UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2022

OR

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

For the transition period from _____ to _____

Commission File Number: 001-39661

ATEA PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in its Charter)

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

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

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

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

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

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

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

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

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

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

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

As of November 4, 2022, the registrant had 83,287,639 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 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 or the timing for initiation, recruitment, completion, or 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 commercialization, marketing and manufacturing 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 competitors, competing treatments and vaccines and our industry;
- our expectations regarding federal, state and foreign laws and regulations;
- our ability to attract, motivate, and retain key personnel; and
- the impact of COVID-19 on our business, including in particular the impact on our preclinical studies and clinical trials.

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.
- Bemnifosbuvir will face significant competition from other treatments for COVID-19 that are currently marketed or are in development.
- The COVID-19 pandemic and future variant fueled pandemic surges may materially and adversely affect our business opportunities, clinical trials and financial results.
- We have a limited operating history and no organizational 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 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 if our other product candidates for the treatment of hepatitis C ("HCV") or dengue fail in nonclinical or clinical development, 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 U.S. Food and Drug Administration (“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. 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 and/or commercializing any product candidate we develop.
- 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 therapies, 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 clinical trials, and may in the future choose to conduct additional clinical trials, of our product candidates in sites outside the United States, and 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, including 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 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, deficiencies or intrusions which could materially affect our results.
- We will 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.
- 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 share 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.
- If our information systems, or those maintained on our behalf, fail or suffer security breaches, such events could result in, without limitation, the following: a significant disruption of our product development programs; an inability to operate our business effectively; unauthorized access to or disclosure of the personal information we process; and other adverse effects on our business, financial condition, results of operations and prospects.
- We could be subject to securities class action litigation.

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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)

	September 30, 2022	December 31, 2021
Assets		
Current assets		
Cash and cash equivalents	$ 176,410	$ 764,375
Marketable securities	488,565	—
Accounts receivable	4,514	—
Prepaid expenses and other current assets	12,446	8,028
Total current assets	681,935	772,403
Property and equipment, net	1,810	23
Restricted cash	305	305
Operating lease right-of-use assets, net	2,526	161
Total assets	$ 686,576	$ 772,892
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,118	$ 4,534
Accrued expenses and other current liabilities	13,805	52,152
Current portion of operating lease liabilities	711	197
Total current liabilities	15,634	56,883
Operating lease liabilities	2,585	—
Income taxes payable	5,170	5,932
Total liabilities	23,389	62,815
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 as of September 30, 2022, and December 31, 2021	—	—
Common stock, $0.001 par value; 300,000,000 shares authorized as of September 30, 2022 and December 31, 2021; 83,287,639 and 83,102,730 shares issued and outstanding as of September 30, 2022 and December 31, 2021, respectively	83	83
Additional paid-in capital	689,407	653,964
Accumulated other comprehensive loss	(855)	—
Retained earnings (accumulated deficit)	(25,448)	56,030
Total stockholders' equity	663,187	710,077
Total liabilities and stockholders' equity	$ 686,576	$ 772,892

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 Income (Loss)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
Collaboration revenue	$ —	$ 32,811	$ —	$ 159,187
Operating expenses				
Research and development	4,905	43,019	54,396	109,394
General and administrative	11,376	11,939	36,355	32,597
Total operating expenses	16,281	54,958	90,751	141,991
Income (loss) from operations	(16,281)	(22,147)	(90,751)	17,196
Interest income and other, net	4,382	53	5,560	162
Income (loss) before income taxes	(11,899)	(22,094)	(85,191)	17,358
Income tax benefit (expense)	3,833	(6,100)	3,713	(13,300)
Net income (loss)	$ (8,066)	$ (28,194)	$ (81,478)	$ 4,058
Other comprehensive income (loss)				
Unrealized gains (losses) on available-for-sale investments	$ (855)	$ —	$ (855)	$ —
Comprehensive income (loss)	$ (8,921)	$ (28,194)	$ (82,333)	$ 4,058
Net income (loss) per share attributable to common stockholders				
Basic	$ (0.10)	$ (0.34)	$ (0.98)	$ 0.05
Diluted	$ (0.10)	$ (0.34)	$ (0.98)	$ 0.05
Weighted-average common shares outstanding				
Basic	83,258,537	82,815,636	83,231,146	82,727,268
Diluted	83,258,537	82,815,636	83,231,146	88,462,074

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)

