

**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 March 31, 2023

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

(State or other jurisdiction of
incorporation or organization)

**225 Franklin Street, Suite 2100
Boston, MA**

(Address of principal executive offices)

46-0574869

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

02110

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

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

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

As of May 5, 2023, the registrant had 83,399,377 shares of common stock, \$0.001 par value per share, outstanding.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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,” “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 clinical trials for our product candidates, including projected costs, study designs and the timing for initiation, recruitment, completion, and reporting top-line data;
- the potential therapeutic benefits of our product candidates and the potential indications and market opportunities therefor;
- the potential of bemnifosbuvir to retain antiviral activity against circulating COVID-19 variants of concern and to treat COVID-19;
- the safety profile and related adverse events of our 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 obtain and maintain regulatory approvals for our product candidates;
- 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;
- our estimates regarding future revenue, expenses and results of operations;
- the progress of, timing of and amount of expenses associated with our research, development and commercialization activities;
- our future financial position, capital requirements, needs for additional financing and the availability of such financing;
- our business strategy;
- developments relating to our industry and our competitors, including competing treatments and vaccines for diseases we are treating;
- our expectations regarding federal, state and foreign laws and regulations;
- our ability to attract, motivate, and retain key personnel; and
- the impact on our business as COVID-19 becomes endemic.

These forward-looking statements are based on management’s current expectations. 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 data 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.” 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. 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.

SUMMARY RISK FACTORS

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

- There is significant uncertainty around our development of bemnifosbuvir as a potential treatment for COVID-19.
- We are highly dependent on our management, directors and other key personnel.
- We may expend resources in anticipation of potential clinical trials and commercialization of bemnifosbuvir, which we may not be able to recover if bemnifosbuvir is not approved for the treatment of COVID-19, we are not successful at commercializing bemnifosbuvir or bemnifosbuvir is rendered inferior or obsolete due to rapid changes in COVID -19 epidemiology as a result of the emergence of new SARS-CoV-2 variants or subvariants.
- The market for new therapeutics for the treatment of COVID-19 may be reduced, perhaps significantly, if vaccines and current therapeutics remain effective in minimizing serious consequences of the disease.
- If approved, bemnifosbuvir will face significant competition from other treatments for COVID-19 that are currently marketed or are in development.
- The continuing evolution of the COVID-19 pandemic may materially and adversely affect our business opportunities, clinical trials and financial results.
- 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. We expect our expenditures will increase for the foreseeable future. We have no products that have generated any commercial revenue and we may never again achieve or maintain profitability.
- We will 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.
- 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 most advanced product candidates, including bemnifosbuvir. If we fail to successfully develop bemnifosbuvir for the treatment of COVID-19 or the combination of bemnifosbuvir and ruzasvir for the treatment of hepatitis C or we are unable to obtain regulatory approval or successfully commercialize any of our product candidates, or are significantly delayed in doing so, our business will be harmed.
- The regulatory approval processes of the US Food and Drug Administration ("FDA") and comparable foreign regulatory authorities are lengthy, expensive, time-consuming and inherently unpredictable.
- Clinical development, including enrollment 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 intend to develop 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.
- 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.
- We have only a limited number of employees, which may be inadequate to manage and operate our business.
- Our business and operations may suffer in the event of system failures, security breaches, deficiencies or intrusions which could materially affect our results.
- We may need to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.
- We may engage in acquisitions or strategic partnerships that could disrupt our business, cause dilution to our stockholders, reduce our financial resources, cause us to incur debt or assume contingent liabilities, and subject us to other risks.
- We or the third parties upon whom we depend 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 attention to, and evolving expectations for, environmental, social, and governance (“ESG”) initiatives could increase our costs, harm our reputation, or otherwise adversely impact our business.
- 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. and Subsidiary

Condensed Consolidated Balance Sheets

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

	March 31, 2023	December 31, 2022
Assets		
Current assets		
Cash and cash equivalents	\$ 183,255	\$ 188,460
Marketable securities	437,233	458,249
Prepaid expenses and other current assets	11,902	14,213
Total current assets	632,390	660,922
Property and equipment, net	1,601	1,705
Restricted cash	198	198
Other assets	1,691	1,494
Operating lease right-of-use assets, net	2,251	2,389
Total assets	<u>\$ 638,131</u>	<u>\$ 666,708</u>
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	\$ 700	\$ 2,551
Accrued expenses and other current liabilities	10,931	15,206
Current portion of operating lease liabilities	730	721
Total current liabilities	12,361	18,478
Operating lease liabilities	2,215	2,403
Income taxes payable	5,373	5,255
Total liabilities	19,949	26,136
Commitments and contingencies (see Note 12)		
Stockholders' equity:		
Preferred stock, \$0.001 par value per share; 10,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock, \$0.001 par value; 300,000,000 shares authorized; 83,399,377 and 83,287,639 shares issued and outstanding as of March 31, 2023 and December 31, 2022, respectively	83	83
Additional paid-in capital	713,752	701,052
Accumulated other comprehensive loss	(307)	(684)
Accumulated deficit	(95,346)	(59,879)
Total stockholders' equity	618,182	640,572
Total liabilities and stockholders' equity	<u>\$ 638,131</u>	<u>\$ 666,708</u>

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

ATEA PHARMACEUTICALS, INC. and Subsidiary

Condensed Consolidated Statements of Operations and Comprehensive Loss

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

	Three Months Ended	
	2023	March 31, 2022
Operating expenses:		
Research and development	\$ 28,954	\$ 29,633
General and administrative	12,615	12,542
Total operating expenses	41,569	42,175
Loss from operations	(41,569)	(42,175)
Interest income and other, net	6,299	98
Loss before income taxes	(35,270)	(42,077)
Income tax expense	(197)	—
Net loss	\$ (35,467)	\$ (42,077)
Other comprehensive income:		
Unrealized gains on available-for-sale investments	377	—
Comprehensive loss	\$ (35,090)	\$ (42,077)
Net loss per share - basic and diluted	\$ (0.43)	\$ (0.51)
Weighted-average number of common shares used in computing net loss per share - basic and diluted	83,332,397	83,176,408

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

ATEA PHARMACEUTICALS, INC. and Subsidiary

Condensed Consolidated Statements of Stockholders' Equity

(in thousands, except share amounts)

(Unaudited)

	Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Other Comprehen- sive Loss	Accumulated Deficit	Stockhol- ders' Equity
Balance—December 31, 2022	83,287,639	\$ 83	\$ 701,052	\$ (684)	\$ (59,879)	\$ 640,572
Issuance upon vesting of restricted stock units	53,935	—	—	—	—	—
Issuance of common stock under employee stock purchase plan	57,803	—	165	—	—	165
Stock-based compensation expense	—	—	12,535	—	—	12,535
Other comprehensive income	—	—	—	377	—	377
Net loss	—	—	—	—	(35,467)	(35,467)
Balance—March 31, 2023	<u>83,399,377</u>	<u>\$ 83</u>	<u>\$ 713,752</u>	<u>\$ (307)</u>	<u>\$ (95,346)</u>	<u>\$ 618,182</u>

	Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Other Comprehen- sive Loss	Accumulated Deficit	Stockhol- ders' Equity
Balance—December 31, 2021	83,102,730	\$ 83	\$ 653,964	\$ —	\$ 56,030	\$ 710,077
Exercise of stock options	154,861	—	223	—	—	223
Stock-based compensation expense	—	—	11,661	—	—	11,661
Net loss	—	—	—	—	(42,077)	(42,077)
Balance—March 31, 2022	<u>83,257,591</u>	<u>\$ 83</u>	<u>\$ 665,848</u>	<u>\$ —</u>	<u>\$ 13,953</u>	<u>\$ 679,884</u>

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

ATEA PHARMACEUTICALS, INC. and Subsidiary

Condensed Consolidated Statements of Cash Flows

(in thousands)
(Unaudited)

	Three Months Ended March 31,	
	2023	2022
Cash flows from operating activities		
Net loss	\$ (35,467)	\$ (42,077)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	12,535	11,661
Non-cash lease expense	—	16
Depreciation and amortization expense	104	7
Accretion of premium and discounts on marketable securities	(3,087)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	2,311	275
Other assets	(197)	—
Accounts payable	(1,851)	(877)
Accrued expenses and other liabilities	(4,157)	(28,014)
Operating lease liabilities	(41)	—
Net cash used in operating activities	<u>(29,850)</u>	<u>(59,009)</u>
Cash flows from investing activities		
Additions to property and equipment	—	(44)
Purchases of marketable securities	(156,626)	—
Sales and maturities of marketable securities	181,106	—
Net cash provided by (used in) investing activities	<u>24,480</u>	<u>(44)</u>
Cash flows from financing activities		
Proceeds from issuance of common stock for exercise of stock options	—	223
Proceeds from issuance of common stock under ESPP	165	—
Net cash provided by financing activities	<u>165</u>	<u>223</u>
Net decrease in cash, cash equivalents and restricted cash	(5,205)	(58,830)
Cash, cash equivalents and restricted cash at the beginning of period	188,658	764,680
Cash, cash equivalents and restricted cash at the end of period	<u>\$ 183,453</u>	<u>\$ 705,850</u>
Cash, cash equivalents and restricted cash at the end of period:		
Cash and cash equivalents	\$ 183,255	\$ 705,545
Restricted cash	198	305
Total cash, cash equivalents and restricted cash	<u>\$ 183,453</u>	<u>\$ 705,850</u>
Supplemental cash flow information:		
Property and equipment purchases unpaid at period end	\$ —	\$ 702
Right of use assets obtained in exchange for operating lease liabilities	\$ —	\$ 2,938

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

ATEA PHARMACEUTICALS, INC. and Subsidiary

Notes to Condensed Consolidated Financial Statements

(in thousands, except share and per share amounts)

(Unaudited)

1. Nature of Business

Background

Atea Pharmaceuticals, Inc., together with its subsidiary, Atea Pharmaceuticals Securities Corporation, is referred to on a consolidated basis as the "Company".

The Company is a clinical-stage biopharmaceutical company focused on discovering, developing and commercializing antiviral therapeutics to improve the lives of patients suffering from severe viral infections.

Risks and Uncertainties

The Company is subject to risks and uncertainties common to clinical-stage biopharmaceutical companies. These risks include, but are not limited to, potential failure of preclinical and clinical studies, 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 health care 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 currently dependent on third-party service providers for much of its preclinical research, clinical development and manufacturing activities. Product candidates currently under development will require significant amounts of additional capital, and additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval, prior to commercialization. Even if the Company is able to generate revenues from the sale of its product candidates, if approved, 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 believes that its cash and cash equivalents and marketable securities of \$620,488 as of March 31, 2023 will be sufficient to fund its operations as currently planned through at least twelve months from the issuance of this Quarterly Report on Form 10-Q.

In November 2021, the Company entered into an 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 for an aggregate offering price of up to \$200.0 million, 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 filed with the Securities and Exchange Commission ("SEC") on November 24, 2021, as amended. 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 March 31, 2023, no shares have been issued under the Sales Agreement.

The Company is also subject to risks associated with the COVID-19 global pandemic, including actual and potential delays associated with certain of its ongoing and anticipated trials, and potential negative impacts on the Company's business operations and its ability to raise additional capital to finance its operations. Geopolitical events, including civil or political unrest (such as the ongoing war between Ukraine and Russia), have resulted in a significant disruption of global business and financial markets. In addition, recent or future market volatility, increased inflation and higher interest rates, if sustained, may increase our cost of financing and may restrict our access to potential sources of future liquidity.

2. Summary of Significant Accounting Policies

Basis of Presentation

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 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, 2022 included in the Company’s Annual Report on Form 10-K filed with the SEC on February 28, 2023.

Unaudited Interim Financial Information

The accompanying condensed consolidated balance sheet as of March 31, 2023, the condensed consolidated statements of operations and comprehensive loss for the three months ended March 31, 2023 and 2022, the condensed consolidated statements of stockholders’ equity for the three months ended March 31, 2023 and 2022, and the condensed consolidated statements of cash flows for the three months ended March 31, 2023 and 2022 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 March 31, 2023, the results of its operations for the three months ended March 31, 2023 and 2022 and its cash flows for the three months ended March 31, 2023 and 2022. The results for the three months ended March 31, 2023 are not necessarily indicative of results to be expected for the year ending December 31, 2023, or any other interim period.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and in these accompanying notes. The Company bases its estimates on historical experience, known trends and other market-specific or other relevant factors and assumptions that it believes to be reasonable under the circumstances. On an ongoing basis, management evaluates its estimates, which include but are not limited to estimates of accrued research and development expenses, valuation of marketable securities, the valuation of stock-based awards, valuation of operating lease right-of-use assets and lease liabilities and income taxes. Changes in estimates are recorded in the period in which they become known.

Principles of Consolidation

The 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

There were no changes in the Company’s significant accounting policies as described in the Annual Report on Form 10-K for the year ended December 31, 2022 filed with the SEC on February 28, 2023.

Recently Issued Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standard Board (“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 consolidated financial statements and disclosures.

3. Collaboration Agreement

Background

In October 2020, the Company entered into a License Agreement (the “Roche License Agreement”) with F. Hoffmann-LaRoche Ltd. and Genentech, Inc. (together, “Roche”) under which the Company granted an exclusive license for certain development and commercialization rights related to bemnifosbuvir outside of the United States (other than for certain HCV uses) to Roche.

On November 12, 2021, Roche provided the Company with a notice of termination of the Roche License Agreement which became effective in February 2022. Upon termination, the rights and licenses granted by the Company to Roche under the Roche License Agreement were returned to the Company, resulting in the Company having all rights to continue the clinical development and future commercialization of bemnifosbuvir worldwide. Global development plan activities and related cost sharing between the parties continued through the effective date of the termination.

