientist's request. On August 14, 2026, we filed an interlocutory petition to exclude the rejoinder. We are currently awaiting further action on this matter by the Indian Patent Office. In addition to the Pre-Grant Opposition related to AT-511 or a pharmaceutically acceptable salt thereof (which bemnifosbuvir would fall under), we received notification of a second Pre-Grant Opposition filed by the Sankalp Rehabilitation Trust. This second Pre-Grant Opposition challenges our pending patent claims to bemnifosbuvir. In October 2023, we responded to this second Pre-Grant Opposition. A hearing on the matter was held in April 2024. In June 2024, the Indian Patent Office issued a decision refusing the claims to bemnifosbuvir on the basis that a new salt of a known compound is not patentable under section 3(d) of the Indian Patent Act. This decision was not appealed. While we intend to vigorously defend our patent claims on AT-511 or a pharmaceutically acceptable salt thereof and their use to treat HCV in India, we cannot guarantee that the Indian Patent Office will decide in our favor with respect to the pending Pre-Grant Opposition and allow our patent claims to AT-511 or a pharmaceutically acceptable salt thereof (which bemnifosbuvir would fall under). In addition, Pre-Grant Oppositions in India can proceed very slowly, and therefore these proceedings may not be resolved for several years. Our patent applications will not issue as a patent on AT-511 or a pharmaceutically acceptable salt thereof or their use to treat HCV in India unless and until the Pre-Grant Opposition is resolved in our favor. If it is not resolved in our favor, we may not receive patents on AT-511, bemnifosbuvir or their use to treat HCV in India. Further, there is no guarantee that other companies will not also file Pre-Grant Opposition Proceedings, or if the patent issues, one or more Post-Grant Oppositions, challenging our patent rights in AT-511.

Changes in patent laws and enforcement by courts and other authorities in the US and other jurisdictions may impact our ability to protect our patents.

The US Supreme Court and lower courts have issued opinions in patent cases in the last few years that many consider may weaken patent protection in the US, either by narrowing the scope of patent protection available in

certain circumstances, holding that certain kinds of innovations are not patentable or generally otherwise making it easier to invalidate patents in court. Additionally, there have been recent proposals for additional changes to the patent laws of the US and other countries that, if adopted, could impact our ability to obtain patent protection for our proprietary technology or our ability to enforce our proprietary technology. Depending on future actions by the US Congress, the US courts, the USPTO and the relevant law-making and other bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce and defend our existing patents and patents that we might obtain in the future.

In June 2023, the European Unitary Patent system and the European Unified Patent Court ("UPC") were launched. European patentees now have the option, upon grant of a patent, of obtaining a Unitary Patent which is subject to the jurisdiction of the UPC, or nationalizing the patent directly in one or all European countries that are members of the EPO. In addition, conventional European patents, both already granted at the time the new system began and granted thereafter, are subject to the jurisdiction of the UPC, unless actively opted out. This was a significant change in European patent practice. Deciding whether to opt-in or opt-out of Unitary Patent practice entails strategic and cost considerations. The UPC provides our competitors with a new forum to centrally revoke our European patents and makes it possible for a competitor to obtain pan-European injunctions against us. It will be several years before we will understand the scope of patent rights that will be recognized and the strength of patent remedies that will be provided by the UPC. While we have the right to opt our patents out of the UPC over the first seven years of the court's existence, doing so may preclude us from realizing the benefits of the UPC. Moreover, the decision whether to opt-in or opt-out of Unitary Patent status will require coordinating with co-applicants, if any, adding complexity to any such decision.