	Common Stock		Additional Paid-in	Other	Retained Earnings	Total Stockholders'
	Shares	Amount	Capital	Comprehensive Loss	(Accumulated Deficit)	Equity
Balance—December 31, 2021	83,102,730	$ 83	$ 653,964	$ —	$ 56,030	$ 710,077
Issuance of common stock upon exercise of stock options	154,861	—	223	—	—	223
Stock-based compensation expense	—	—	11,661	—	—	11,661
Net income (loss)	—	—	—	—	(42,077)	(42,077)
Balance—March 31, 2022	83,257,591	83	665,848	—	13,953	679,884
Issuance of common stock upon exercise of stock options	—	—	—	—	—	—
Stock-based compensation expense	—	—	11,908	—	—	11,908
Net income (loss)	—	—	—	—	(31,335)	(31,335)
Balance—June 30, 2022	83,257,591	83	677,756	—	(17,382)	660,457
Issuance of common stock upon exercise of stock options	1,012	—	7	—	—	7
Issuance of common stock under ESPP	29,036	—	140	—	—	140
Stock-based compensation expense	—	—	11,504	—	—	11,504
Other comprehensive loss	—	—	—	(855)	—	(855)
Net income (loss)	—	—	—	—	(8,066)	(8,066)
Balance—September 30, 2022	83,287,639	$ 83	$ 689,407	$ (855)	$ (25,448)	$ 663,187

	Common Stock		Additional Paid-in	Other	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Comprehensive Loss	Deficit	Equity
Balance—December 31, 2020	82,436,937	$ 82	$ 612,879	$ —	$ (65,160)	$ 547,801
Issuance of common stock upon exercise of stock options	300,000	1	470	—	—	471
Stock-based compensation expense	—	—	7,273	—	—	7,273
Net income (loss)	—	—		—	30,713	30,713
Balance—March 31, 2021	82,736,937	83	620,622	—	(34,447)	586,258
Issuance of common stock upon exercise of stock options	40,000	—	57	—	—	57
Stock-based compensation expense	—	—	10,007	—	—	10,007
Net income (loss)	—	—	—	—	1,539	1,539
Balance—June 30, 2021	82,776,937	83	630,686	—	(32,908)	597,861
Issuance of common stock upon exercise of stock options	270,142	—	795	—	—	795
Stock-based compensation expense	—	—	10,990	—	—	10,990
Net income (loss)	—	—	—	—	(28,194)	(28,194)
Balance—September 30, 2021	83,047,079	$ 83	$ 642,471	$ —	$ (61,102)	$ 581,452

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)

	Nine Months Ended September 30,	
	2022	**2021**
Cash flows from operating activities		
Net income (loss)	$ (81,478)	$ 4,058
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Stock-based compensation expense	35,073	28,270
Depreciation and amortization expense	156	22
Accretion of premium and discounts on marketable securities	(2,465)	—
Changes in operating assets and liabilities:		
Accounts receivable	(4,514)	—
Prepaid expenses and other current assets	(4,484)	4,259
Other assets	—	(227)
Accounts payable	(3,416)	27,945
Accrued expenses and other liabilities	(39,109)	33,278
Deferred revenue	—	(109,187)
Operating lease liabilities	800	—
Net cash used in operating activities	(99,437)	(11,582)
Cash flows from investing activities		
Additions to property and equipment	(1,943)	—
Purchases of marketable securities	(486,955)	—
Net cash used in investing activities	(488,898)	—
Cash flows from financing activities		
Cash flows from financing activities		
Proceeds from issuance of common stock for exercise of stock options	230	1,323
Proceeds from issuance of common stock under ESPP	140	—
Net cash provided by financing activities	370	1,323
Net decrease in cash, cash equivalents and restricted cash	(587,965)	(10,259)
Cash, cash equivalents and restricted cash at the beginning of period	764,680	850,224
Cash, cash equivalents and restricted cash at the end of period	$ 176,715	$ 839,965
Cash, cash equivalents and restricted cash at the end of period:		
Cash and cash equivalents	$ 176,410	$ 839,660
Restricted cash	305	305
Total cash, cash equivalents and restricted cash	$ 176,715	$ 839,965
Supplemental cash flow information:		
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 discover and 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, 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 or be able to sustain profitability. 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 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.

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 $664,975 as of September 30, 2022 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 (the “Sales Agreement”) with Jeffries LLC (“Jeffries”), 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 Jeffries, 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 (the “SEC”) on November 24, 2021, as amended. The Company has agreed to pay Jeffries a commission of up to 3.0% of the aggregate gross proceeds from each sale of shares, reimburse legal fees and disbursements and provide Jeffries with customary indemnification and contribution rights. As of September 30, 2022, no shares have been issued under the Sales Agreement.