The activities undertaken as a part of the global development plan were accounted for under ASC 808. Expenses incurred and reimbursements made or received from Roche were accounted for pursuant to ASC 730, *Research and Development*. As such, the Company was expensing costs as incurred, including any reimbursements made to Roche, and recognizing reimbursement received from Roche as a reduction of research and development expense through the effective date of the termination.

For the three months ended March 31, 2022, costs reimbursable by Roche, which are reflected as a reduction to research and development expenses were \$845. The Company recorded research and development expense of \$9,578 during the three months ended March 31, 2022, related to its share of costs incurred by Roche.

The Company recorded a credit to research and development expense of \$1,000 for the three months ended March 31, 2023. The credit recorded represents a change in estimate as a result of close out activities and related reporting of amounts incurred by Roche associated with the global development plan. Included in prepaid expenses and other current assets as of March 31, 2023 is a net balance due from Roche of \$1,000.

4. Marketable Securities

	As of March 31, 2023			
	Amortized Cost	Unrealized Gain	Unrealized Losses	Fair Value
Marketable Securities				
US Treasury obligations	\$ 64,741	\$ —	\$ (158)	\$ 64,583
US Government agency securities	33,555	64	(19)	33,600
Commercial paper	246,131	—	—	246,131
Corporate bonds	82,306	33	(195)	82,144
Asset-backed securities	10,807	—	(32)	10,775
Total	\$ 437,540	\$ 97	\$ (404)	\$ 437,233

	As of December 31, 2022			
	Amortized Cost	Unrealized Gain	Unrealized Losses	Fair Value
Marketable Securities				
US Treasury obligations	\$ 59,422	\$ —	\$ (304)	\$ 59,118
US Government agency securities	15,000	—	(59)	14,941
Commercial paper	310,433	—	—	310,433
Corporate bonds	61,504	—	(255)	61,249
Asset-backed securities	12,574	—	(66)	12,508
Total	\$ 458,933	\$ —	\$ (684)	\$ 458,249

As of March 31, 2023, the Company held 17 securities that were in an unrealized loss position of \$404 with an aggregate fair value of \$152,790. 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 three months ended March 31, 2023. The Company had no marketable securities prior to July 2022.

None of the securities had remaining maturities longer than one year as of March 31, 2023 or December 31, 2022.

The Company received proceeds of \$181,106 from sales and maturities of marketable securities during the three months ended March 31, 2023.

5. 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 March 31, 2023			
	Level 1	Level 2	Level 3	Total
Cash equivalents				
Money market funds	\$ 178,062	\$ —	\$ —	\$ 178,062
Commercial paper	—	4,997	—	4,997
Marketable Securities				
US Treasury obligations	—	64,583	—	64,583
US Government agency securities	—	33,600	—	33,600
Commercial paper	—	246,131	—	246,131
Corporate bonds	—	82,144	—	82,144
Asset-backed securities	—	10,775	—	10,775
Total	\$ 178,062	\$ 442,230	\$ —	\$ 620,292

	Fair Value Measurements as of December 31, 2022			
	Level 1	Level 2	Level 3	Total
Cash equivalents				
Money market funds	\$ 167,584	\$ —	\$ —	\$ 167,584
Marketable Securities				
US Treasury obligations	—	59,118	—	59,118
US Government agency securities	—	14,941	—	14,941
Commercial paper	—	310,433	—	310,433
Corporate bonds	—	61,249	—	61,249
Asset-backed securities	—	12,508	—	12,508
Total	\$ 167,584	\$ 458,249	\$ —	\$ 625,833

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 March 31, 2023 and December 31, 2022.

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

There were no transfers among Level 1, Level 2 or Level 3 categories in the three months ended March 31, 2023.

6. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following:

	March 31, 2023	December 31, 2022
Research and development, including manufacturing and clinical expenditures	\$ 7,347	\$ 7,667
Income taxes	178	99
Payroll and payroll related	2,400	6,459
Professional fees and other	1,006	981
Total accrued expenses and other current liabilities	\$ 10,931	\$ 15,206

7. Common Stock

At March 31, 2023, the authorized capital of the Company included 300,000,000 shares of common stock, of which 83,399,377 shares of common stock were issued and outstanding. On all matters to be voted upon by the holders of common stock, holders of common stock are entitled to one vote per share. The holders of common stock have no preemptive, redemption or conversion rights.

8. Stock-based Compensation

In October 2020, the Company's shareholders 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 or 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 also 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, 2022, the shares available under the plan were increased by 8,285,983 shares. In January 2023, the shares of the Company's common stock available under the 2020 Plan were increased by 4,164,381 shares. As of March 31, 2023, 7,067,749 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"). Upon any cancellation of outstanding option awards to purchase up to 5,982,266 shares of common stock under the 2013 Plan, such shares will be made available for grant under the 2020 Plan.

Restricted Stock Units

During the three months ended March 31, 2023 and 2022, respectively, the Company granted 2,065,800 and 182,350 restricted stock units to employees under the 2020 Plan with an aggregate grant date fair market value of \$9,565 and \$1,302, respectively. The restricted stock unit awards vest in three annual installments. Below is the activity related to restricted stock units for the three months ended March 31, 2023.

	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding at January 1, 2023	161,750	\$ 7.14
Granted	2,065,800	\$ 4.63
Released	(53,935)	\$ 7.14
Cancelled	(27,998)	\$ 5.62
Unvested shares at March 31, 2023	2,145,617	\$ 4.74

As of March 31, 2023, total unrecognized compensation expense related to restricted stock units was \$9,615, which amount is being recognized over a remaining weighted average period of 2.8 years.

Performance-based Restricted Stock Units

During the three months ended March 31, 2022, the Company granted 742,070 performance-based restricted stock units to employees under the 2020 Plan with an aggregate grant date fair value of \$5,298. The performance stock unit awards provide for a performance period from February 1, 2022 through January 31, 2025 to achieve up to six defined performance metrics. The percentage of each award eligible to vest will be determined based on the number of metrics achieved during the performance period and may range from 0% to 200%. The Company has not recognized any compensation expense through March 31, 2023, as the minimum performance criteria had not been deemed probable. The vesting of any eligible awards will occur in equal installments on January 31, 2025 and January 31, 2026.

During the year ended December 31, 2022, 17,100 performance-based restricted stock units were canceled due to terminations.

The following table summarizes the activity related to performance-based restricted stock units for the three months ended March 31, 2023.

	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding at January 1, 2023	724,970	\$ 7.14
Granted	—	\$ —
Released	—	\$ —
Cancelled	—	\$ —
Unvested shares at March 31, 2023	724,970	\$ 7.14

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, 2023	13,632,278	\$ 18.48	7.7	\$ 10,937
Granted	3,303,050	\$ 4.59		
Exercised	—	\$ —		
Cancelled	(283,154)	\$ 22.17		
Outstanding at March 31, 2023	16,652,174	\$ 15.66	7.8	\$ 6,070
Vested and expected to vest at March 31, 2023	16,652,174	\$ 15.66	7.8	\$ 6,070
Vested and exercisable at March 31, 2023	8,375,736	\$ 16.31	6.6	5,871

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 Company's common stock for those options that had exercise prices lower than the fair value of the Company's common stock.

Option grants generally vest over a service period of four years and have a contractual term of ten years. As of March 31, 2023, total unrecognized compensation expense related to stock option awards was \$87,997, which amount is being recognized over a remaining weighted average period of 2.7 years.

The aggregate grant date fair value of options granted during the three months ended March 31, 2023 and 2022 was \$11,123 and \$14,811, respectively.

Employee Stock Purchase Plan

In October 2020, the Company's shareholders approved the ESPP, which became effective upon the closing of the Company's IPO 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 the Company's 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, 2022, there was no increase in the number of shares reserved for issuance under the ESPP. In January 2023, the number of shares of the Company's common stock available for issuance under the ESPP was increased by 832,876 shares.

In April 2022, the Company initiated its first offering period under the ESPP. Each offering period is six months in duration with the purchase date being the last trading day of the offering period. During the three months ended March 31, 2023, the Company issued 57,803 shares for proceeds of \$165.

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 March 31,	
	2023	2022
Stock options	\$ 11,880	\$ 11,591
Restricted stock units	600	70
Performance-based stock units	—	—
Employee stock purchase plan	55	—
Total stock-based compensation expense	\$ 12,535	\$ 11,661

Stock-based compensation expense is classified as follows:

	Three Months Ended March 31,	
	2023	2022
Research and development expense	\$ 5,928	\$ 5,428
General and administrative	6,607	6,233
Total stock-based compensation expense	\$ 12,535	\$ 11,661

9. Net Loss Per Share

Basic and diluted earnings per share are calculated as follows:

	Three Months Ended March 31,	
	2023	2022
Net loss	\$ (35,467)	\$ (42,077)
Weighted average common shares outstanding, basic and diluted	83,332,397	83,176,408
Net loss per share, basic and diluted	\$ (0.43)	\$ (0.51)

Stock options for the purchase of 16,652,174 shares, 2,145,617 restricted stock units and 724,970 performance-based restricted stock units were excluded from the computation of the net loss per share for the three months ended March 31, 2023, due to net loss during the period as their effect is antidilutive.

Stock options for the purchase of 13,182,944 shares, 182,350 restricted stock units and 742,070 performance-based restricted stock units were excluded from the computation of the net loss per share for the three months ended March 31, 2022, due to net loss during the period as their effect is antidilutive.

10. 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.

In connection with the 225 Lease commencement, the Company recorded a right-of-use asset and operating lease liability of \$2,938 and \$2,873 as of January 1, 2022.

The following assets and liabilities are recorded on the Company's consolidated balance sheet as of March 31, 2023.

	As of March 31, 2023
Right-of-use asset	\$ 2,251
Current lease liability	730
Non-current lease liability	2,215

Future minimum payments under the 225 Lease, currently the Company's only operating lease as of March 31, 2023 were as follows.

	As of March 31, 2023
2023	\$ 604
2024	821
2025	838
2026	855
Total lease payments	3,118
Less amount representing implied interest	(173)
Total lease liability	\$ 2,945
Current portion of operating lease liabilities	\$ 730
Noncurrent portion of operating lease liabilities	\$ 2,215

For the three months ended March 31, 2023 and 2022, the Company recorded operating lease costs of \$162 and \$232, respectively, relating to its operating lease agreements.

The Company maintains a bank deposit of \$198, to collateralize a letter of credit which is classified as restricted cash in the consolidated balance sheet as of March 31, 2023.

11. Income Taxes

The Company recorded income tax expense of \$197 and \$0 for the three months ended March 31, 2023 and 2022, respectively. The Company maintained a full valuation allowance for the three months ended March 31, 2023 and 2022 due to uncertainty regarding its ability to utilize deferred tax assets.

12. Commitments and Contingencies

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 \$5.0 million. 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 requires 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, (ii) contracts under which the Company must indemnify directors and certain officers and consultants for liabilities arising out of their relationship, 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.

13. 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 March 31, 2023 and 2022, the Company recognized expense of \$394 and \$240, respectively, relating to matching contributions to the 401(k) Plan.

14. Related Party Transactions

The Company is party to 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 March 31, 2023 and 2022.

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, 2022, filed with the Securities and Exchange Commission ("SEC") on February 28, 2023. 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 clinical-stage biopharmaceutical company focused on discovering, developing, and commercializing antiviral therapeutics to improve the lives of patients suffering from serious viral infections. We are developing our lead product candidate, bennifosbuvir, for the treatment of COVID-19, the disease caused by infection with SARS-CoV-2 and its variants. We are also developing bennifosbuvir in combination with ruzasvir for the treatment of HCV.

COVID-19 has caused a global health crisis resulting in millions of deaths and lingering medical issues for many survivors. While there have been many rapid advances in the prevention and treatment of COVID-19, due to the limitations of the current vaccine and treatment options, there remains a significant unmet medical need for large numbers of high-risk individuals both in the US and globally. Our COVID-19 strategy, centered on the development of bennifosbuvir as a monotherapy and potentially as a part of a COVID-19 therapy that combines bennifosbuvir with another antiviral agent, focuses on high-risk patients for whom current vaccines and treatments remain inadequate. Our goal is to deliver a safe, effective, and convenient treatment option for individuals that remain vulnerable to hospitalization and death as a result of infection with SARS-CoV-2.

While the WHO recently determined that COVID-19 no longer fit the definition of a public health emergency and the US government has announced its plan to let the declaration of a public health emergency associated with COVID-19 ("PHE") expire on May 11, 2023, COVID-19 is expected to remain a serious endemic threat for an indefinite future period. The reasons contributing to the likelihood of COVID-19 remaining an endemic threat include: (1) viral transmission before symptom onset; (2) uneven global rollout of vaccinations; (3) ongoing vaccine hesitancy; (4) limited duration of immunity conferred by both natural infection and vaccination; (5) limited vaccine efficacy against certain SARS-CoV-2 variants; (6) limitations of current oral antivirals such as drug-drug interactions, safety concerns and tolerability; (7) uncertain impact of vaccines on transmission; (8) continuing evolution of the virus evading endogenous and vaccine-induced immunity; and (9) diminution of virus transmission mitigation behaviors, such as wearing masks and social distancing.

As COVID-19 continues to persist as a serious global endemic disease, we believe that the COVID-19 therapeutic market will remain a multi-billion-dollar opportunity for many years to come with the US continuing to comprise the most significant commercial market. In the US, we anticipate that the COVID-19 commercial market will soon transition from a single government payer to more traditional payer channels such as Medicare, Medicaid and private commercial insurance. We anticipate a major consideration for determining reimbursement by these third party payers will be a cost/value analysis that is driven in part by the economic burden of hospitalization, especially for at-risk populations.