The laws of some foreign jurisdictions do not protect intellectual property rights to the same extent as in the US and many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. If we encounter such difficulties in protecting or are otherwise precluded from effectively protecting our intellectual property rights in foreign jurisdictions, our ability to compete and our business prospects in such marketplaces could be substantially harmed. For example, we have been notified that a Pre-Grant Opposition has been filed with the Controller General of Patents, Designs and Trademarks at the Indian Patent Office relating to our pending patent claims to AT-511 or a pharmaceutically acceptable salt thereof (which claim bemnifosbuvir would fall under) and its use to treat HCV in India. While we intend to defend our patent claims for AT-511 or a pharmaceutically acceptable salt thereof (which claim bemnifosbuvir would fall under) and its use to treat HCV, we cannot provide any assurance that we will succeed or that the Indian patent office will allow the patent claims to grant. A second Pre-Grant Opposition relating to patent claims to bemnifosbuvir was filed in September 2022. We responded to this second Pre-Grant Opposition in October 2023, and a hearing was held in April 2024. On June 3, 2024, the Indian patent office refused our claims to bemnifosbuvir on the basis that a new salt of a known compound is not patentable under section 3(d) of the Indian Patent Act. This decision was not appealed. While we intend to defend our patent claims for AT-511, or a pharmaceutically acceptable salt thereof (which bemnifosbuvir would fall under) and its use to treat HCV, we cannot provide any assurance that we will succeed or that the Indian patent office will allow the patent claims to grant. The cost of foreign adversarial proceedings can also be substantial, and in many foreign jurisdictions, the losing party must pay the attorney fees of the winning party.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The USPTO, EPO and other patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the US in several stages over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we employ an outside firm and rely on our outside counsel to pay such fees due to non-US patent agencies. While, in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors or other third parties might be able to enter the market with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

Filing, prosecuting and defending patents on our product candidates in all countries throughout the world may be prohibitively expensive. Therefore, we may choose not to pursue or maintain protection for certain intellectual property in certain jurisdictions. The requirements for patentability may differ in certain countries, particularly in developing countries. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may obtain patent protection, but where patent enforcement is not as strong as that in the US. These products may compete with our products in jurisdictions where we do not have any issued or licensed patents and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by changes in foreign intellectual property laws. Additionally, laws of some countries outside of the US and Europe do not afford intellectual property protection to the same extent as the laws of the US and Europe. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, including India, China and other developing countries, may not favor the enforcement of our patents and other intellectual property rights.

This could make it difficult for us to stop the infringement of our patents or the misappropriation or other violation of our other intellectual property rights. A number of foreign countries have stated that they are willing to issue compulsory licenses to patents held by innovator companies on approved drugs to allow the government or one or more third-party companies to sell the approved drug without the permission of the innovator patentee where the foreign government concludes it is in the public interest. India, for example, has used such a procedure to allow domestic companies to make and sell patented drugs without innovator approval. There is no guarantee that patents covering any of our drugs will not be subject to a compulsory license in a foreign country, or that we will have any influence over if or how such a compulsory license is granted. Further, Brazil allows its regulatory agency ANVISA to participate in deciding whether to grant a drug patent in Brazil, and patent grant decisions are made based on several factors, including whether the patent meets the requirements for a patent and whether such a patent is deemed in the country's interest. In addition, several other countries have created laws that make it more difficult to enforce drug patents than patents on other kinds of technologies. Further, under the treaty on the Trade-Related Aspects of Intellectual Property, as interpreted by the Doha Declaration, countries in which drugs are manufactured are required to allow exportation of the drug to a developing country that lacks adequate manufacturing capability. Therefore, our drug markets in the US or foreign countries may be affected by the influence of current public policy on patent issuance, enforcement or involuntary licensing in the healthcare area.

We rely on our ability to stop others from competing by enforcing our patents, however some jurisdictions may require us to grant licenses to third parties. Such compulsory licenses could be extended to include some of our product candidates, which may limit our potential revenue opportunities.

Many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties, in certain circumstances. For example, compulsory licensing, or the threat of compulsory licensing, of life-saving products and expensive products is becoming increasingly popular in developing countries, either through direct legislation or international initiatives. Compulsory licenses could be extended to include some of our product candidates, if they receive marketing approval, which may limit our potential revenue opportunities. Consequently, we may not be able to prevent third parties from practicing our inventions in certain countries outside the US and Europe. Competitors may also use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, if our ability to enforce our patents to stop infringing activities is inadequate. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and resources from other aspects of our business. Furthermore, while we intend to protect our intellectual property rights in major markets for our products where such patent rights exist, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our products. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate.