The COVID-19 pandemic, including the rapid emergence of new variants of COVID-19, and 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 Securities and Exchange Commission ("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, 2021 included in the Company's Annual Report on Form 10-K filed with the SEC on February 28, 2022.

Unaudited Interim Financial Information

The accompanying condensed consolidated balance sheet as of September 30, 2022, the condensed consolidated statements of operations and comprehensive income (loss) for the three and nine months ended September 30, 2022 and 2021, the condensed consolidated statements of stockholders' equity for the three and nine months ended September 30, 2022 and 2021, and the condensed consolidated statements of cash flows for the nine months ended September 30, 2022 and 2021 are unaudited. The unaudited interim financial statements have been prepared on the same basis as the audited annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair statement of the Company's financial position as of September 30, 2022, the results of its operations for the three and nine months ended September 30, 2022 and 2021 and its cash flows for the nine months ended September 30, 2022 and 2021. The results for the nine months ended September 30, 2022 are not necessarily indicative of results to be expected for the year ending December 31, 2022, or any other interim period.

Use of Estimates

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

Significant Accounting Policies

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, 2021 filed with the SEC on February 28, 2022, except for as noted below.

Cash and Cash Equivalents

The Company considers all highly-liquid investments with an original maturity, or a remaining maturity at the time of purchase, of three months or less to be cash equivalents. The Company's cash equivalents include money market funds and commercial paper, which are highly liquid and have strong credit ratings. These investments are subject to minimal credit and market risks. Cash and cash equivalents are stated at cost, which approximates market value.

Marketable Securities

The Company's investment strategy is focused on capital preservation. The Company invests in instruments that meet the credit quality standards outlined in the Company's investment policy. Marketable securities consist of investments with maturities greater than three months. Marketable securities include U.S. treasury obligations, U.S. agency obligations, corporate debt, commercial paper and asset-backed securities. The Company classifies all of its marketable securities as available-for-sale. Accordingly, these investments are recorded at fair value. Unrealized gains and losses are recorded as a component of other comprehensive income within stockholders' equity. Amortization and accretion of discounts and premiums are recorded as interest income.

Fair Value Measurements

Fair value is defined as the price that would be received upon sale of an asset or paid to transfer a liability between market participants at measurement dates. ASC 820, *Fair Value Measurement,* establishes a three-level valuation hierarchy for instruments measured at fair value. The hierarchy is based on the transparency of inputs to the valuation of an asset or liability as of the measurement date. The three levels are defined as follows:
Level 1—Inputs to the valuation methodology are quoted prices (unadjusted) for identical assets or liabilities in active markets.
Level 2—Inputs to the valuation methodology include quoted prices for similar assets and liabilities in active markets, and inputs that are observable for the asset or liability, either directly or indirectly, for substantially the full term of the financial instrument.
Level 3—Inputs to the valuation methodology are unobservable and significant to the fair value measurement.

Concentration of Credit Risk and Off-balance Sheet Risk

Financial instruments that potentially subject the Company to concentrations of credit risk primarily consist of cash equivalents and marketable securities. Under its investment policy, the Company limits amounts invested in such securities by credit rating, maturity, industry group, investment type and issuer, except for securities issued by the U.S. government. The Company does not believe that it is subject to any significant concentrations of credit risk from these financial instruments. The Company has no financial instruments with off-balance sheet risk, such as foreign exchange contracts, option contracts, or other foreign hedging arrangements.

Reclassification

Certain items in the prior year's condensed consolidated financial statements have been reclassified to conform to the current presentation.

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 Revenue

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 Company concluded that the notice of termination represented a contract modification for accounting purposes. The Company further concluded that upon receipt of the notice of termination, all of the Company's performance obligations had been completely satisfied. As a result, the Company recognized all remaining

deferred revenue as collaboration revenue within the consolidated statements of operations and comprehensive income (loss) for the year ended December 31, 2021.

Prior to receipt of the termination notice, the Company classified all revenues recognized under the Roche License Agreement as collaboration revenue within the accompanying consolidated statements of operations and comprehensive income (loss). For the three and nine months ended September 30, 2021, the Company recognized collaboration revenue of $32,811 and $159,187, respectively, related to the Roche License Agreement.

The activities to complete 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 and nine months ended September 30, 2022, costs reimbursable by Roche, which are reflected as a reduction to research and development expenses were $0 and $845, respectively. For the three and nine months ended September 30, 2021, costs reimbursable by Roche, which are reflected as a reduction to operating expenses, were $1,726 and $7,623 respectively. The Company recorded a credit to research and development expense of $14,572 and $4,994 during the three and nine months ended September 30, 2022, respectively, related to its share of costs incurred by Roche. The credit recorded during the three months ended September 30, 2022 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. The Company recorded research and development expense of $25,257 and $62,986 during the three and nine months ended September 30, 2021, respectively, related to its share of costs incurred by Roche. Arising as a result of the credit recorded for the cost share agreement, as of September 30, 2022 the Company recorded accounts receivable of $4,514 related to a net refund due from Roche. As of December 31, 2021, the Company recorded accrued expenses of $10,417, related to amounts payable to Roche pursuant to the cost share agreement.