Bennifosbuvir

We utilized our team's expertise and experience, gained from decades of developing innovative antiviral treatments, to design bennifosbuvir, an investigational, proprietary, potent, and selective, nucleotide polymerase inhibitor, which may be developed as each of a monotherapy and in combination with other antiviral agents. Bennifosbuvir (AT-527) has been derived from our internal discovery program that combines unique nucleotide scaffolds with novel double prodrugs for the purpose of inhibiting the enzymes central to viral replication. Utilizing this double prodrug moiety approach, we believe that we have been able to maximize formation of the active metabolite of bennifosbuvir thereby creating an oral antiviral product candidate that is designed to prevent replication of single stranded RNA viruses while avoiding toxicity to host cells. Additionally, in nonclinical studies we have demonstrated that bennifosbuvir has a unique mechanism of action that includes both RNA dependent RNA polymerase chain termination and inhibition of the nucleotidyltransferase of the SARS-CoV-2 virus and variants. By targeting these highly conserved sites through this unique dual mechanism of action, bennifosbuvir has the potential to create a high barrier to resistance. Additionally, in *in vitro* studies we have conducted,

bemnifosbuvir maintained its antiviral activity across COVID-19 variants of concern, including all Omicron subvariants that have been tested.

COVID-19 Clinical Studies

In November 2022, we initiated SUNRISE-3, a global, multicenter, randomized, double-blind, placebo-controlled Phase 3 clinical trial. SUNRISE-3 is evaluating bemnifosbuvir (550 mg BID for five days) in at least 1500 high-risk non-hospitalized patients with mild or moderate COVID-19. The trial is being conducted at clinical trial sites in the US, Europe, Japan, and other regions of the world. The patient population consists of those at the highest risk for disease progression, including patients ≥ 80 years old, patients ≥ 65 years old with one or more major risk factors, and immunocompromised patients ≥ 18 years old, all regardless of COVID-19 vaccination status.

SUNRISE-3 is designed to evaluate bemnifosbuvir as monotherapy (primary analysis) but will also explore the effect of combination therapy in a smaller sub-set of patients who receive an antiviral drug along with bemnifosbuvir (secondary analysis). The trial will include two populations derived from the type of SOC received: 1) "supportive care population" (those patients who do not qualify for an approved antiviral treatment or where antivirals are not locally available) which will assess bemnifosbuvir given as monotherapy (primary analysis) and 2) "combination antiviral population" which will assess combination therapy if the SOC includes treatment with other compatible antiviral drugs against COVID-19 (secondary analysis). Patients are being randomized 1:1 to receive either bemnifosbuvir 550 mg BID plus locally available SOC or placebo BID plus locally available SOC for five days.

The primary endpoint of the SUNRISE-3 study is all-cause hospitalization or death through Day 29 in at least 1,300 patients in the supportive care population and is powered to detect a clinically meaningful reduction in hospitalization/death versus placebo in this population. By enriching the patients enrolling in the trial with those who are at the highest risk for disease progression, we are targeting rates of hospitalization/death of ~4-6%. An interim analysis will be conducted by a data safety monitoring board ("DSMB") after 60% patient enrollment in the arm of the study enrolling the supportive care population. Secondary endpoints in each of the supportive care patient population and the combination antiviral population include COVID-19 complications, medically attended visits, symptom rebound/relapse and viral load rebound.

In parallel to conducting our SUNRISE-3 clinical trial, we are engaging in efforts to discover a protease inhibitor product candidate that we may combine with bemnifosbuvir for the treatment of specific COVID-19 patient populations that are unable to mount immune response to vaccines and require combination therapy. We have conducted *in vitro* studies that have demonstrated an additive antiviral effect when bemnifosbuvir was combined with antivirals from the protease inhibitor class, including nirmatrelvir. The data that we anticipate obtaining from the SUNRISE-3 clinical trial in the subset of patients who receive combination therapy will be, we believe, the first clinical data evaluating the combination of bemnifosbuvir and certain other currently authorized antiviral treatments. This data will be instrumental for further informing our design of the clinical development of the combination therapy.

Hepatitis C Virus (HCV) Clinical Studies

For the treatment of chronic HCV infection, we are advancing the combination of bemnifosbuvir and ruzasvir, an investigational NS5A inhibitor. Approximately 58 million people globally, including ~2.4 million in the US, are living with chronic HCV infection. The WHO reports a global incidence of 1.5 million cases per year and 399,000 deaths per year. The US HCV prevalence is expected to remain constant over the coming years as rising HCV incidence offsets the number of new patients treated.

We believe that the combination of bemnifosbuvir and ruzasvir has the potential to improve upon the current standard of care by offering a differentiated short duration, pan-genotypic protease-sparing regimen for HCV-infected patients with or without cirrhosis.

During the second quarter of 2023, we plan to initiate enrollment of a Phase 2 clinical trial of bemnifosbuvir in combination with ruzasvir in treatment-naïve, HCV-infected patients either without cirrhosis or with compensated cirrhosis. This study is designed to evaluate the safety and efficacy of the pan-genotypic combination consisting of 550 mg QD of bemnifosbuvir and 180 mg QD of ruzasvir after eight weeks of treatment. Approximately 280 HCV-infected, treatment-naïve patients across all genotypes, including a lead-in cohort of approximately 60 patients are expected to be enrolled in this Phase 2 clinical trial. The primary endpoints of the study are safety and sustained virologic response (SVR) at Week 12 post-treatment. Other virologic endpoints include virologic failure, SVR at Week 24 post-treatment and resistance.

Dengue

In February 2023, after advancing AT-752 to a Phase 2 clinical trial, we determined not to pursue further clinical development of AT-752 for the treatment and prophylaxis of dengue. This action was taken due to the long timelines anticipated for patient enrollment, expected clinical operational challenges, including the challenge of successfully administering an antiviral very shortly after infection which is not feasible with the current diagnostic tests, and estimated resource burdens, including substantial costs, associated with the further clinical development of an antiviral for each of the treatment and prophylaxis of dengue.

Financial Resources

We believe we are well capitalized to advance our current programs. We had \$620.5 million in cash, cash equivalents and marketable securities at March 31, 2023. Based on our current plans, we anticipate these financial resources will allow us to advance our current and planned clinical programs to and through key inflection points and to fund our activities into 2026.

Roche License Agreement

In October 2020, with Roche, we entered into the Roche License Agreement in connection with the global development, manufacture and commercialization of bemnifosbuvir, products containing bemnifosbuvir and related companion diagnostics. During the term of the Roche License Agreement, Roche and we jointly developed bemnifosbuvir for COVID-19 on a worldwide-basis and equally shared the costs associated with such development activities.

The Roche License Agreement terminated on February 10, 2022, and, accordingly, our obligations to share costs with Roche also ended. As a result of the termination of the Roche License Agreement, we have regained worldwide exclusive rights from Roche to research, develop, manufacture and commercialize bemnifosbuvir, products containing bemnifosbuvir and related companion diagnostics in all fields of use.

Financial Operations Overview

As of March 31, 2023, we had cash, cash equivalents and marketable securities of \$620.5 million. Net cash used in operating activities was \$29.9 million for the three months ended March 31, 2023.

We expect that our net cash used in operating activities will increase significantly as we advance our product candidates through preclinical and clinical development, seek regulatory approval, and prepare for and, if approved, proceed to commercialization; acquire, discover, validate and develop additional product candidates; obtain, maintain, protect and enforce our intellectual property portfolio; and 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 and cash equivalents will be sufficient to fund our planned operations into 2026.

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 or 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 contract 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 significantly higher expenses over the next several years. We anticipate that our expenses will increase significantly in connection with our ongoing activities, as we:

- continue clinical development of bemnifosbuvir as a monotherapy for the treatment of COVID-19;
- continue the clinical development of the combination of bemnifosbuvir and ruzasvir for the treatment of HCV;

- continue discovery and IND-enabling activities in anticipation of nominating a protease inhibitor product candidate for the treatment of COVID-19;
- initiate clinical development of bemnifosbuvir in combination with a protease inhibitor for the treatment of COVID-19;
- manufacture increasing quantities of bemnifosbuvir drug substance and drug product in anticipation of potential commercialization;
- seek market approval and prepare for potential commercialization of product candidates we may successfully develop;
- 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 research, development and administrative personnel; 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 to date, we have not generated any revenue from product sales.

Operating Expenses

Research and Development Expenses

Substantially all of our research and development expenses consist of expenses incurred in connection with the 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 product 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.

As discussed in Note 3 to our unaudited condensed consolidated financial statements, during the term of the Roche License Agreement which terminated in February 2022, we and Roche shared certain manufacturing and clinical development costs on a 50/50 basis. Billings to us by Roche for our percentage share of such expenses were recorded in research and development expenses. During the three months ended March 31, 2023, we recorded a net reduction to research and development expenses of \$1.0 million related to credits received from Roche. These credits were the result, following the termination of the Roche License Agreement, of changes and adjustments by Roche in estimated amounts of expenses reported by Roche during the period in which we and Roche shared costs associated with the development of bemnifosbuvir.

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

	Three Months Ended March 31,	
	2023	2022
	(in thousands)	
COVID-19 external costs	\$ 8,949	\$ 13,331
Dengue external costs	3,293	3,227
HCV external costs	3,373	1,424
RSV external costs	—	537
Internal research and development costs	13,339	11,114
Total research and development costs	\$ 28,954	\$ 29,633

We are focusing substantially all of our resources on the development of our product candidates, particularly bempifosbuvir. We expect our research and development expenses to increase substantially for at least the next few years, as we seek to initiate additional clinical trials for our product candidates, complete our clinical programs, pursue regulatory approval of our product candidates and prepare for the possible commercialization of these product candidates. Predicting the timing or cost to complete our clinical programs or validation of our commercial manufacturing and supply processes 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, we could be required to expend significant additional financial resources and time on the completion of clinical development. Furthermore, we are unable to predict when or if our product candidates will receive regulatory approval with any certainty.

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, allocated overhead, including rent, equipment, depreciation, information technology costs and utilities, and other general operating expenses not otherwise classified as research and development expenses.

We anticipate that our general and administrative expenses may increase as a result of increased personnel costs, expanded infrastructure, increased consulting, legal and accounting services costs associated with complying with Nasdaq and SEC requirements and increased investor relations costs as the Company continues to grow.

Interest Income and Other, Net

Interest income and other, net, consists primarily of interest income earned on our cash, cash equivalents and marketable securities.

Income Taxes

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

Results of Operations

Comparison of the Three Months Ended March 31, 2023 and 2022

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

	Three Months Ended March 31,		Change
	2023	2022	
	(in thousands)		
Operating expenses:			
Research and development	\$ 28,954	\$ 29,633	\$ (679)
General and administrative	12,615	12,542	73
Total operating expenses	41,569	42,175	(606)
Loss from operations	(41,569)	(42,175)	606
Interest income and other, net	6,299	98	6,201
Loss before income taxes	(35,270)	(42,077)	6,807
Income tax expense	(197)	—	(197)
Net loss and comprehensive loss	\$ (35,467)	\$ (42,077)	\$ 6,610

Research and Development Expenses

Total research and development expenses decreased \$0.6 million from \$29.6 million for the three months ended March 31, 2022 to \$29.0 million for the three months ended March 31, 2023. Research and development expenses primarily consists of external expenses incurred related to services provided by the CROs and CMOs in conjunction with the advancement of product candidates. Research and development expenses recorded for the Roche cost share agreement for the three months ended March 31, 2022 were \$9.6 million compared to a credit of \$1.0 million recorded for the three months ended March 31, 2023.

General and Administrative Expenses

General and administrative expenses remained relatively consistent at approximately \$12.6 million for the three months ended March 31, 2022 and for the three months ended March 31, 2023.

Interest Income and Other, Net

Interest income and other, net, increased by \$6.2 million from less than \$0.1 million for the three months ended March 31, 2022 to \$6.3 million during the three months ended March 31, 2023. The increase was primarily a result of investing in higher yield marketable securities and higher interest rates.

Income Tax Expense

We recorded income tax expense of \$0.2 million and \$0 million for the three months ended March 31, 2023 and 2022 respectively. We maintained a full valuation allowance for the three months ended March 31, 2023 and 2022 due to uncertainty regarding our ability to utilize deferred tax assets.

Liquidity and Capital Resources

Sources of Liquidity

As of March 31, 2023, we had cash, cash equivalents and marketable securities of \$620.5 million. Based upon our current operating plan, we believe that our available cash, cash equivalents and marketable securities will be sufficient to fund our planned operations into 2026.

We entered into an open market sales agreement ("Sales Agreement") with Jefferies LLC ("Jefferies"), in 2021 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 March 31, 2023, no shares have been issued under the Sales Agreement.

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 increased expenditures for the foreseeable future, and we expect our expenses to increase as we continue the development of, and seek regulatory approvals for, our product candidates 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 as we continue to operate as a public company and expand our organization to support more advanced clinical development of our product candidates and the initiation of activities in preparation for potential commercialization of our product candidates.

We will continue to require additional capital to develop our product candidates and fund operations for the foreseeable future. We may seek to raise capital through public or private equity or 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 drug discovery efforts, preclinical development activities, laboratory testing and clinical trials for our product candidates;
- the number and scope of clinical programs we decide to pursue;
- the cost, timing and outcome of preparing for and undergoing regulatory review of our product candidates;
- the scope and costs of development and commercial manufacturing activities;
- the cost and timing associated with commercializing our 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 efforts to enhance operational systems and our ability to attract, hire and retain qualified personnel, including personnel to support the development of our product candidates and, ultimately, the sale of our products, following regulatory approval;
- our implementation 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 the development of any of our product candidates could significantly change the costs and timing associated with the development 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. Any future debt financing into which we enter may impose upon us additional covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our common stock, make certain investments or engage in certain merger, consolidation or asset sale transactions. Any 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 and clinical trials 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 concerns associated with the evolution or potential resurgence of the COVID-19 pandemic and geopolitical events, including civil or political unrest (such as the ongoing conflict between Ukraine and Russia), 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 Statement of Cash Flows

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

	Three Months Ended March 31,	
	2023	2022
	(in thousands)	
Net cash provided by (used in):		
Operating activities	\$ (29,850)	\$ (59,009)
Investing activities	24,480	(44)
Financing activities	165	223
Net decrease in cash, cash equivalents and restricted cash	\$ (5,205)	\$ (58,830)

Cash Flows from Operating Activities

Net cash used in operating activities for the three months ended March 31, 2023 was \$29.9 million. Cash used in operating activities was primarily due to net loss of \$35.5 million, accretion of premium and discounts on marketable securities of \$3.1 million and a decrease in accounts payable and accrued expenses of \$6.0 million, partially offset by stock-based compensation of \$12.5 million and a decrease in prepaid expenses of \$2.3 million.