In addition, some countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may be limited to monetary relief and may be unable to enjoin infringement if a government is the infringer, which could materially diminish the value of the patent.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is either not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our product candidate discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with parties who have access to them, such as our employees, CROs, consultants, scientific advisors and other contractors. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached and our trade secrets could be disclosed, and we may not have adequate remedies for any such breach. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the US are less willing or unwilling to protect trade secrets. Misappropriation or unauthorized disclosure of our trade secrets or other confidential proprietary information could cause us to lose trade secret protection, impair our competitive position and have a material adverse effect on our business. Additionally, if the steps taken to maintain our trade secrets or other confidential proprietary information are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret or other confidential proprietary information.

Further, we cannot provide any assurances that competitors or other third parties will not otherwise gain access to our trade secrets and other confidential proprietary information or independently discover or develop substantially equivalent technology and processes. If we are unable to prevent disclosure of the trade secrets and other non-patented intellectual property related to our product candidates and technologies to third parties, there is no guarantee that we will have any such enforceable trade secret protection and we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties, that our employees have wrongfully used or disclosed alleged trade secrets of their former employers, or asserting ownership of what we regard as our own intellectual property.

We have employed, and may in the future employ, individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any of such individuals' former employers or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, or our ability to hire personnel, which, in any case of the foregoing, could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Although it is our policy to require all of our employees and consultants to assign their inventions to us, to the extent that employees or consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. We may also be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Our proprietary rights may not adequately protect our technologies and product candidates, and intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and 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 products that are the same as or similar to our product candidates but that are not covered by the claims of our patents;
- others, including inventors or developers of our patented technologies who may become involved with competitors, may independently develop similar technologies that function as alternatives or replacements for any of our technologies without infringing, misappropriating or otherwise violating our intellectual property rights;
- we might not have been the first to conceive and reduce to practice the inventions covered by our patents or patent applications;
- we might not have been the first to file patent applications covering certain of our inventions;
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third-party may subsequently file a patent covering such intellectual property;
- our pending patent applications might not result in issued patents;
- there might be prior public disclosures that could invalidate our patents;
- our issued patents may not provide us with any commercially viable products or competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors or other third parties;
- the Supreme Court of the US, other US federal courts, Congress, the USPTO or similar foreign authorities may change the standards of patentability and any such changes could narrow or invalidate, or change the scope of, our patents;
- patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time;
- our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights, or in countries where research and development safe harbor laws exist, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- ownership, validity or enforceability of our patents or patent applications may be challenged by third parties; and
- the patents or pending or future applications of third parties, if issued, may have an adverse effect on our business.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Risks Related to Employee Matters, Managing Operations and Other Risks Related to Our Business

We may be unable to realize expected benefits from our cost reduction efforts and our business might be adversely affected.

In the first quarter of 2025, in order to reduce costs and support longer term business sustainability, we implemented a reduction in our workforce.

These types of cost reduction activities are complex and may result in unintended consequences and costs. For example, the duties and obligations of the employees terminated as a result of the workforce reduction have been distributed and assumed among our remaining employees. As a result of this increase in responsibilities for our current employees, this reduction in workforce could make it more difficult for us to pursue, or prevent us from pursuing, new opportunities and initiatives due to insufficient personnel, or require us to incur additional and

unanticipated costs to hire new personnel to pursue such opportunities or initiatives. If we do not successfully manage our current initiatives or any other similar activities that we may undertake in the future, expected efficiencies and benefits might be delayed or not realized, and our business, financial condition, and results of operations may be materially adversely affected.

Our future success depends upon our ability to retain officers, directors and key employees and attract, retain and motivate qualified personnel.

We are highly dependent on our officers, directors and key employees. Due to the specialized knowledge each of our officers, directors and key employees possesses with respect to our product candidates and our operations, the loss of service of any of one or more of our officers, directors or key employees could seriously delay, harm or prevent the planning and execution of clinical trials and other key activities required for the successful advancement of our business. Although we have employment agreements with our executive officers, in general, these agreements do not prevent our executive officers from terminating their employment with us at any time.

We do not carry key person life insurance on any officers or directors.