4. Marketable Securities

	As of September 30, 2022			
	Amortized Cost	Unrealized Gain	Unrealized Losses	Fair Value
Marketable Securities				
U.S. Treasury obligations	$ 69,035	$ —	$ (301)	$ 68,734
U.S. Government agency securities	15,000	—	(119)	14,881
Commercial paper	331,064	—	—	331,064
Corporate bonds	51,838	—	(347)	51,491
Asset-backed securities	22,483	—	(88)	22,395
Total	$ 489,420	$ —	$ (855)	$ 488,565

As of September 30, 2022, the Company held securities that were in an unrealized loss position of $855 with an aggregate fair value of $157,501. 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 September 30, 2022. The Company had no marketable securities prior to July 2022.

As of September 30, 2022, none of the securities had remaining maturities longer than one year. The Company did not hold any marketable securities as of December 31, 2021.

The Company did not receive any proceeds from sales or maturities of marketable securities during the three months ended September 30, 2022.

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 September 30, 2022			
	Level 1	Level 2	Level 3	Total
Cash equivalents				
Money market funds	$ 141,480	$ —	$ —	$ 141,480
Commercial paper	—	30,766	—	30,766
Marketable Securities				
U.S. Treasury obligations	—	68,734	—	68,734
U.S. Government agency securities	—	14,881	—	14,881
Commercial paper	—	331,064	—	331,064
Corporate bonds	—	51,491	—	51,491
Asset-backed securities	—	22,395	—	22,395
Total	$ 141,480	$ 519,331	$ —	$ 660,811

	Fair Value Measurements as of December 31, 2021			
	Level 1	Level 2	Level 3	Total
Cash equivalents				
Money market funds	$ 731,767	$ —	$ —	$ 731,767
Total	$ 731,767	$ —	$ —	$ 731,767

The Company's assets with fair value categorized as Level 1 within the fair value hierarchy include money market funds. Money market funds are publicly traded mutual funds and are presented as cash equivalents on the unaudited condensed consolidated balance sheets as of September 30, 2022 and December 31, 2021.

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 September 30, 2022.

6. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following:

	September 30, 2022	December 31, 2021
Research and development, including manufacturing and clinical expenditures	$ 7,669	$ 18,080
License fee	—	25,000
Income taxes	708	2,572
Payroll and payroll related	4,395	4,209
Professional fees and other	1,033	2,291
Total accrued expenses and other current liabilities	$ 13,805	$ 52,152

7. Common Stock

At September 30, 2022, the authorized capital of the Company included 300,000,000 shares of common stock, of which 83,287,639 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 stockholders approved the Company's 2020 Incentive Award Plan (the "2020 Plan"). The 2020 Plan provided for the initial issuance of up to 7,924,000 shares of common stock and for 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 of common stock as is determined by the board of directors. In January 2022 and 2021, the shares of common stock available for issuance under the 2020 Plan were increased by 4,155,136 and 4,130,847 shares, respectively.

The 2020 Plan replaced and is the successor of the 2013 Equity Incentive Plan, as amended (the "2013 Plan"). Any cancellation of outstanding option awards to purchase up to 5,982,266 shares of common stock under the 2013 Plan will be made available for grant under 2020 Plan.

As of September 30, 2022, there were 8,102,653 shares of common stock remaining available for future issuance under the 2020 Plan.

Stock Options

During the three and nine months ended September 30, 2022, the Company granted 358,500 and 3,740,917 options, respectively, to employees with an aggregate grant date fair market value of $2,188 and $19,217, respectively.

During the three and nine months ended September 30, 2022, 127,212 and 611,325 options were cancelled due to terminations.

During the three and nine months ended September 30, 2021, the Company granted 206,000 and 3,440,295 options, respectively, to employees with an aggregate grant date fair market value of $3,933 and $136,216, respectively.

During the three and nine months ended September 30, 2021, 159,183 and 292,517 options were cancelled due to terminations.

Restricted Stock Units

During the three and nine months ended September 30, 2022, the Company granted 0 and 182,350 restricted stock units, respectively, to employees with an aggregate grant date fair market value of $0 and $1,302, respectively. The restricted stock unit awards vest in three annual installments, the first of which will occur on January 31, 2023. No restricted stock units were granted during the three and nine months ended September 30, 2021.