Net cash used in operating activities for the three months ended March 31, 2022 was \$59.0 million. Cash used in operating activities was primarily due to net loss of \$42.1 million and a decrease in accounts payable and accrued expenses of \$28.9 million, partially offset by stock-based compensation of \$11.7 million and a decrease in prepaid and other current assets of \$0.3 million.

Cash Flows from Investing Activities

Cash provided by investing activities for the three months ended March 31, 2023 was \$24.5 million and consisted of sales and maturities of marketable securities of \$181.1 million partially offset by purchases of marketable securities of \$156.6 million.

Cash used in investing activities for the three months ended March 31, 2022 was less than \$0.1 million and consisted of purchases of fixed assets.

Cash Flows from Financing Activities

Net cash provided by financing activities was \$0.2 million for the three months ended March 31, 2023 and consisted of proceeds from the shares sold under the Company's ESPP.

Net cash provided by financing activities was \$0.2 million for the three months ended March 31, 2022 and consisted of proceeds from the exercise of stock options.

Contractual Obligations and Commitments

There have been no material changes to our contractual obligations during the three months ended March 31, 2023 from those previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2022.

We enter into contracts in the normal course of business with third-party contract organizations including CROs and CMOs for preclinical and clinical studies and testing, manufacture and supply of our preclinical materials and 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 cancellation consist only of payments for services provided and expenses incurred up to the date of cancellation.

Critical Accounting Policies and Estimates

Our financial statements have been prepared in accordance with 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 under different assumptions or conditions.

Our critical accounting policies and estimates are described under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Estimates” in our Annual Report on Form 10-K for the year ended December 31, 2022. We believe that these accounting policies are critical to understanding our historical and future performance, as these policies relate to significant areas involving management’s judgments and estimates. During the three months ended March 31, 2023, there were no material changes to our critical accounting policies and estimates from those discussed in our Annual Report on Form 10-K.

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 reduces our exposure and enables 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 March 31, 2023, we had cash, cash equivalents and marketable securities of \$620.5 million, consisting of interest-bearing money market funds 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.

We do not believe that inflation, interest rate changes or foreign currency exchange rate fluctuations have had a material 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 Exchange Act). Based on that evaluation, our principal executive officer and principal financial officer concluded that, as of March 31, 2023, 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 March 31, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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 Results of Operations and Financial Condition." 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 COVID-19***There is significant uncertainty around our development of bempifosbuvir as a potential treatment for COVID-19.***

Since the start of the COVID-19 pandemic, we have focused substantive efforts on the development of bempifosbuvir for the treatment of COVID-19. We may not succeed in developing, securing market authorization or approval, or commercializing bempifosbuvir as a potential treatment for COVID-19.

In October 2020, we entered into a license agreement (as amended, "Roche License Agreement") with F. Hoffmann-LaRoche Ltd. and Genentech, Inc. (together, "Roche") under which we granted to Roche an exclusive license to development and commercialization rights related to certain of our compounds, including bempifosbuvir, outside of the US (other than for certain HCV uses). Together with Roche, in April 2021, we initiated a randomized, double blind, multi-center, placebo-controlled Phase 3 MORNINGSKY clinical trial to study bempifosbuvir in adult and adolescent patients with mild or moderate COVID-19 in the outpatient setting and we subsequently initiated MEADOWSPRING, a Phase 3 six month follow-up study, to assess the impact of bempifosbuvir treatment on long-term sequelae of COVID-19 in the patients previously enrolled in MORNINGSKY. These Phase 3 clinical trials were begun while two initial Phase 2 clinical trials evaluating bempifosbuvir in patients with COVID-19 were ongoing. One of these Phase 2 clinical trials enrolled hospitalized patients and the other Phase 2 MOONSONG clinical trial enrolled outpatients. In October 2021, we, together with Roche, completed MOONSONG, and we announced that we did not meet the primary endpoint of reduction from baseline in the amount of SARS-CoV-2 virus in patients with mild or moderate COVID-19 compared to placebo in the overall study population, of which approximately two-thirds of enrolled patients were low-risk with mild symptoms. In November 2021, Roche notified us that it was terminating the Roche License Agreement effective February 10, 2022. In December 2021, due to the changing COVID-19 treatment landscape, including the availability of new oral antiviral treatment regimens, we determined to discontinue each of the Phase 3 MORNINGSKY and MEADOWSPRING clinical trials. We did not enroll a sufficient number of patients in either Phase 3 study to conduct prespecified statistical analyses. In January 2022 we determined to close out the Phase 2 clinical trial in hospitalized patients.

Nonetheless, we are advancing the development of bempifosbuvir for the treatment of COVID-19 in high risk non-hospitalized patients pursuing both a mono- and combination strategy. We do not know if either monotherapy or combination therapy approach will be successful. In November 2022, we initiated SUNRISE-3, a global, multicenter, randomized, double blind, placebo-controlled Phase 3 clinical trial evaluating bempifosbuvir (550 mg BID for 5 days) in at least 1500 high-risk non-hospitalized patients with mild or moderate COVID-19.

In parallel with the conduct of SUNRISE-3, we are also engaging in efforts to discover a proprietary protease inhibitor that could potentially be combined with bempifosbuvir for the treatment of COVID-19. Our efforts to internally discover and develop a potential protease inhibitor to evaluate in combination with bempifosbuvir are at a very early stage and we do not know if such efforts will be successful, or if successful, when a protease inhibitor product candidate generated from our discovery efforts may be permitted to enter clinical development. Before we can begin clinical development of a newly discovered protease inhibitor product candidate, or any other product candidate, we will need to complete extensive preclinical studies to support the submission of an IND to the FDA or CTA to a comparable regulatory authority outside the US.

Conducting preclinical testing of any product candidate and the related manufacture of sufficient quantities of material that can be used in clinical trials, is a complex, lengthy, time consuming and expensive process. As a

result, we cannot be certain that we will be able to submit such INDs or CTAs on the timelines we expect, if at all, and we cannot be certain that regulatory authorities will allow clinical trials of a protease inhibitor that we newly discover to begin.

Alternatively, we may in-license or acquire the rights to develop and commercialize a protease inhibitor drug candidate from a third-party. Proposing, negotiating and implementing acquisition or in-license of a protease inhibitor or any other product candidate that may be combined with bemnifosbuvir for the potential treatment of COVID-19 may be a lengthy and complex process. Other companies, including those with substantially greater financial, marketing and sales resources, may compete with us for the acquisition of such product candidates. We may not be able to acquire the rights to additional product candidates on terms that we find acceptable, if at all.

In addition, clinical trials evaluating combination regimens such as the one we are proposing with the combination of bemnifosbuvir and a protease inhibitor are subject to additional costs, time and risks, including the requirement to sufficiently demonstrate the effect, if any, of each constituent component of the combination regimen to the satisfaction of the FDA or other regulatory authorities. For example, we expect that we will be required to conduct early stage clinical trials evaluating the safety of any newly discovered protease inhibitor candidate before we can conduct later stage clinical trials evaluating the combination of bemnifosbuvir with such protease inhibitor.

We have committed and plan to continue to commit significant financial and personnel resources to the development of bemnifosbuvir as a monotherapy, to the discovery of a protease inhibitor candidate to combine with bemnifosbuvir and to the combination of bemnifosbuvir and a protease inhibitor candidate for the treatment for COVID-19 (each, a "bemnifosbuvir COV19 product candidate"). If we are unable to successfully develop one or more bemnifosbuvir COV19 product candidates, we will have taken resources away from other development programs and may not be able to recuperate the resources dedicated to developing bemnifosbuvir COV19 product candidates, which could have a material adverse impact on our business.

If we are unable to complete the SUNRISE-3 clinical trial in the manner or on the timeline we anticipate or if data from our Phase 3 SUNRISE-3 clinical trial and other clinical trials are not supportive of further development or commercialization of one or more bemnifosbuvir COV19 product candidates, or the investor community otherwise has a negative reaction to any of the design of our clinical trial, expected time to complete our clinical trial or the clinical trial data, the demand for our common stock could decrease significantly, and the price of our common stock could decline substantially, which could result in significant losses for our stockholders.

Further, while we believe there is currently an urgent need for additional oral antiviral treatments for COVID-19, the longevity and extent of the ongoing COVID-19 pandemic is uncertain and it is unclear whether SARS-CoV-2 will become an endemic human coronavirus that may circulate in the human population after the current pandemic has subsided. If the serious public health consequences associated with COVID-19 and infection with SARS-CoV-2 variants or subvariants were to dissipate, whether due to a significant and sustained decrease in the number or severity of new infections, the effectiveness of vaccines, the effectiveness of other treatment options, or otherwise, the need for treatments could decrease significantly. If the need for a new treatment decreases before or soon after commercialization of a bemnifosbuvir COV19 product candidate, if successfully developed and approved, our business would be adversely impacted.

A bemnifosbuvir COV19 product candidate, even if successfully developed and approved, is expected to face significant competition from other treatments and vaccines for COVID-19 which have been authorized or approved for use or are in development.

Many biotechnology and pharmaceutical companies have and are continuing to develop treatments for COVID-19 or vaccines against SARS-CoV-2, the virus that causes COVID-19. Many of these companies, which include large pharmaceutical companies, have greater resources for development and established commercialization capabilities.

Currently in the US and elsewhere, there are several vaccines and associated vaccine boosters approved or authorized for use for COVID-19 and there are therapeutics available for the treatment of COVID-19 including two oral antiviral therapies, Paxlovid™ developed by Pfizer Inc., and Lagevrio™ developed by Merck and Ridgeback Therapeutics, each of which are authorized for emergency use for high risk COVID-19 patients. Additionally, Veklury, a nucleotide prodrug developed by Gilead Sciences, is approved for the treatment of COVID-19 in adults and pediatric patients who are hospitalized or if not hospitalized have mild to moderate COVID-19 and are at high risk for progression to severe COVID-19, including hospitalization and death. In Japan, the oral antiviral, Xocova® developed and marketed by Shinogi & Co., Ltd., is approved for emergency use in patients with mild to moderate SARS-CoV-2 infection.

Treatments in development for COVID-19 include obeldesivir (GS-5245), an oral nucleoside prodrug, that is being developed by Gilead Sciences and is currently being evaluated in two Phase 3 clinical trials including a randomized, double-blind placebo controlled Phase 3 clinical trial in non-hospitalized COVID patients who are at high risk of progression to hospitalization.

In addition to therapeutics, vaccines indicated for active immunization to prevent COVID-19 and vaccine “boosters,” which are intended to extend the immunizing effect initiated with the administration of the initial vaccine have been approved or authorized for emergency use by the FDA. Vaccine manufacturers, including Pfizer and BioNTech SE and Moderna, Inc., are continuing to develop new vaccines and boosters that may have greater and longer immunizing effects against current and future variants of SARS-CoV-2.

Additional vaccines and therapeutics are in development by other pharmaceutical and biopharmaceutical companies. Other companies developing oral direct acting antivirals for treatment of COVID-19 include Enanta Pharmaceuticals, Inc., Shionogi & Co., Ltd., Pardes Biosciences, Inc., Junshi Biosciences, Jiangsu Simcere Pharmaceuticals, and SyneuRx.

Given the products currently approved or authorized for use as well as those in development by others, any treatment we may develop could face significant competition. If we are unable to develop a treatment that can be distinguished based on efficacy, safety, cost or other factors from the growing number of treatments for COVID-19 or if any treatment becomes the standard of care, can be administered more conveniently or at a lower cost, or any entity is more successful at commercializing an authorized or approved treatment, even if a bemnifosbuvir COVID-19 product candidate is approved, we may not be able to successfully commercialize such a product for the treatment of COVID-19, or compete with other treatments or vaccines, which would adversely impact our business and operations.

Our business, operations and financial results may be adversely affected by the continuing evolution of the COVID-19 pandemic or the occurrence of any similar public health crises.

The evolving and constantly changing impact of COVID-19, which was declared a global pandemic by the WHO in March 2020, will directly affect the potential commercial prospects of our product candidates for the treatment of COVID-19. In May 2023, three years into the pandemic, the WHO determined that COVID-19 no longer fit the definition of the public health emergency of international concern. While noting that this determination did not mean that the pandemic itself is ended, the WHO concluded that the global emergency COVID-19 has caused is concluded for the time being. In reaching this conclusion, the WHO considered evidence of reducing risks to human health driven mainly by high population-level immunity from infection, vaccination or both; consistent virulence of currently circulating SARS-CoV-2 Omicron sub-lineages and improved clinical case management. Further, the WHO considered that these factors have contributed to a decline in the weekly number of COVID-19 related deaths and hospitalizations since the beginning of the pandemic and that while SARS-CoV-2 continues to evolve, the currently circulating variants do not appear to be associated with increased severity.

The rates of infection, severity of the disease, the availability, administration and acceptance of vaccines, monoclonal antibodies, antiviral agents and other therapies, potential vaccine mandate policies, and “herd immunity” by the global population if achieved and sustained may materially affect the design and will impact the enrollment of our clinical trials, the potential regulatory authorization or approval of our product candidates and the commercialization of our product candidates, if authorized or approved.

To date, we have experienced some disruption and delays certain of our clinical programs and timelines as a result of the COVID-19 pandemic. For example, in 2020 we paused our hepatitis C virus clinical development program when clinical trial sites closed due to COVID-19 precautions by the countries and medical facilities where the clinical trial was to be conducted. We expect to re-initiate patient enrollment in HCV clinical trials prior to the end of the second quarter of 2023.