Retaining qualified scientific, clinical and manufacturing personnel as well as recruiting qualified sales and marketing personnel if we elect to establish our own commercial organization will be critical to our success. Our ability to identify, hire and retain additional personnel and, if necessary, replace departed executive officers and key employees may be difficult or costly and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to discover or otherwise identify and develop product candidates and gain regulatory approval of and commercialize products successfully. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or effectively incentivize these additional key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be engaged by entities other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

Our reduction in force in January 2025 may make it more difficult for us to hire qualified personnel in the future. If we seek to hire but are unable to attract such additional personnel, our ability to develop and commercialize product candidates will be limited.

We rely on consultants, advisors and third parties for the performance of critical aspects of our business operations.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to assist us in formulating our research and development and commercialization strategy and to provide certain services, including substantially all aspects of clinical trial conduct and execution, international regulatory affairs activities and manufacturing. There can be no assurance that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by independent organizations, advisors or consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing independent organizations, advisors or consultants or find other competent outside independent organizations, advisors and consultants on economically reasonable terms, or at all. If we are not able to effectively expand our organization by hiring new employees and expanding our groups of advisors and consultants, or we are not able to effectively maintain or obtain facilities to accommodate this expansion, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and share price.

The global economy, including credit and financial markets, has recently experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, increases in interest rates, increases in inflation

rates and uncertainty about economic stability. For example, the COVID-19 pandemic resulted in widespread unemployment, economic slowdown and extreme volatility in the capital markets. Similarly, international conflicts, terrorism and political instability have created extreme volatility in the capital markets. These conditions may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive. In addition, there is a risk that one or more of our CROs, suppliers, CMOs or other third-party providers may not survive an economic downturn. As a result, our business, results of operations and price of our common stock may be adversely affected.

Our business could face adverse consequences as a result of the actions of activist shareholders.

We have been in the past and may in the future be subject to unsolicited attempts to gain control of our company, proxy contests, and other forms of shareholder activism. When a stockholder, by itself or in conjunction with other stockholders or as part of a group, engages in activist activities with respect to us, our business could be adversely affected because responding to an unsolicited offer, proxy contest or other actions by activist stockholders can be costly and time-consuming, disruptive to our operations and divert the attention of management and our employees from the execution of our strategy. In addition, actual or perceived uncertainties as to our future direction caused by activist activities may cause or appear to cause instability, potentially making it more difficult to attract and retain qualified personnel and collaborators or leading to the loss of collaboration opportunities, and if individuals are elected to our board of directors with a specific agenda, it may adversely affect our ability to effectively and timely implement our strategic plans. Activist stockholder activities may also cause significant fluctuations in our stock price based on temporary or speculative market perceptions, or other factors that do not necessarily reflect the fundamental underlying value of our business. Finally, we might experience a significant increase in legal fees and administrative and associated costs incurred in connection with responding to an unsolicited offer, proxy contest or related action. These actions could also negatively affect the price of our common stock.

Risks Related to Our Common Stock

If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline, even if our business is doing well.

The trading market for our common stock is influenced by the research and reports that industry or securities analysts publish about us or our business. We currently have limited research coverage by securities and industry analysts. If any of the analysts who cover us, or may cover us, downgrades our common stock or issues an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our preclinical studies, clinical trials, commercial opportunity prospects or operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts ceases coverage of us (which has occurred in the past) or fails to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

Provisions in our restated certificate of incorporation and amended and restated bylaws and under Delaware law could make an acquisition of our Company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our restated certificate of incorporation and our amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions may also limit the price that investors are willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions include those establishing:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;

- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from filling vacancies on our board of directors;
- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;
- the ability of our board of directors to alter our bylaws without obtaining stockholder approval;
- the required approval of the holders of at least two-thirds of the shares entitled to vote at an election of directors to adopt, amend or repeal our bylaws or repeal the provisions of our restated certificate of incorporation regarding the election and removal of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by the chairman of the board of directors, the chief executive officer, the president or the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of us.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Our restated certificate of incorporation designates specific courts as the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us.

Our restated certificate of incorporation, specifies that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for most legal actions involving claims brought against us by stockholders, other than suits brought to enforce any liability or duty created by the Securities Exchange Act of 1934, as amended (the "Exchange Act") or any other claim for which the federal courts have exclusive jurisdiction and any action that the Court of Chancery of the State of Delaware has dismissed for lack of subject matter jurisdiction, which may be brought in another state or federal court sitting in the State of Delaware. Our restated certificate of incorporation also specifies that unless we consent in writing to the selection of an alternate forum, the federal district courts of the US shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act of 1933, as amended (the "Securities Act"). Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our restated certificate of incorporation described above.