During the three and nine months ended September 30, 2022, 600 and 20,600 restricted stock units, respectively, were cancelled due to terminations.

Performance-based Restricted Stock Units

During the three and nine months ended September 30, 2022, the Company granted 0 and 742,070 performance-based restricted stock units, respectively, to employees with an aggregate grant date fair market value of $0 and $5,298, respectively. No performance-based restricted stock units were granted during the three and nine months ended September 30, 2021. The performance stock unit awards provide for a performance period from February 1, 2022 through January 31, 2025 to complete up to six defined performance metrics. The percentage of awards 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 September 30, 2022, as the minimum performance criteria had not been achieved. The vesting of any eligible awards will occur in equal installments on January 31, 2025 and January 31, 2026.

During the three and nine months ended September 30, 2022, 0 and 17,100 restricted stock units, respectively, were cancelled due to terminations.

Employee Stock Purchase Plan

In October 2020, the Company's shareholders approved the 2020 Employee Stock Purchase Plan (the "ESPP"), which became effective upon the closing of the Company's initial public offering in November 2020. The Company initially reserved a total of 1,187,000 shares of common stock for issuance under the ESPP. The ESPP provides that the number of shares reserved and available for issuance under the ESPP will be increased on January 1 of each calendar year by 1% of the number of shares of common stock issued and outstanding on the immediately preceding December 31 or such lesser amount as specified by the compensation committee of the board of directors. To date, there has been no increase in the number of shares reserved for issuance under the ESPP.

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 day of the offering period.

On September 30, 2022, the first offering period concluded and the Company issued 29,036 shares of its common stock for proceeds of $140.

Stock-based Compensation Expense

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
Stock options	$ 11,362	$ 10,990	$ 34,727	$ 28,270
Restricted stock units	97	—	256	—
Performance-based stock units	—	—	—	—
Employee stock purchase plan	45	—	90	—
Total stock-based compensation expense	$ 11,504	$ 10,990	$ 35,073	$ 28,270

Stock-based compensation expense is classified as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
Research and development expense	$ 5,370	$ 5,022	$ 16,390	$ 12,793
General and administrative	6,134	5,968	18,683	15,477
Total stock-based compensation expense	$ 11,504	$ 10,990	$ 35,073	$ 28,270

9. Net Income (Loss) Per Share Attributable to Common Stockholders

Basic and diluted earnings per share are calculated as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
Net income (loss)	$ (8,066)	$ (28,194)	$ (81,478)	$ 4,058
Weighted average common shares outstanding, basic	83,258,537	82,815,636	83,231,146	82,727,268
Dilutive effect of outstanding stock options	—	—	—	5,734,806
Weighted average common shares outstanding, diluted	83,258,537	82,815,636	83,231,146	88,462,074
Net income (loss) per share, basic	$ (0.10)	$ (0.34)	$ (0.98)	$ 0.05
Net income (loss) per share, diluted	$ (0.10)	$ (0.34)	$ (0.98)	$ 0.05

Stock options for the purchase of 13,490,691 shares, restricted stock units of 161,750 and performance-based restricted stock units of 724,970 were excluded from the computation of the net loss per share attributable to

common stockholders for both the three and nine months ended September 30, 2022, due to net loss during the periods.

Stock options for the purchase of 5,119,092 weighted average shares were excluded from the computation of the net loss per share attributable to common stockholders for the three months ended September 30, 2021 due to net loss during the period as their effect is anti-dilutive. Stock options for the purchase of 2,466,086 weighted average shares were excluded from the computation of diluted net income per share attributable to common stockholders for the nine months ended September 30, 2021 because those options had an anti-dilutive impact due to the assumed proceeds per share using the treasury stock method being greater than the average fair value of the Company's common shares for the period.

10. Leases

In July 2021, the Company entered into a non-cancelable operating lease agreement pursuant to which the Company leased office space in Boston, Massachusetts at 225 Franklin Street (the "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. The Company began to occupy the space during the three months ended June 30, 2022. Previously, the Company's principal office was located at 125 Summer Street in Boston, Massachusetts pursuant to a lease that expired in July 2022.

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.

Future minimum payments under the 225 Lease, currently the Company's only operating lease as of September 30, 2022 were as follows:

	As of September 30, 2022
2022	$ 198
2023	805
2024	821
2025	838
2026	855
Total lease payments	3,517
Less amount representing implied interest	(221)
Total lease liability	$ 3,296
Current portion of operating lease liabilities	711
Noncurrent portion of operating lease liabilities	$ 2,585

For the three and nine months ended September 30, 2022, the Company recorded operating lease costs of $185 and $649, respectively relating to its operating lease agreements. For the three and nine months ended September 30, 2021, the Company recorded operating lease costs of $71 and $211, respectively relating to its operating lease agreements.