As a result of the evolution of the COVID-19 pandemic or the occurrence of any other public health crises, we may experience additional disruptions that could severely impact our clinical trials, including but not limited to:

- delays or difficulties in enrolling patients in a clinical trial as a result of rapidly evolving treatment paradigms, particularly in the case of patients with COVID-19;
- patients that may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators, and clinical site staff, or the overwork of existing investigators and staff;

- diversion or prioritization of healthcare resources away from the conduct of clinical trials and towards the COVID-19 pandemic or other public health crises, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruptions or delays in preclinical studies due to restricted or limited operations at research and development laboratory facilities;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal, state or provincial governments, employers and others;
- the risk that participants enrolled in our non-COVID-19-related clinical trials will contract COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events;
- limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials;
- interruption in global shipping that may affect the transport of clinical trial materials, such as investigational drug product and supplies;
- changes in local regulations as part of a response to the evolution of the COVID-19 pandemic or in response to another public health crises that may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees; and
- the refusal of the FDA or foreign regulatory authorities to accept data from clinical trials in these affected geographies.

The impact to our operations due to a resurgence of the COVID-19 pandemic or the occurrence of any similar public health crises could be severe and could negatively affect our business, financial condition, and results of operations. To the extent that the evolution of the COVID-19 pandemic or the occurrence of a similar public health crises adversely affects our business and financial results, it may also have the effect of heightening many of the other risk factors described in this “Risk Factors” section

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-stage biopharmaceutical company. 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 complete any late-stage or pivotal clinical trials, obtain marketing approval, manufacture a product at 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. For example, due to changes in the COVID-19 landscape, we discontinued our Phase 3 MORNINGSKY trial in December 2021. In November 2022, we initiated a subsequent Phase 3 clinical trial, SUNRISE-3, evaluating bemnifosbuvir for the treatment of high risk outpatients with mild or moderate COVID-19. The primary endpoint of the SUNRISE-3 trial is all cause hospitalization or death through day 29 in the population of enrolled patients who receive only bemnifosbuvir or placebo without co-administration of the local standard

care therapeutic. Our current study design and sample size contemplates that the rate of hospitalization in the placebo cohort will be at least 4%. If the actual rate of hospitalization in the placebo cohort of patients is less, the sample size and number of patients enrolling overall in the trial may need to be increased. This would make the trial more difficult to complete, if at all, and the time and cost for completion of the trial would be expected to increase. As the COVID-19 landscape has evolved, rates of testing, diagnosis and hospitalization for COVID-19 have and continue to vary substantially. Reported rates of hospitalization in many geographic regions have and may continue to fluctuate significantly including being reported below 4% for the overall patient population in specific regions. Additionally, it is uncertain what effect the lapse of the US declaration of the PHE and the migration of government provided therapeutics, testing kits and other related items to more traditional commercial channels may have on rates of testing and diagnoses among other things. To the extent that additional costs will be incurred by patients, it is reasonable to anticipate that rates of testing may decline after the lapse of the PHE declaration.

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 supporting commercial activities. We may not be successful in this transition.

As we continue to build our business, 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 2023 and for the foreseeable future.

We have incurred significant operating expenses since our inception. For the three months ended March 31, 2023 and the year ended December 31, 2022, our operating expenses were \$41.6 million and \$130.7 million, respectively.

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 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, expand our research and development activities, discover or acquire and develop product candidates, including any product candidate we may seek to combine with bemnifosbuvir for the potential treatment of COVID-19, complete preclinical studies and clinical trials, 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 an 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 animal tests, which are referred to as nonclinical or preclinical studies, as well as human tests, which are referred to as clinical trials.

Furthermore, the costs of advancing product candidates into each succeeding clinical phase tend to increase substantially over time. The total costs to advance any of our product candidates to marketing approval in even a single jurisdiction would be substantial and difficult to accurately predict. Because of the numerous risks and uncertainties associated with the development of drug products, 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. As we advance clinical development activities, particularly our Phase 3 SUNRISE-3 clinical trial for the treatment of high risk outpatients with mild or moderate COVID-19 and our Phase 2 clinical trial evaluating the combination of bemnifosbuvir and ruzasvir for the treatment of HCV, we expect our expenses will increase substantially. Additionally, our expenses will also increase substantially if or as we:

- initiate clinical trials of a potential bemnifosbuvir combination regimen for the treatment of patients with COVID-19;
- continue to discover and develop additional product candidates;

- seek regulatory and marketing approvals for product candidates that successfully complete clinical trials, if any;
- establish manufacturing and supply chain capacity sufficient to provide commercial quantities of any product candidates for which we may obtain marketing approval, if any;
- establish a sales, marketing, internal systems and distribution infrastructure 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 co-promotion 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 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 license agreement we entered into in December 2021 with MSD International GmbH, an affiliate of Merck & Co, Inc. (“Merck”) with respect to the development and commercialization of ruzasvir 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. Each of our product candidates and any future product candidate we may discover, license or otherwise acquire, will require additional preclinical and/or clinical development, 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 a commercial organization, substantial investment and significant marketing efforts before we generate any revenue from product sales. 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 foreseeable future, 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 clinical development of our product candidates; obtaining necessary regulatory approvals from the FDA and foreign regulatory authorities; establishing manufacturing and sales capabilities; 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, our business, prospects, and results of operations may be materially adversely affected.

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 \$250,000 Federal Deposit Insurance Corporation (“FDIC”) insurance limits. 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 by the financial institutions with which we have arrangements directly facing liquidity constraints or failures. 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 operational expenses or make other payments.

We will 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 the conduct of the Phase 3 SUNRISE-3 clinical trial for the treatment of high risk outpatients with mild or moderate COVID-19 and our Phase 2 clinical trial evaluating the combination of bemnifosbuvir and ruzasvir for the treatment of HCV. Additionally, we anticipate that we will incur substantial expenses in connection with the development of a combination bemnifosbuvir COVID-19 product candidate and in connection with the discovery, acquisition and development of other product candidates.

We will continue to need additional capital to fund future clinical trials and preclinical development, which we may raise through equity offerings, 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 do not succeed in raising additional funds on acceptable terms, we might be unable to initiate or complete planned clinical trials or seek regulatory approvals of any of our product candidates from the FDA, or any foreign regulatory authorities, and could be forced to discontinue product development. 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 efforts.

Based on our current operating plan, we believe that our cash and cash equivalents as of March 31, 2023 will be sufficient to fund our operating expenses and capital expenditure requirements into 2026. This estimate is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. We will require significant additional funds in order to launch and commercialize our current and any future product candidates to the extent that such launch and commercialization are not the responsibility of a collaborator. In addition, other unanticipated costs may arise in the course of our development efforts. Because the design and outcome of our planned and anticipated clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and, if approved, commercialization of any product candidate we develop.

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 our Phase 3 SUNRISE-3 clinical trial;
- the timing of and costs associated with discovery, license or acquisition of a protease inhibitor or another direct acting antiviral product candidate to combine with bemnifosbuvir and develop for the treatment of patients with COVID-19;
- 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;
- 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 costs of 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 establishing product sales, marketing, distribution and manufacturing capabilities;
- 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 which are anticipated as a result of the enactment of the Inflation Reduction Act of 2022 ("IRA") and other legislation and regulations that may be subsequently enacted;
- subject to receipt of regulatory approval, revenue, if any, received from commercial sales for any approved indications for any of our product candidates;
- 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;
- the continued growth of our headcount and associated costs as we expand our research and development capabilities and 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.

Currently, we do not have any committed external source of funds or other support and we cannot be certain that additional funding will be available on acceptable terms, or at all. In recent years, COVID-19, macroeconomic trends and geopolitical events, including civil or political unrest (such as the ongoing war between Ukraine and Russia), have resulted in significant disruption of global financial markets. In addition, recent or future market volatility, increased inflation and higher interest rates, if sustained, may increase our cost of financing and may restrict our access to potential sources of future liquidity. 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 have not generated any revenue from product sales and may not be able to achieve profitability.

We incurred a net loss of \$35.5 million for the three months ended March 31, 2023 and \$115.9 million for the year ended December 31, 2022. 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 product candidates are in varying stages of development, which is expected to necessitate additional preclinical studies in some cases and in all cases will require additional clinical development as well as regulatory review and approval, substantial investment, 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 for at least the next several years. Our ability to generate revenue depends on a number of factors, including, but not limited to:

- completion of our Phase 3 SUNRISE-3 clinical trial for the treatment of high risk outpatients with mild to moderate COVID-19 on the timeline we anticipate and timely initiation and completion of other clinical trials including the Phase 2 trial evaluating the combination of bemnifosbuvir and ruzasvir for the treatment of HCV and potentially initiation and completion of clinical trials evaluating a bemnifosbuvir combination regimen for the treatment of COVID-19, preclinical studies and other future clinical trials of other product candidates, 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 IND enabling studies and successfully submit INDs, CTAs or comparable applications to allow us to initiate clinical trials for any 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 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 product candidates or any future product candidates;
- the prevalence, duration and severity of potential side effects or other safety issues experienced with our product candidates or future product candidates, if any;
- the timely receipt of necessary marketing approvals from the FDA or similar foreign regulatory authorities;
- the availability, actual and perceived advantages and relative cost, convenience, safety and efficacy of any bemnifosbuvir COVID-19 product candidate, we may be able to commercialize, compared to other COVID-19 therapies as well as the accuracy and sufficiency of clinical evidence supporting its performance;

- 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 any of our product candidates or future product candidates that may be 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 current 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 successfully establish a commercial strategy and thereafter commercialize our current or 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 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 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 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 continue operations.

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, 2022, we had US federal net operating loss carryforwards (“NOLs”), of \$19.4 million, which may be available to offset future taxable income, if any, of which \$0.4 million begin to expire in 2034 and of which \$19.0 million do not expire but are limited in their usage (for taxable years beginning after December 31, 2022) to an annual deduction equal to 80% of annual taxable income. In addition, as of December 31, 2022, we had state NOLs of \$30.0 million, which may be available to offset future taxable income, if any, and begin to expire in 2042. During the year ending December 31, 2021, we utilized each of federal and state NOLs of approximately \$52.8 million and \$52.6 million, respectively, and federal and state research and development credit carryforwards of \$0.7 million and \$0.3 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 each of the year ended December 31, 2022 and 2021, 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. In

February 2023, after advancing AT-752 to Phase 2 clinical trial, we suspended the clinical development of AT-752 for the treatment and prophylaxis of dengue. This action was taken due to the anticipated long timelines and other challenges associated with the clinical development of an antiviral for the treatment of dengue. We have also recently terminated our efforts to discover a product candidate for the treatment of RSV. This action was taken to facilitate enhanced focus of our management team and resources for therapeutic indications where our programs are more advanced. These actions and any other similar delays, suspensions or terminations of other clinical programs or product candidates 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 our ability to develop one or more bennifosbuvir COV19 product candidates. If we are not successful in developing a bennifosbuvir COV19 product candidate, our business will be harmed. Our business is also highly dependent on the success of our other most advanced product candidates, including the combination of bennifosbuvir and ruzasvir for the treatment of HCV, which will require significant additional clinical testing before we can seek regulatory approval and potentially launch commercial sales. If these product candidates fail in clinical development, do not receive regulatory approval or are not successfully commercialized, or are 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 one or more bennifosbuvir COV19 product candidates and the combination of bennifosbuvir and ruzasvir for the treatment of HCV. We currently have no products that are approved for commercial sale and have not 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 that a substantial portion of our efforts and expenditures will continue to be devoted to developing a potential bennifosbuvir COV19 product candidate. Among other things, this effort will require the successful completion of our Phase 3 SUNRISE-3 clinical trial for the treatment of high risk outpatients with mild to moderate COVID-19 and additional nonclinical and clinical development and the incurrence of expenses related to discovering, acquiring or in-licensing a drug or drug candidate to combine with bennifosbuvir for the treatment of COVID-19. COVID-19, while currently a global pandemic, is unpredictable and therapies, including any bennifosbuvir COV19 product candidate, may be adversely impacted up to the point of obsolescence by the emergence of new variants or subvariants as well as by the development and authorization and approval of new vaccines, vaccine boosters and therapeutics.

Additionally, we expect that a substantial portion of our efforts and expenditures over the next few years will be devoted to developing the combination of bennifosbuvir and ruzasvir for the treatment of HCV which will require additional clinical development, management of clinical, medical affairs and manufacturing activities, obtaining regulatory approvals in multiple jurisdictions, securing of manufacturing supply, building of a commercial organization, substantial investment and significant marketing efforts. We cannot be certain that any of our current or future product candidates will be successful in clinical trials, 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.

If our competitors develop products to treat diseases and, if applicable, specified patient populations which our current or future product candidates are being developed to treat, before we are able to successfully develop a product candidate, or if our competitors develop any products that are superior to our product candidates, our potential market share could become smaller or non-existent. Even if we receive approval to market any product candidate, we cannot be certain that our product candidates will be as or more effective than other commercially available alternatives, successfully commercialized or widely accepted in the marketplace. Nor can we be certain that, if approved, the safety and efficacy profile of any product will be consistent with the results observed in clinical trials, or in the case of a bennifosbuvir COV19 product candidate, that it will demonstrate efficacy against continuing mutations of the SARS-COV-2 virus, the causative agent of COVID-19. If we are not successful in the clinical development of a bennifosbuvir COV19 product candidate or our other most advanced product candidates, the required regulatory approvals for these product candidates are not obtained, there are significant delays in the development or approval of these product candidates, or any approved products are 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, particularly with respect to COVID-19, which continues to evolve rapidly. 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. We have not submitted an NDA for, or obtained regulatory approval of, any product candidate. We must complete additional preclinical or nonclinical studies and clinical trials 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 existing product candidates or any product candidates we may seek to develop in the future 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.