We believe this provision benefits us by providing increased consistency in the application of Delaware law by chancellors particularly experienced in resolving corporate disputes or federal judges experienced in resolving Securities Act disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, the provision may have the effect of discouraging lawsuits against our directors, officers, employees and agents as it may limit any stockholder's ability to bring a claim in a judicial forum that such stockholder finds favorable for disputes with us or our directors, officers, employees or agents. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with any applicable action brought against us, a court could find the choice of forum provisions contained in our restated certificate of incorporation to be inapplicable or unenforceable in such action. If a court were to find the choice of forum provision contained in our restated certificate of incorporation to be inapplicable or unenforceable

in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business, financial condition or results of operations.

General Risk Factors

Raising additional capital may cause additional dilution to our stockholders, restrict our operations, require us to relinquish rights to our technologies or product candidates, and could cause our share price to fall.

Until such time, if ever, as we can generate substantial revenue from product sales, we may finance our cash needs through a combination of equity offerings, additional term loans under the Loan and Security Agreement (to the extent we meet the required terms for remaining tranches), other debt financings, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. While we remain open to consideration of a broad range of strategic alternatives, including strategic partnerships, acquisition, merger, or other business combination, sale of assets or other strategic transactions, we believe that it is most likely that actionable alternatives may be available after we receive the results from our HCV Phase 3 clinical program.

In addition, even if we believe that we have sufficient funds for our current or future operating plans, we may seek additional capital due to favorable market conditions or strategic considerations. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Similar to the Loan and Security Agreement, other debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our operations, our ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends, redeeming our stock, making certain investments and engaging in certain merger, consolidation or asset sale transactions, among other restrictions.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

We or the third parties upon whom we depend may be adversely affected by natural disasters or pandemics and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Natural disasters (including, but not limited to earthquakes, fires, storms, floods, droughts, and extreme temperatures) or pandemics could severely disrupt our operations and have a material adverse effect on our business, results of operations, financial condition and prospects. Climate change may increase the frequency or intensity of such events. Moreover, climate change may result in various chronic changes in the physical environment, such as changes in temperature or precipitation patterns or sea-level rise, as well as changes to the availability of certain natural resources, that may also have an adverse impact on our operations. If a natural disaster, power outage, pandemic, such as the COVID-19 pandemic, or other event occurred that prevented us from using all or a significant portion of our headquarters or the virtual network capabilities upon which our employees depend to collaborate and access critical business records, that damaged critical infrastructure, such as the manufacturing facilities on which we rely, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business.

Evolving and varied expectations for ESG initiatives could increase our costs, harm our reputation, or otherwise adversely impact our business.

Companies across industries, including our industry, are facing evolving and varied expectations related to their ESG and sustainability practices from certain investors, government entities, customers, employees, and other stakeholders or third parties. Expectations regarding voluntary ESG initiatives and disclosures may result in increased costs (including but not limited to increased costs related to compliance, stakeholder engagement, contracting and insurance), enhanced compliance or disclosure obligations, increased litigation or reputational

damage relating to ESG practices or performance, or other adverse impacts to our business, financial condition, or results of operations.

While we may at times engage in voluntary initiatives (such as voluntary disclosures, certifications, or goals, among others), such initiatives may be costly and may not have the desired effect. Moreover, we may not be able to successfully complete such initiatives due to factors that are within or outside of our control. Even if this is not the case, our actions may subsequently be determined to be insufficient by various stakeholders, and we may be subject to investor or regulator engagement relating to our ESG efforts, even if such initiatives are currently voluntary.

Certain market participants use third-party benchmarks and scores to assess companies' ESG profiles in making investment or voting decisions. Unfavorable ESG ratings or other reputational issues could result in various negative impacts, including negative investor sentiment, decreased interest in our shares, changes in the cost of capital, or our ability to attract/retain employees, customers, or business partners. Simultaneously, some parties are seeking to restrict or eliminate companies' attention to ESG matters, and any ESG initiatives we undertake may result in negative reputational impacts from these stakeholders. Both advocates and opponents to certain ESG matters are increasingly resorting to a range of activism forms, including media campaigns and litigation, to advance their perspectives. To the extent we are subject to such activism or litigation, it may require us to incur costs or otherwise adversely impact our business.