The 225 Lease includes a leasehold improvement allowance of $877. As of September 30, 2022, all amounts related to the improvement allowance have been received.

11. Income Taxes

The Company recorded a net benefit for income taxes of $3,833 and $3,713 for the three and nine months ended September 30, 2022. The benefit for income taxes was primarily the result of changes in estimates between the Company's initial provision for 2021 income taxes and the actual amounts reflected in income tax returns as filed.

The Company recorded a provision for income taxes of $6,100 and $13,300 for the three and nine months ended September 30, 2021. The tax expense recorded in the three and nine months ended September 30, 2021 is due to the application of a year-to-date effective tax rate rather than an annual effective rate estimated for the entire year as the Company determined that using a year-to-date approach resulted in a better estimate of its income tax expense/benefit. The Company used a year-to-date effective tax rate during the three and nine months ended September 30, 2021 due to a change in forecast resulting in the Company anticipating federal and state taxable

income for the year, while maintaining a full valuation allowance on its net deferred tax assets, as it is more likely than not that any future benefit beyond 2021 will not be realized.

12. Commitments and Contingencies

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 require the Company to indemnify various parties against claims from third parties. These contracts primarily relate to (i) the Company's bylaws, under which the Company must indemnify directors and executive officers, and may indemnify other officers and employees, for liabilities arising out of their relationship, (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 potentially 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

During the year ended December 31, 2021, the Company implemented a defined contribution plan under Section 401(k) of the Internal Revenue Code (the "401(k) Plan"). The 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 each participant's eligible compensation. During the three and nine months ended September 30, 2022, the Company recognized expense of $97 and $463 relating to matching contributions under the 401(k) Plan. During the three and nine months ended September 30, 2021 the Company recognized expense of $102 and $178, respectively, relating to matching contributions to the 401(k) Plan.

14. Related Party Transactions

The Company is a party to a consulting agreement with an entity controlled by one of its directors. This agreement, which was entered into in May 2021, provides for an annual retainer of $110. The Company recognized expense in connection with this consulting agreement in the amount of $27 and $81, respectively, for the three and nine months ended September 30, 2022. The Company recognized expense in connection with this consulting agreement in the amount of $27 and $41, respectively, for the three and nine months ended September 30, 2021.

In May 2022, the Company entered into a consulting agreement with one of its directors. The Company recognized expense of zero and $1 in connection with this consulting agreement for the three and nine months ended September 30, 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, dated December 31, 2021, filed with the Securities and Exchange Commission ("SEC") on February 28, 2022. 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 severe viral infections. Leveraging our deep understanding of nucleos(t)ide chemistry, biology and virology and the expertise of our experienced management and scientific team, we have built a proprietary purine nucleos(t)ide prodrug platform to develop novel product candidates to treat single stranded ribonucleic acid viruses, which are a prevalent cause of severe viral diseases. Currently, we are focused on the development of orally available, potent, and selective nucleos(t)ide prodrugs for difficult to treat, life-threatening viral infections, including SARS-CoV-2, the virus that causes COVID-19, dengue virus, chronic hepatitis C infection ("HCV"), and respiratory syncytial virus ("RSV").

COVID-19

Despite the availability of vaccines, vaccine boosters and therapeutics for the treatment of COVID-19, COVID-19 remains a leading cause of death in the United States with approximately 350 to 400 persons dying daily from COVID-19 and its complications. Populations at the highest risk of death or hospitalization include the elderly (80 years and older), older adults (65 years and older) with COVID-19 risk factors and persons who are immunocompromised.

COVID-19 – Bemnifosbuvir

Our most advanced product candidate for the treatment of COVID-19 is bemnifosbuvir, an investigational, novel, orally administered guanosine nucleotide analog polymerase inhibitor. Bemnifosbuvir has a unique dual mechanism of action at both the RNA-dependent RNA polymerase (RdRp) and NiRAN active sites on the highly conserved SARS-CoV-2 RNA polymerase.

SUNRISE-3 Phase 3 Clinical Trial

Prior to the end of 2022, we expect to initiate our SUNRISE-3 Phase 3 clinical trial evaluating bemnifosbuvir administered concurrently with locally available standard of care ("SOC"). The study is designed to enroll at least 1,500 high-risk non-hospitalized patients with mild or moderate COVID-19, with a global footprint consisting of approximately 300 clinical trial sites throughout the United States, Europe, Japan and rest of the world. Patients will be randomized 1:1 to receive either bemnifosbuvir 550 mg twice-daily (BID) plus locally available SOC or placebo BID plus locally available SOC for five days.