This lengthy approval process, as well as the unpredictability of the results of clinical trials, may result in our failing to obtain regulatory approval to market any of our product candidates, which would seriously harm our business. In addition, 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 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

October 2021 of bemnifosbuvir to meet the primary endpoint in the overall patient population in the Phase 2 MOONSONG clinical trial. The outcome of preclinical studies and early-stage clinical trials may not be predictive of the success of later clinical trials. This may be particularly true in the development of therapeutics for the treatment of COVID-19, including our development of bemnifosbuvir COVID-19 product candidates, where the evolution of the virus and disease have occurred at such a rapid rate that product candidates in development have the potential to become obsolete before clinical development is completed. Moreover, preclinical and clinical data, particularly the analysis of exploratory endpoints and analysis of data derived from patient subgroups, such as the data from the MORNINGSKY study upon which we have relied to continue clinical development and initiate the Phase 3 SUNRISE-3 clinical trial, are often susceptible to varying interpretations, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their drugs. To date, we have not completed any late-stage or pivotal clinical trials for any of our product candidates. 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 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 if these trials begin, issues may arise that could cause regulatory authorities to suspend or terminate such clinical trials. A failure of one or more clinical trials can occur at any stage of testing, and our future clinical trials may not be successful. 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 authorization to commence a clinical trial;
- delays in reaching agreement on acceptable terms with prospective 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 IRB 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;
- 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, or if the FDA or a foreign regulatory authority finds that the investigational protocol or plan is clearly deficient to meet its stated objectives;
- delays caused by patients withdrawing from clinical trials or failing to return for post-treatment follow-up, including due to the COVID-19 pandemic or political unrest and war, including the current conflict between the Ukraine and Russia and any escalation or spillover into additional regions;
- 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;
- subjects enrolled in our clinical trials or clinical sites deviating from the clinical trial protocol or dropping out of a trial;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- changes in the standard of care on which a clinical development plan was based, which may require 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 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.

In addition, events, occurrences and disruptions caused by the continuing evolution of COVID-19 may increase the likelihood that we encounter difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials. In particular, the rate of incidence, testing and diagnosis of COVID-19, changes in the standard of care for the treatment of COVID-19, which is rapidly evolving due to the mutation of the virus, rapidly increasing knowledge being obtained by healthcare providers, rates and durability of vaccines and population immunity, and availability of an increasing number of therapeutic options, may impact the successful completion of our Phase 3 SUNRISE-3 clinical trial and other COVID-19-related clinical trials we may initiate.

Any inability to successfully complete our Phase 3 SUNRISE-3 clinical trial, our Phase 2 clinical trial evaluating the combination of becnifosbuvir and ruzasvir for the treatment of HCV or the completion of any other planned clinical trials we may initiate could result in additional costs to us or impair our ability to 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 bring 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 IRBs of the institutions at which such trials are being conducted suspend or terminate the participation of their 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, as we are currently doing and otherwise expect to continue doing for other product candidates, 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.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

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 bring 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 may change and additional government regulations may be enacted. For instance, the regulatory landscape related to clinical trials in the European Union ("EU") recently evolved. The EU CTR which was adopted in April 2014 and repeals the EU Clinical Trials Directive ("Clinical Trial Directive"), became applicable on January 31, 2022. While the Clinical Trials Directive required a separate CTA to be submitted in each member state, to both the competent national health authority and an independent ethics committee, the CTR introduces a centralized process and only requires the submission of a single application to all member states concerned. 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. The CTR foresees a three-year transition period. The extent to which ongoing and new clinical trials will be governed by the CTR varies. For clinical trials whose CTA was made under the Clinical Trials Directive before January 31, 2022, the Clinical Trials Directive will continue to apply on a transitional basis for three years. Clinical trials for which an application was submitted (i) prior to January 31, 2022 under the Clinical Trials Directive, or (ii) between January 31, 2022 and January 31, 2023 and for which the sponsor has opted for the application of the Clinical Trials Directive remain governed by said Directive until January 31, 2025. After this date, all clinical trials (including those which are ongoing) will become subject to the provisions of the CTR. Through January 31, 2023, submissions of CTAs that we made in connection with each of our SUNRISE-3 Phase 3 clinical trial and our Phase 2 HCV clinical trial were made using the Clinical Trial Directive. We have only begun submitting CTAs under the CTR since February 1, 2023. Our experience with submissions under the CTR is limited. Compliance with the CTR requirements by us and our third-party service providers, such as clinical research organizations ("CROs"), may impact our developments plans.

It is currently unclear to what extent the UK will seek to align its regulations with the EU. The UK regulatory framework in relation to clinical trials is derived from existing EU legislation (as implemented into UK law, through secondary legislation). On January 17, 2022, the UK Medicines and Healthcare products Regulatory Agency ("MHRA") launched an eight-week consultation on reframing the UK legislation for clinical trials. The consultation closed on March 14, 2022 and aims to streamline clinical trials approvals, enable innovation, enhance clinical trials transparency, enable greater risk proportionality, and promote patient and public involvement in clinical trials. The outcome of the consultation is being closely watched and will determine whether the UK chooses to align with the CTR or diverge from it to maintain regulatory flexibility. A decision by the UK not to closely align its regulations with the new approach that has been adopted in the EU may have an effect on the cost of conducting clinical trials in the UK as opposed to other countries.

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 intend to develop 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. We are currently developing the combination of benvnifosbuvir and ruzasvir for the treatment of HCV and we are planning to develop a combination therapy for the treatment of COVID-19. 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 benvnifosbuvir in combination with ruzasvir, a product candidate that has not yet been approved for marketing by the FDA or similar foreign regulatory authorities. For the treatment of COVID-19, in addition to our development of benvnifosbuvir as a monotherapy, we anticipate that we will develop a combination product consisting of benvnifosbuvir and an investigational protease inhibitor that is currently the subject of internal discovery efforts. We may not be able to market and sell any product candidate we develop in combination with any such unapproved therapies that do not ultimately obtain marketing approval.

If the FDA or similar foreign regulatory authorities do not approve these other combination agents or revoke their approval thereof, or if safety, efficacy, manufacturing, or supply issues arise with the drugs or biologics 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, 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 serious adverse events occur, clinical trials or commercial distribution of any product candidates or products we 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 candidates or products 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 candidates or products may be harmed, and our ability to generate product revenues from them or other product candidates that we develop 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 patients in our clinical trials, 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 in the trial until its conclusion. The enrollment of patients 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; and
- other factors outside of our control, such as the COVID-19 pandemic which has, among other things, created substantial burdens on healthcare providers who may be required to prioritize immediate critical patient care over clinical research and political unrest and war, including the current conflict between the Ukraine and Russia and any escalation or spillover into additional regions.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates or similar areas, 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. For example, we are aware of a number of clinical trials sponsored by our potential competitors that are evaluating oral antivirals for the treatment of high risk outpatients with mild to moderate COVID-19, the same patient population that we are seeking to enroll in SUNRISE-3, including the Phase 3 clinical trials that Gilead is sponsoring for the evaluation of obeldesivir (GS 5245), an oral nucleoside. 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 as a result of competition, or in the case of COVID-19 in particular, evolution of the disease and treatment paradigms as well as rates of infection, testing, diagnoses, hospitalizations and deaths or for other reasons 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.

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. In April 2023, the FDA granted Fast Track designation to bempifosbuvir for the treatment of COVID-19. As the sponsor of a product candidate that has received Fast Track designation, we may have opportunities for more frequent interactions with the FDA review team during product development and, once a New Drug Application (“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 other product candidates, but cannot assure you that the FDA would decide to grant it. Even though bempifosbuvir has received the Fast Track designation, 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 authority 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 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, and the results and related findings and conclusions are subject to change 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 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. For example, we are currently engaged in internal efforts to discover a protease inhibitor product candidate that we may be able to combine with bennifosbuvir for the treatment of COVID-19. These efforts and any subsequent discovery efforts we initiate to identify other novel 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, on 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 a potential product candidate that ultimately proves to be unsuccessful, or to 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 candidates, particularly bemnifosbuvir COVID-19 product candidates and bemnifosbuvir in combination with ruzasvir for the treatment of HCV, and as such, we may forego 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 future product candidate, we may relinquish valuable rights to those future product candidates 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 certain 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. In addition, in December 2022, the President signed an omnibus appropriations bill to fund the US government through fiscal year 2023. Included in the omnibus bill is the Food and Drug Omnibus Reform Act of 2022, which among other things, introduced reforms intended to expand the FDA's ability to regulate products receiving accelerated approval, including by increasing the FDA's oversight over the conduct of confirmatory trials; however, the ultimate impact of these reforms remains unclear.

In the EU, a “conditional” marketing authorization may be granted in cases where all the required safety and efficacy data are not yet available. A conditional marketing authorization is subject to conditions to be fulfilled for generating missing data or ensuring increased safety measures. A conditional marketing authorization is valid for one year and has to be renewed annually until fulfillment of all relevant conditions. Once the applicable pending studies are provided, a conditional marketing authorization can become a “standard” marketing authorization. However, if the conditions are not fulfilled within the timeframe set by the European Medicines Agency (“EMA”), the marketing authorization will cease to be renewed. Furthermore, marketing authorizations 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 the introduction of specific procedures. This may arise 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 type of marketing authorization is close to a conditional marketing authorization as it is reserved to 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 marketing authorization. However, unlike a conditional marketing authorization, the applicant does not have to provide the missing data and will never have to. Although a marketing authorization “under exceptional circumstances” is granted definitively, the risk-benefit balance of the medicinal product is reviewed annually and the marketing authorization may be withdrawn where 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 none of the product candidates we are developing or 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 is currently undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. The European Commission's proposal for revision of several legislative instruments related to medicinal products (potentially revising the duration of regulatory exclusivity, eligibility for expedited pathways, etc.) was published on April 26, 2023. The proposed revisions have yet to be agreed and adopted by the European Parliament and European Council (not expected before the end of 2024 or early 2025) and may have a significant impact on the pharmaceutical industry 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.

We may seek an EUA from the FDA or comparable emergency use authorizations from foreign regulatory authorities with respect to our bempifosbuvir COVID-19 product candidates in development for the treatment of COVID-19, and if we fail to obtain or maintain such authorizations, we may be required to pursue a more lengthy clinical development process than we expect, and our business may be harmed.

If available at the time we have sufficient data from our Phase 3 SUNRISE-3 clinical trial and other COVID-19 clinical trials, we may seek an EUA from the FDA or comparable emergency use authorizations from other foreign regulatory authorities with respect to our bempifosbuvir COVID-19 product candidates. The FDA has the authority to issue an EUA, pursuant to the Federal Food, Drug and Cosmetic Act (FDCA) and a declaration by the Secretary of the Department of Health and Human Services, or HHS, that circumstances exist justifying the issuance of EUAs for certain types of products (referred to as EUA declarations). On March 27, 2020, the Secretary of HHS declared that circumstances then existed that justified authorization of drugs and biologics during the COVID-19 pandemic, subject to the terms of any EUA that subsequently issued for a specific product. Once an EUA declaration has been issued and remains in place, the FDA can issue EUAs for products that fall within the scope of that declaration. To issue an EUA, the FDA Commissioner must conclude that (1) the chemical, biological, radioactive or nuclear agent, or CBRN, that is referred to in the EUA declaration can cause serious or life-threatening diseases or conditions; (2) based on the totality of scientific evidence available, it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing the disease or condition attributable to the CBRN and that the product's known and potential benefits outweigh its known and potential risks; and (3) there is no adequate, approved, and available alternative to the product.

Currently in the US there are two oral direct acting antivirals Paxlovid™ (nirmatrelvir and ritonavir) and LAGEVRIO® (molnupiravir) authorized for emergency use for high risk COVID-19 patients.

The FDA's standards for granting an EUA are lower than for approving NDAs in accordance with traditional review procedures, and even if we seek and obtain an EUA for one or more of our product candidates, we cannot assure you that the FDA would approve a NDA for such product candidate, if such approval is required. Accordingly, even if we obtain an EUA for a bempifosbuvir COVID-19 product candidate, we may be required to conduct additional clinical trials before we are able to submit an NDA or comparable marketing applications for such product candidate.

The authorization to market products under an EUA is limited to the period of time the EUA declaration is in effect. If the Secretary of HHS determines that the circumstances justifying the issuance of EUAs have also lapsed, the HHS Secretary will provide advance notice that the EUA declaration will be terminated. After an EUA declaration is terminated, all EUAs issued under that declaration also terminate and therefore emergency use of all products under the EUA declaration is no longer authorized. The FDA can also revoke an EUA in certain circumstances even if the EUA declaration has not been terminated.

The FDA's policies regarding an EUA can change unexpectedly. We cannot predict how long any authorization, if obtained, will remain in place. The FDA's policies regarding vaccines and other products used to diagnose, treat or mitigate COVID-19 remain in flux as the FDA responds to new and evolving public health information and clinical evidence. Moreover, the federal government has taken recent steps to terminate distinct emergency

authorizations related to COVID-19. For example, on April 10, 2023, President Biden signed legislation terminating a national emergency regarding COVID-19, although this action does not affect any EUAs granted by FDA with respect to its authority to authorize drugs and biologics for the diagnosis, treatment, or prevention of COVID-19 and related conditions, FDA has also announced its intent to adjust policies and operations implemented during the COVID-19 pandemic to a resumption of normal operations, including a transition of products marketed under EUAs, to the ordinary FDA requirements, including premarket authorization requirements.

Therefore, even if we believe the data from our Phase 3 SUNRISE-3 clinical trial and any other COVID-19 clinical trials we may initiate are positive, we may be unable to obtain an EUA or other emergency authorizations for a becnifosbuvir COV19 product candidate. Moreover, even if we do obtain an EUA or comparable emergency authorization, it is possible that such EUA or other authorizations may be revoked and we may be required to cease any commercialization activities, until, if ever, we receive NDA approval for such product. Any cessation of commercialization activities would adversely impact our business, financial condition and results of operations.