We may become subject to conflicting laws and regulations related to sustainability and ESG matters. There are requirements that may require us to incur significant additional costs to comply, including the implementation of significant additional internal controls processes and procedures regarding matters that have not been subject to such controls in the past, and impose increased oversight obligations on our management and board of directors. These and other changes in stakeholder expectations may lead to increased costs as well as scrutiny that could heighten all of the risks identified in this risk factor. Additionally, our suppliers and business partners may be subject to similar expectations, which may augment or create additional risks, including risks that may not be known to us.

Litigation against us could be costly and time-consuming to defend and could result in additional liabilities.

We may from time to time be subject to legal proceedings and claims that arise in the ordinary course of business or otherwise, such as claims brought by third parties in connection with commercial disputes and employment claims made by our current or former employees. Claims may also be asserted by or on behalf of a variety of other parties, including government agencies, patients or vendors of our customers, or stockholders. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities.

Any litigation involving us may result in substantial costs, operationally restrict our business, and may divert management's attention and resources, which may seriously harm our business, overall financial condition and results of operations. Insurance may not cover existing or future claims, be sufficient to fully compensate us for one or more of such claims, or continue to be available on terms acceptable to us. A claim brought against us that is uninsured or underinsured could result in unanticipated costs, thereby adversely impacting our results of operations and resulting in a reduction in the trading price of our stock.

The market price of our common stock has been volatile and may fluctuate substantially.

Our stock price has been and is likely to remain volatile. Extreme fluctuations have occurred in our stock price. Additionally, the stock market in general, and The Nasdaq Global Select Market-listed companies and biopharmaceutical companies in particular have experienced extreme volatility in trading volume that exacerbates, is disproportionate to or in some cases has been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your common stock at a profit. The market price for our common stock may be influenced by many factors, including but not limited to:

- the success of competitive products or technologies;
- actual or expected changes in our growth rate relative to our competitors;
- results of our ongoing, planned or any future preclinical studies, clinical trials or clinical development of our product candidates or those of our competitors;
- unanticipated serious safety concerns related to the use of our product candidates;

- developments related to our existing or any future collaborations;
- developments concerning our manufacturers or our manufacturing plans;
- our inability to obtain adequate product supply for any approved product or inability to do so at acceptable prices;
- regulatory actions with respect to our product candidates or our competitors' products and product candidates;
- regulatory or legal developments in the US and other countries;
- development of third-party product candidates that may address our markets and make our product candidates less attractive;
- changes in physician, hospital or healthcare provider practices that may make our product candidates less useful;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- our failure to commercialize our product candidates;
- announcements by us, our partners or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- developments or disputes concerning patent applications, issued patents or other intellectual property or proprietary rights;
- the recruitment or departure of key scientific or management personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- changes in accounting practices;
- the trading volume of our common stock;
- our cash and investments position;
- our ability to effectively manage our growth;
- sales of our common stock by us or our stockholders in the future;
- publication of research reports about us or our industry, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- ineffectiveness of our internal controls;
- significant lawsuits, including intellectual property or stockholder litigation;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;
- actual or expected changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- actual or anticipated variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions, including rising inflation and interest rates; and
- the other factors described in this "Risk Factors" section.

Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In the past, securities class action litigation has often been instituted against

companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, financial condition and results of operations.

If we fail to maintain effective internal control over financial reporting and effective disclosure controls and procedures, we may not be able to accurately report our financial results in a timely manner or prevent fraud, which may adversely affect investor confidence in our company.

We are required to comply with the SEC's rules implementing Sections 302 and 404 of the Sarbanes-Oxley Act, which require management to certify financial and other information in our quarterly and annual reports and provide an annual management report on the effectiveness of controls over financial reporting. In addition, we have in the past and may in the future be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm and our independent registered public accounting firm has in the past and may be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404. Our independent registered public accounting firm may issue a report that is adverse in the event material weaknesses have been identified in our internal control over financial reporting.