The trial will enroll patients 80 years old and older, patients 65 years old and older with at least one major COVID-19 risk factor, and immunocompromised patients 18 years old and older, all regardless of COVID-19 vaccination status.

The trial will be comprised of two populations being the supportive care population and the combination population. The supportive care population will include patients who do not qualify for an authorized oral antiviral treatment or are located in a region where oral antivirals are not locally available. The combination antiviral population will include patients who receive combination therapy being bemnifosbuvir plus SOC consisting of other compatible COVID-19 antivirals.

The primary endpoint of the study is all-cause hospitalization or death through Day 29 in the supportive care population in at least 1,300 patients. Secondary endpoints in each patient population include: COVID-19 complications, medically attended visits, symptom rebound / relapse and viral load rebound.

Previously reported topline results from our MORNINGSKY Phase 3 clinical trial demonstrated a 71% reduction in hospitalization (2.9% versus 10%) (p=0.047, unadjusted, exploratory) in the bemnifosbuvir arm (n=137) versus

placebo (n=70). In the MORNINGSKY trial, the primary endpoint, time to symptom alleviation, was not achieved. There were no deaths in the trial.

MORNINGSKY was a randomized, double-blind, multi-center, placebo-controlled Phase 3 trial designed to evaluate the antiviral activity, safety and pharmacokinetics of bemnifosbuvir in up to 1,400 patients randomized 2:1 to receive bemnifosbuvir 550 mg twice-daily (BID) or placebo in an outpatient setting. The study was closed out early in December 2021 having enrolled and treated 216 patients of which 207 were evaluable for efficacy. Atea plans to publish the full results of this study in a scientific journal.

COVID-19 Protease Inhibitor Program

As part of a multipronged approach against COVID-19, we are advancing an internal program focused on the discovery of second-generation protease inhibitors that have clinical profiles well suited for combination therapy with bemnifosbuvir. As part of this effort, our target profile is a protease inhibitor that is highly potent, has a good safety profile with limited drug-drug interactions and does not require a booster (e.g., ritonavir). The optimization of lead compounds is ongoing for selection of a candidate to further advance toward the clinic.

HCV - Bemnifosbuvir in combination with ruzasvir

Hepatitis C viral (HCV) infection is a leading cause of chronic liver disease and liver transplants.
For the treatment of chronic HCV infection, we are advancing a novel combination of bemnifosbuvir and ruzasvir, an investigational nonstructural protein 5A (NS5A) inhibitor that we exclusively in-licensed from Merck in December 2021. As single agents, both bemnifosbuvir and ruzasvir have demonstrated potent pan-genotypic antiviral activity against HCV. We expect to submit clinical trial applications to regulatory authorities prior to year end 2022 in anticipation of initiating a Phase 2 combination study of bemnifosbuvir and ruzasvir.

Dengue – AT-752

Dengue is a mosquito-borne viral infection that infects up to 400 million people worldwide a year, causing substantial public health and economic burden. Currently there are no antiviral therapies approved by either the U.S. Food and Drug Administration (“FDA”) or the European Commission.

To address this unmet medical need, we are developing AT-752, an oral, purine nucleotide prodrug product candidate for the treatment of dengue. AT-752 targets the inhibition of the dengue viral polymerase and, in preclinical studies, the drug candidate showed potent *in vitro* activity against all dengue serotypes tested, as well as potent *in vivo* antiviral activity in small animal models.

We are currently conducting the global Phase 2 DEFEND-2 (**DE**ngue **F**ever **END**) study of AT-752 for the treatment of dengue. The randomized, double-blind, placebo-controlled study is designed to evaluate multiple doses of AT-752 in three cohorts with each cohort consisting of 20 adult patients infected with dengue. The primary objective of the study is to evaluate antiviral activity, with change from baseline in dengue virus (DENV) viral load as the primary endpoint [DENV RNA by reverse transcription-polymerase chain reaction (RT-PCR)].

In addition to the DEFEND-2 study, we are currently conducting a dengue human challenge trial. This trial, which is being run exclusively in the United States, is designed to evaluate the effect of AT-752 in healthy volunteers who are challenged with an attenuated DENV-1 virus strain after receiving AT-752 or placebo.