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 antiviral products are well established in the medical community for the treatment of HCV and in the US, two oral antivirals, Paxlovid and Lagevrio, are currently authorized for the treatment of COVID-19, and doctors 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:

- efficacy and potential advantages compared to alternative treatments;
- the ability to offer our products, if approved, for sale at competitive prices;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- the ability to obtain sufficient third-party coverage and adequate reimbursement, including with respect to the use of the approved product as a combination therapy;
- adoption of a companion diagnostic and/or complementary diagnostic; and

- the prevalence and severity of any side effects.

Disruptions at the FDA and foreign regulatory authorities caused by funding shortages or global health concerns 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 including a rapid substantial influx of applications from numerous sponsors as occurred with COVID-19. 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, over the last several years, the US government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the COVID-19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. Even though the FDA has since resumed standard inspection operations of domestic facilities where feasible, the FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates as it adapts to the evolving COVID-19 pandemic, and any resurgence of the virus or emergence of new variants may lead to further inspectional delays. Regulatory authorities outside the US have adopted similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, 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 policies we currently maintain include general liability, property, auto, workers' compensation, 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, 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 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 and 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, however, 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., 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. As a result of the COVID-19 pandemic, 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 attacks increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. 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.

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 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 and the further development of our product candidates could be delayed.

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 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 Centers for Medicare & Medicaid Services (“CMS”), other divisions of 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.

Enacted and future healthcare 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. In addition, new regulations and interpretations of existing healthcare statutes and regulations are frequently adopted.

In March 2010, the Patient Protection and Affordable Care Act (“ACA”), was enacted, which substantially changed the way healthcare is financed 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;
- a Medicare Part D coverage gap discount program, requiring manufacturers to agree to offer point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their

- coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- 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. 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 2031. Further, on March 11, 2021 the American Rescue Plan Act of 2021 was signed into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, beginning January 1, 2024.

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 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. Most recently, on August 16, 2022, the Inflation Reduction Act ("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 (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services ("HHS") to implement many of these provisions through guidance, as opposed to regulation, for the initial years. For that and other reasons, it is currently unclear how the IRA will be effectuated. 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 and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. 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, 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. This 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 one 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 contract manufacturers 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 contract manufacturers' 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 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 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 (“CCPA”) went into effect on January 1, 2020 and creates individual privacy rights for California consumers, increases the privacy and security obligations of entities handling certain personal information, requires new disclosures to California individuals and affording such individuals new abilities to opt out of certain sales of personal information, and provides for civil penalties for violations as well as a private right of action for data breaches that is expected to increase data breach litigation. Further, the California Privacy Rights Act (“CPRA”), which generally went into effect on January 1, 2023, significantly amends the CCPA and imposes additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It has also created a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement, and additional compliance investment and potential business process changes may be required. Similar laws have passed in Virginia, Colorado, Connecticut and Utah, and have been proposed in other states and at the 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. In the event that we are subject to or affected by the CCPA, the CPRA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these 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 may also be subject to increased 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 European Economic Area (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). 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). 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; in July 2020 the Court of Justice of the EU (“CJEU”) limited how organizations could lawfully transfer personal data from the EEA to the US by invalidating the Privacy Shield for purposes of international transfers and imposing further restrictions on use of the standard contractual clauses (“SCCs”). In March 2022, the US and EU announced a new regulatory regime intended to replace the invalidated regulations; however, this new EU-US Data Privacy Framework has not been implemented beyond an executive order signed by President Biden on October 7, 2022 on Enhancing Safeguards for US Signals Intelligence Activities. European court and regulatory decisions subsequent to the CJEU decision of July 16, 2020 have taken a restrictive approach to international data transfers. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the SCCs cannot be used, and/or start taking enforcement action, we could suffer additional costs, 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 provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

In addition, from 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.

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, in the course of our research collaborations. As such, we may 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 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 adopted the EU Clinical Trials regulation, which came into effect on January 31, 2022. This regulation imposes new 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 about 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.

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 has been 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 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 may also have products already approved or in development in the therapeutic categories that we are targeting with our product candidates. In addition, many of these competitors, either alone or together with their collaborative partners, may operate larger research and development programs or have substantially greater financial resources than we do, as well as 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 safer, more effective, or less expensive therapeutics or vaccines, 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. 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.

Significant competition exists from approved treatments and, in the case of COVID-19, authorized treatments or treatments in development for the diseases that we are targeting. Many of the approved drugs are well-established therapies or products and are widely accepted by physicians, patients and third-party payors. There are pharmaceutical and biotechnology companies at various stages of development and approval of vaccines and therapeutics for COVID-19 and treatments for each of the disease indications we are targeting. Currently there are several vaccines and associated vaccine boosters approved or authorized for use for COVID-19 and there are therapeutics available for the treatment of COVID-19 including two oral antiviral therapies, Paxlovid™ and Lagevrio™ each of which are authorized for emergency use for high risk COVID-19 patients. Additionally, Veklury, a nucleotide prodrug, which is intravenously administered is approved for the treatment of COVID-19 in adults and pediatric patients who are hospitalized or if not hospitalized have mild to moderate COVID-19 and are at high risk for progression to severe COVID-19, including hospitalization and death.

Treatments in development for COVID-19 include obeldesivir (GS-5245), an oral nucleoside prodrug, that is being developed by Gilead Sciences and is currently being evaluated in two Phase 3 clinical trials including a randomized, double-blind placebo controlled trial in non-hospitalized COVID patients who are at high risk of progression to hospitalization. There are also several drugs, including oral antivirals such as Eplclusa® which is manufactured and sold by Gilead Sciences, and Mavyret® which is marketed and sold by AbbVie, Inc. approved

for the treatment of HCV. Our product candidates, if approved, are expected to compete directly or indirectly with existing products and products currently in development. Even if approved and commercialized, our product candidates may fail to achieve market acceptance with hospitals, physicians or patients. Hospitals, physicians or patients may conclude that our products are less safe or effective or otherwise less attractive than existing drugs. If our product candidates do not receive market acceptance for any reason, our revenue potential would be diminished, which would materially adversely affect our ability to become profitable.

Many of our competitors have substantially greater capital resources, robust product candidate pipelines, established presence in the market and 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 achieve product commercialization or patent or other intellectual property protection earlier than we can. 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. 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. 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. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Even if we show improved efficacy 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. These 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 provide 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. We expect to experience pricing pressures in connection with the sale of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes resulting from legislative actions, including the recently enacted IRA. The downward pressure on healthcare costs in general, particularly prescription drugs and biologics and surgical procedures and other treatments, has become intense. As a result, increasingly high barriers are being erected to the entry of new products.

In addition, since the Secretary of HHS in March 2020 declared a PHE at the outset of the COVID-19 pandemic, the US federal government has been a primary purchaser of therapeutics for the treatment of COVID-19. Based on current COVID-19 trends, HHS is planning to terminate the PHE for COVID-19 on May 11, 2023. As a result, it is uncertain for how long the US federal government will remain a primary purchaser of COVID-19 therapeutics. Recently, there have been announcements regarding the intention of the US federal government to transition the procurement and distribution of COVID-19 therapeutics, vaccines and diagnostic tests to traditional commercial market channels. The time at which this transition will occur is uncertain and is subject to many conditions including among others whether substantial incremental appropriations will be available to further fund the US federal government COVID-19 response. The effects of such a transition from US federal government procurement and distribution to commercial market channels are many and will include discontinuation of free or heavily subsidized access by many US persons to COVID-19 therapeutics, vaccines and diagnostics, including test kits. Such changes in patient access may affect product utilization and could limit our ability to successfully commercialize our product candidates and obtain a satisfactory financial return on our product candidates in this therapeutic space.

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 or 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.

We may build our own focused sales, distribution and marketing infrastructure to market our product candidates, if approved, in the US and other markets around the world. 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 to 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.

If we are unable or decide not to establish internal sales, marketing and distribution capabilities, or decide not to do so for a particular country, we may pursue collaborative arrangements. If we pursue a collaborative arrangement, our sales will largely 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 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, that have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third-party 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 for which we may rely on collaboration with third parties. We do not currently have any collaborator for the commercialization of any of our product candidates in foreign markets. We are evaluating the opportunities for the development and commercialization of our product candidates in foreign markets. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the applicable regulatory authority in that foreign market, and we may never receive such regulatory approval for any of our product candidates. To obtain separate regulatory approvals in other countries, we may be required 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 our product candidates 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 if we are relying on third parties;
- 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;
- longer accounts receivable collection times;
- our ability to supply our product candidates on a timely and large-scale basis in local markets;
- longer lead times for shipping which may necessitate local manufacture of our product candidates;
- 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;
- 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 is approved for commercialization, we may selectively partner with third parties to market it in certain jurisdictions 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 will 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 such as South America and Southeast Asia. Many US-based biotechnology 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. There is a risk that foreign governments may nationalize private enterprises in certain countries where we may operate. In certain countries or regions, terrorist activities and the response to such activities may threaten our operations more 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 some countries, 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.

The use of our product candidates in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. 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:

- impairment of our business reputation and significant negative media attention;
- withdrawal of participants from our clinical trials;
- injury to our reputation;
- 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 corporate collaborators. Although we have clinical trial insurance, our insurance policies also 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 corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim 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 we do not 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 a long-term agreement 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, 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.

For ruzasvir, we have sole suppliers located in China for our active pharmaceutical ingredients, and for all our product candidates, including bempifosbuvir, 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. Any disruption in production or inability of our manufacturers in China to produce adequate quantities to meet our needs, whether as a result of the current outbreak of COVID-19, a natural disaster, other pandemics, trade disruptions or other causes, could impair our ability to operate our business on a day-to-day basis and to continue our research and development of our product candidates. For example, the Uyghur Forced Labor Prevention Act bans imports from China's Xinjiang region unless it can be shown that the goods were not produced using forced labor and this legislation may have an adverse effect on global supply chains which could adversely impact our business and results of operations.

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 or others, 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 product candidates. 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 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. If we obtain regulatory approval for any of our product candidates, we would need to expand the supply of their components in order to commercialize them.

We do not have multiple sources of supply for all of the components used in the manufacture of bemnifosbuvir or ruzasvir or any of our other product candidates. For ruzasvir, we have sole suppliers located in China for our active pharmaceutical ingredients, and for all our product candidates, including 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 on acceptable terms. Manufacturing suppliers are subject to cGMP quality and regulatory requirements and similar regulatory 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 on commercially reasonable terms, if at all. It could also require significant time and expense to redesign our manufacturing processes to work with another company 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 marketing approval, regulatory authorities conduct inspections that must be successful prior to the approval of the product. Failure of manufacturing suppliers to successfully complete these regulatory inspections will result in delays. If supply from the approved supplier is interrupted, there could be a significant disruption in commercial supply. An alternative vendor would need to be qualified through a 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 our Phase 3 SUNRISE-3 clinical trial, our Phase 2 clinical trial evaluating the combination of bemnifosbuvir and ruzasvir, our preclinical studies and our other clinical trials and we expect to rely on third parties to conduct future clinical trials and preclinical studies for our product

candidates. 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 approval 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 cash and cash equivalents 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 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 may collaborate with third parties for the development and commercialization of our candidates. 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.

We may seek collaborative relationships for the development and commercialization of our product candidates. If we enter into any collaborative arrangements with any third parties, we will likely have shared or limited control over 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 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 and, if terminated, may result in a need for additional capital to pursue further development or commercialization or result in delays to 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.

For example, in February 2022, the Roche License Agreement under which we exclusively granted to Roche certain rights to develop bemnifosbuvir and certain rights to commercialize bemnifosbuvir outside of the US terminated. As a result, substantially all activities that Roche was conducting in connection with the development and manufacture of bemnifosbuvir, including global manufacture of clinical trial material and certain operations necessary for the conduct of clinical trials, ceased. Substantially all of these activities are necessary for the continued global development of a bemnifosbuvir COV19 product candidate and we are now solely responsible for the conduct and cost of such activities.

We may face significant competition in seeking appropriate collaborations. Business combinations among biotechnology 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 or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development 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 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 ruzasvir in combination with bemnifosbuvir, our lead product candidate for the treatment of HCV, 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, scientists and collaborators 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 product candidates 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 includes 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 US Patent and Trademark Office ("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 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. Many companies in intellectual property-dependent industries, including the pharmaceutical industry, have employed intellectual property litigation as a means to gain an advantage over their competitors. As the pharmaceutical industry expands and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. Some 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 that 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. In order to successfully challenge the validity of a US patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such US patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such US patent. 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 obtained a license under the applicable patents, which may not be available at all or on commercially reasonable terms, or until such patents expire.

The legal threshold for initiating litigation or contested proceedings is low, so that even lawsuits or proceedings with a low probability of success might be initiated and require significant resources to defend. Litigation and contested proceedings can also 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 and as we gain the greater visibility associated with being a public company. 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 obtain injunctive or other equitable relief, which could 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 could 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 products, which are nucleotide prodrugs, 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.