To comply with the requirements of Section 404, we may need to undertake additional actions, such as implementing new internal controls and procedures and hiring additional accounting or internal audit staff. We will need to continue to dedicate internal resources, engage outside consultants, adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing whether such controls are functioning as documented, and implement a continuous reporting and improvement process for internal control over financial reporting. Testing and maintaining internal control can divert our management's attention from other matters that are also important to the operation of our business. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. When evaluating our internal control over financial reporting, we may identify material weaknesses that we may not be able to remediate in time to meet the applicable deadline imposed upon us for compliance with the requirements of Section 404. If we identify any material weaknesses in our internal controls over financial reporting or we are unable to comply with the requirements of Section 404 in a timely manner or assert that our internal control over financial reporting is effective, or if our independent registered public accounting firm, if required, is unable to express an opinion as to the effectiveness of our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports. As a result, the market price of our common stock could be materially adversely affected.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act. We are continuing to refine our disclosure controls and procedures to provide reasonable assurance that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Issuer Purchases of Equity Securities

The Company did not repurchase any equity securities in the three months ended September 30, 2026.

Recent Sales of Unregistered Securities

None.

Item 5. Other Information

(a) On November 9, 2026, Wayne Foster, the Company's Executive Vice President, Chief Accounting Officer, informed the Company of his resignation, effective November 13, 2026. Mr. Foster intends to provide consulting services to the Company initially through February 2027 to facilitate the transition of his role.

(b) None.

(c) During the three months ended September 30, 2026, no director or "officer" (as defined in Rule 16a-1(f) under the Exchange Act) of the Company adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement", as each term is defined in Item 408(a) of Regulation S-K.

Item 6. Exhibits.

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed/ Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
3.1	Restated Certificate of Incorporation.	8-K	001-39661	3.1	11/5/2020	
3.2	Amended and Restated Bylaws.	8-K	001-39661	3.1	6/21/2023	
10.1#+	Loan and Security Agreement	8-K	001-39661	3.1	11/9/2026	
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a).					*
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a).					*
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350.					**
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350.					**
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.					*
101.SCH	Inline XBRL Taxonomy Extension Schema Document					*
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)					*

* Filed herewith.
** Furnished herewith.

Portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.
+ Annexes, schedules and certain exhibits have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Company agrees to furnish supplementally a copy of any omitted annex, schedule or exhibit to the SEC upon request.

SIGNATURES

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

ATEA PHARMACEUTICALS, INC.

Date: November 9, 2026

By: /s/ Jean-Pierre Sommadossi, Ph.D.

Jean-Pierre Sommadossi, Ph.D.
President and Chief Executive Officer
(principal executive officer)

Date: November 9, 2026

By: /s/ Andrea Corcoran

Andrea Corcoran
Chief Financial Officer, Executive Vice President, Legal and Secretary
(principal financial officer)

Exhibit 31.1

CERTIFICATION

I, Jean-Pierre Sommadossi, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Atea Pharmaceuticals, 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 9, 2026

By: /s/ Jean-Pierre Sommadossi

Jean-Pierre Sommadossi, Ph.D.
President and Chief Executive Officer
(principal executive officer)

Exhibit 31.2

CERTIFICATION

I, Andrea Corcoran, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Atea Pharmaceuticals, 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 9, 2026

By: /s/ Andrea Corcoran

Andrea Corcoran
Chief Financial Officer, Executive Vice President, Legal, and Secretary
(principal financial officer)

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Atea Pharmaceuticals, Inc. (the "Company") for the period ended September 30, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of 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.

Date: November 9, 2026

By: /s/ Jean-Pierre Sommadossi, Ph.D.
Jean-Pierre Sommadossi, Ph.D.
President and Chief Executive Officer
(principal executive officer)

Exhibit 32.2

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

In connection with the Quarterly Report on Form 10-Q of Atea Pharmaceuticals, Inc. (the "Company") for the period ended September 30, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of 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.

Date: November 9, 2026

By: /s/ Andrea Corcoran
Andrea Corcoran
Chief Financial Officer, Executive Vice President, Legal, and Secretary
(principal financial officer)