Our product candidates are predominantly 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, Inc.; Merck & Co.; Bristol Myers Squibb; F. Hoffmann-La Roche; University of Cardiff; University College Cardiff Consultants; NuCana, plc; Alios Biopharma; Medivir; 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. On June 3, 2019, we received an anonymous third-party Observation filed in connection with our international Patent Cooperation Treaty patent application for our second patent family, which covers the hemisulfate salt form of AT-511, or bemnifosbuvir. The Observation generally challenges the patentability of the hemisulfate salt bemnifosbuvir over the free base AT-511. On August 1, 2019, we filed a response to the Observation describing that the bemnifosbuvir hemisulfate salt of AT-511 is not obvious in view of the AT-511 free base because bemnifosbuvir disproportionately concentrates in the liver over the heart, as shown in vivo in a dog model, which can provide an increased therapeutic effect to treat HCV, and decreased toxicity because hepatitis C is a disease of the liver. Further, while not raised in the response to the Observation, we have now also shown that bemnifosbuvir has a longer half-life and higher concentration in the lung than in the liver in vivo in monkeys, which is relevant to our COVID-19 indication. On August 10, 2020, an anonymous party filed a third-party Observation against our Patent Cooperation Treaty patent application covering a method to treat HCV patients with compensated or decompensated cirrhosis using our drug bemnifosbuvir. The anonymous party asserted that it would have been obvious that the hemisulfate salt of AT-511 (bemnifosbuvir) would be effective to treat HCV-infected cirrhotic patients. We filed a response to the

Observation on October 2, 2020, wherein we disagreed for several reasons, including that the hemisulfate salt of AT-511 had not been publicly disclosed at the time of the filing of our method of treatment of cirrhosis application and further noted that it is not straightforward that a treatment for patients with compensated cirrhosis would also be effective for patients with decompensated cirrhosis. Our Patent Cooperation Treaty patent application provides human data that supports the efficacy of using benvnifosbuvir to treat cirrhotic HCV-infected patients. The Observations by anonymous third parties as well as our responses are placed in the file and available to be read and considered by any country examining our respective patent applications. In December 2019, the US Patent Office issued a patent to us covering the composition of matter of benvnifosbuvir. However, other than the foregoing issued US patent, there can be no assurance that the Observations will not adversely affect our ability to obtain issued patents from national-stage filings of such Patent Cooperation Treaty patent applications in any jurisdictions. 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, including before or during this registration period. 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.

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 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 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 the 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 after the end of our data exclusivity period, 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 not also 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's 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 candidates might expire before or shortly after such 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 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.

Although we are not currently involved in any relevant litigation, we may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time-consuming and unsuccessful.

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.

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 challenges our pending patent claims to AT-511 or a pharmaceutically acceptable salt thereof. While we intend to vigorously defend our patent claims on AT-511 and its use to treat hepatitis C, we cannot guarantee that the Indian Patent Office will decide in our favor and allow our patent claims to grant. In addition, Pre-Grant Oppositions in India can proceed very slowly, and therefore this proceeding may not be resolved for several years. Our patent application will not issue as a patent on AT-511 or its use to treat HCV in India unless and until this Pre-Grant Opposition is resolved in our favor. If it is not resolved in our favor, we may not receive a patent on AT-511 in India.

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 would 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 ("TRIPS"), 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.

In addition, in November 2015, members of the World Trade Organization ("WTO"), which administers TRIPS, voted to extend the exemption against enforcing pharmaceutical drug patents in least developed countries until 2033. We currently have no patent applications filed in least developed countries, and our current intent is not to file in these countries in the future, at least in part due to this WTO pharmaceutical patent exemption.

Furthermore, the WTO is currently considering a waiver of intellectual property rights for COVID-19 vaccines and the US government recently took a stance in support of the waiver. The current proposal is for a temporary waiver of intellectual property rights that cover COVID-19 vaccines, however, the ultimate timing and scope of the waiver,

if approved, is unknown. The scope and timing of such waiver will likely be subject to extensive negotiations given the complexity of the matter, which may result in prolonged uncertainty and therefore could adversely affect our business. If a waiver is approved and covers COVID-19 treatments, such as bemnifosbuvir, our ability to successfully commercialize bemnifosbuvir and protect our related technology could be adversely affected.

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 Growth and Other Risks Related to Our Business

We will need to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

We expect to experience significant growth over time in the number of our employees and the scope of our operations, particularly in the areas of product candidate development, regulatory and clinical affairs and sales, marketing and distribution. To manage our growth activities, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team, as a group, in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. As we expand our company, we may have difficulty identifying, hiring and integrating new personnel. Future growth would impose significant additional responsibilities on our management, including but not limited to:

- the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors; and
- maintaining our operational, financial and management controls, reporting systems and procedures.

Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow product revenues, if any, could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize any approved products and compete effectively will depend, in part, on our ability to effectively manage any future growth.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including substantially all aspects of clinical trial conduct and execution, 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.

Many of the biotechnology and pharmaceutical companies that we compete against for qualified personnel and consultants have greater financial and other resources, different risk profiles and a longer history in the industry than we do. If we are unable to continue to attract and retain high-quality personnel and consultants, the rate and success at which we can discover and develop product candidates and operate our business will be limited.

We only have a limited number of employees to manage and operate our business.

As of May 5, 2023, we had 73 full-time employees. Our focus on the clinical development of product candidates in two distinct disease indications requires us to manage and operate our business in a highly efficient manner. We cannot assure you that we will be able to hire and/or retain adequate staffing levels to develop our product candidates or run our operations and/or to accomplish all of the objectives that we otherwise would seek to accomplish.

If we lose key management or scientific personnel, cannot recruit qualified employees, directors, officers or other significant personnel or experience increases in our compensation costs, our business may materially suffer.

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.

In addition to retaining the continued service of our officers, directors and key employees, our future success and growth will depend in part on our ability to identify, hire and retain additional personnel.

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. If we are unable to continue to attract and retain high quality personnel, our ability to develop and commercialize product candidates will be limited.

Many of our key employees are vested in a substantial amount of our common stock or options to purchase our common stock. Our employees, including our key employees, may be more likely to leave us if the shares they own have significantly fluctuated in value relative to the original purchase prices of the shares, or if the exercise prices of the options that they hold are significantly below or above the market price of our common stock.

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 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, the conflict between Ukraine and Russia has 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.

The continuing impact of “Brexit” may have a negative effect on our business.

Since the end of the Brexit transition period on January 1, 2021, Great Britain (England, Scotland and Wales) has not been directly subject to EU laws, however under the terms of the Ireland/Northern Ireland Protocol, EU laws generally apply to Northern Ireland. The EU laws that have been transposed into UK law through secondary legislation remain applicable in Great Britain. However, under the Retained EU Law (Revocation and Reform) Bill 2022, which is currently before the UK parliament, any retained EU law not expressly preserved and “assimilated”

into domestic law or extended by ministerial regulations (to no later than June 23, 2026) will automatically expire and be revoked by December 31, 2023. In addition, new legislation such as the CTR is not applicable in Great Britain. The UK government has passed the Medicines and Medical Devices Act 2021, which introduces delegated powers in favor of the Secretary of State or an 'appropriate authority' to amend or supplement existing regulations in the area of medicinal products and medical devices. This allows new rules to be introduced in the future by way of secondary legislation, which aims to allow flexibility in addressing regulatory gaps and future changes in the fields of human medicines, clinical trials and medical devices.

The EU-UK Trade and Cooperation Agreement ("TCA"), came into effect on January 1, 2021. The TCA includes provisions affecting pharmaceutical businesses (including on customs and tariffs). In addition, there are some specific provisions concerning pharmaceuticals. These include the mutual recognition of GMP inspections of manufacturing facilities for medicinal products and GMP documents issued. The TCA does not, however, contain wholesale mutual recognition of UK and EU pharmaceutical regulations and product standards, and it can be expected that there may be divergent local requirements in the UK from the EU in the future, which may impact clinical and development activities that occur in the UK in the future. Similarly, clinical trial submissions and data for activity in the UK will not be able to be bundled with those of EU countries within the EMA Clinical Trial Information System ("CTIS"), adding further complexity, cost and potential risk to future clinical and development activity in the UK. Significant political and economic uncertainty remains about how much the relationship between the UK and EU will differ as a result of the UK's withdrawal.

The long term effects of Brexit on our business in the UK, the EU and worldwide will depend on the effects of the implementation and application of the TCA and any other relevant agreements between the UK and the EU. As of January 1, 2021, the MHRA is the UK's standalone medicines and medical devices regulator. As a result of the Northern Ireland protocol, different rules will apply in Northern Ireland than in England, Wales, and Scotland, together, Great Britain; broadly, Northern Ireland will continue to follow the EU regulatory regime, but its national competent authority will remain the MHRA.

These developments have had and may continue to have a significant adverse effect on global economic conditions and the stability of global financial markets, and could significantly reduce global market liquidity and restrict the ability of key market participants to operate in certain financial markets. In particular, it could also lead to a period of considerable uncertainty in relation to the UK financial and banking markets, as well as on the regulatory process in the UK and in Europe. As a result of this uncertainty, global financial markets could experience significant volatility, which could adversely affect the market price of our common stock. Asset valuations, currency exchange rates, and credit ratings may also be subject to increased market volatility. Lack of clarity about future UK laws and regulations as the UK determines which EU rules and regulations to replace or replicate after withdrawal, including financial laws and regulations, tax and free trade agreements, intellectual property rights, data protection laws, supply chain logistics, environmental, health, and safety laws and regulations, immigration laws, and employment laws, could decrease foreign direct investment in the UK, increase costs, depress economic activity, and restrict our access to capital. If the UK and the EU are unable to negotiate acceptable withdrawal terms or if other EU member states pursue withdrawal, barrier-free access between the UK and other EU member states or among the EEA overall could be diminished or eliminated.

As a result of Brexit and new regulatory regimes, we may also face new regulatory costs and challenges that could have an adverse effect on our operations. In addition, currency exchange rates between the pound sterling, the euro and the US dollar have already been, and may continue to be, affected by Brexit.

Risks Related to Our Common Stock

Our principal stockholders and management own a significant percentage of our shares of common stock and could exert significant influence over matters subject to stockholder approval.

Our executive officers, directors, and >5% stockholders beneficially own a significant percentage of our common stock as of March 31, 2023. Therefore, these stockholders may, if acting together, have the ability to influence us through this ownership position. These stockholders may be able to determine matters requiring stockholders approval. For example, these stockholders may be able to control elections of directors, or influence amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our shares of common stock that you may feel are in your best interest as one of our stockholders.

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 or clinical trials and 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 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 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 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. 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, debt financings, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans.

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. 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.

Weakening 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.

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. While we intend to defend our patent claims for AT-511, 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.

We may engage in acquisitions or strategic collaborations that could disrupt our business, cause dilution to our stockholders, reduce our financial resources, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

In the future, we may enter into transactions to acquire other businesses, products or technologies or enter into strategic collaborations, including licensing transactions. If we do identify suitable acquisition or collaboration candidates, we may not be able to complete such acquisitions or collaborations on favorable terms, or at all. Any acquisitions or collaborations 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 acquisitions or collaborations. We may decide to incur debt in connection with an acquisition or issue our common stock or other equity securities to the stockholders of the acquired company, which would reduce the percentage ownership of our existing stockholders. We could incur losses resulting from undiscovered liabilities of the acquired business or collaboration that are not covered by the indemnification we may obtain from the seller or our collaborator. In addition, we may not be able to successfully integrate any acquired personnel, technologies and operations into our existing business in an effective, timely and non-disruptive manner. Acquisitions or collaborations 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 cash equivalents available for operations and other uses. We cannot predict the number, timing or size of future acquisitions or collaborations or the effect that any such transactions might have on our operating results.

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, other than or in addition to COVID-19, 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, 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.

Increased attention to, and evolving expectations for initiatives could increase our costs, harm our reputation, or otherwise adversely impact our business.

Companies across industries are facing increasing scrutiny from a variety of stakeholders related to their ESG and sustainability practices. 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, 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) to improve the ESG profile of our Company and/or products, 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 on our ESG efforts, even if such initiatives are currently voluntary.

Certain market participants, including major institutional investors and capital providers, use third-party benchmarks and scores to assess companies' ESG profiles in making investment or voting decisions. Unfavorable ESG ratings could lead to increased negative investor sentiment towards us or our industry, which could negatively impact our share price as well as our access to and cost of capital. To the extent ESG matters negatively impact our reputation, it may also impede our ability to compete as effectively to attract and retain employees or customers, which may adversely impact our operations.

In addition, we expect there will likely be increasing levels of regulation, disclosure-related and otherwise, with respect to ESG matters. For example, the SEC has published proposed rules that would require companies to provide significantly expanded climate-related disclosures in their periodic reporting, which 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 will likely lead to increased costs as well as scrutiny that could heighten all of the risks identified in this risk factor. Additionally, many of our customers and suppliers 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, cash equivalents and marketable securities 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 for the year ending December 31, 2023 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 for the year ending December 31, 2023. 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 have undertaken and will 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.

Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, is likely to be your sole source of gain.

We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain all available funds and future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. As a result, capital appreciation, if any, of our common stock is likely to be your sole source of gain on an investment in our common stock for the foreseeable future.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.**Recent Sales of Unregistered Securities; Purchases of Equity Securities by the Issuer or Affiliated Purchaser**

None.

Use of Proceeds

On November 3, 2020, we completed the initial public offering ("IPO") of our common stock pursuant to which we issued and sold 14,375,000 shares of our common stock at a price to the public of \$24.00 per share.

All shares issued and sold in the initial public offering were registered under the Securities Act pursuant to a Registration Statement on Form S-1 (File No.333-249404), as amended (the "Registration Statement"), declared effective by the SEC on October 29, 2020.

We received net proceeds of approximately \$317.6 million after deducting underwriting discounts and commissions and offering expenses.

The remaining net proceeds from our IPO have been invested primarily in money market accounts and marketable securities. There has been no material change in the expected use of the net proceeds from our initial public offering as described in our Prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on October 29, 2020.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Exhibit Description	Incorporated by Reference			Filing Date	Filed/ Furnished Herewith
		Form	File No.	Exhibit		
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	3.2	11/5/2020	
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					*
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					*
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					*
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document					*
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					*
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)					*

* Filed herewith.

** Furnished herewith.

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: May 8, 2023

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

Date: May 8, 2023

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

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: May 8, 2023

By:

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

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;
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: May 8, 2023

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

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

In connection with the Quarterly Report on Form 10-Q of Atea Pharmaceuticals, Inc. (the "Company") for the period ended March 31, 2023 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 result of operations of the Company.

Date: May 8, 2023

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