The FDA has granted Fast Track Designation to AT-752 for the treatment of dengue infection. The FDA’s Fast Track Designation is designed to facilitate the potentially expedited development and review of new drugs and biologics that are intended to treat serious or life-threatening conditions and demonstrate the potential to meet unmet medical needs.

Roche collaboration

In October 2020, we entered into a License Agreement (the “Roche License Agreement”) with F. Hoffmann-LaRoche Ltd. and Genentech, Inc. (together, “Roche”) under which we 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. As partial consideration, Roche paid us an upfront payment of $350.0 million which was received in November 2020. Additionally, upon realization of a development milestone in June 2021, we received an additional $50.0 million from Roche.

In November 2021, we received notice from Roche that they had elected to terminate the Roche License Agreement in its entirety on a worldwide basis including Japan, with an effective date of February 10, 2022. In

December 2021, we delivered to Roche notice that we intended to continue the development of bemnifosbuvir and we have been working with Roche to effect an orderly wind down of activities in accordance with the terms of the Roche License Agreement. The obligations of Roche to equally share the costs associated with development activities terminated on February 10, 2022. We are now responsible for, and alone will bear the costs associated with the development of bemnifosbuvir. Additionally, we remain liable to Roche for certain expenses associated with transition related activities occurring after the effective date of the termination of the Roche License Agreement.

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 in all fields of use.

Financial Operations Overview

As of September 30, 2022, we had cash, cash equivalents and marketable securities of $665.0 million. Net cash used in operating activities was $99.4 million for the nine months ended September 30, 2022.

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 through at least 2025.

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 corporate sources, 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”) and contract manufacturing organizations (“CMOs”), to carry out our preclinical and clinical development and to manufacture and supply the materials to be used during the development and commercialization of our product candidates.

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 for the treatment of COVID-19;
- continue clinical development of AT-752 for the treatment of dengue;
- initiate clinical development 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;
- continue discovery and IND-enabling activities in anticipation of a nominating a product candidate for the treatment of RSV;
- 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

To date, we have not generated any revenue from product sales. Our revenue has been collaboration revenue solely derived from the Roche License Agreement, which was terminated in February 2022. If our development efforts for our product candidates are successful and result in commercialization, we may generate additional revenue in the future from a combination of product sales or payments from collaboration or license agreements that we may enter into with third parties.

Operating Expenses

Research and Development Expenses

Substantially all of our research and development expenses consist of expenses incurred in connection with the development of our product candidates. These expenses include fees paid to third parties, including CROs and CMOs, to conduct certain research and development activities on our behalf, consulting costs, certain 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 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. Our internal research and development costs are primarily personnel-related costs, including stock-based compensation, facility costs, including depreciation and lab consumables. 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. These costs represented a material portion of our total expenses through March 31, 2022. During the three months ended September 30, 2022, we recorded a reduction to research and development expenses of $14.5 million related to a credit received from Roche. The credit recorded was the result of changes in estimated amounts originally reported by Roche and subsequently adjusted following the close out of certain activities conducted by Roche during the period in which we and Roche shared costs.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
	(in thousands)		(in thousands)	
COVID-19 external costs	$ (10,243)	$ 28,515	$ 6,724	$ 75,469
Dengue external costs	2,577	3,214	8,440	6,806
HCV external costs	963	1,338	4,700	1,378
RSV external costs	588	609	1,654	1,552
Internal research and development costs	11,020	9,343	32,878	24,189
Total research and development costs	$ 4,905	$ 43,019	$ 54,396	$ 109,394

We are focusing substantially all of our resources on the development of our product candidates, particularly bemnifosbuvir. 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.

Results of Operations

Comparison of the Three Months Ended September 30, 2022 and 2021

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

	Three Months Ended September 30,		
	2022	**2021**	**Change**
		(in thousands)	
Collaboration revenue	$ —	$ 32,811	$ (32,811)
Operating expenses:			
Research and development	4,905	43,019	(38,114)
General and administrative	11,376	11,939	(563)
Total operating expenses	16,281	54,958	(38,677)
Income (loss) from operations	(16,281)	(22,147)	5,866
Interest income and other, net	4,382	53	4,329
Income (loss) before income taxes	(11,899)	(22,094)	10,195
Income tax benefit (expense)	3,833	(6,100)	9,933
Net income (loss) and comprehensive income (loss)	$ (8,066)	$ (28,194)	$ 20,128

Revenue

Collaboration revenue for the three months ended September 30, 2021 was derived from the Roche License Agreement that was executed in October 2020 and terminated in February 2022. As discussed in Note 3 to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q, following receipt in November 2021 of the notice from Roche terminating the agreement, we recognized all remaining revenue in 2021. We had no collaboration revenue for the three months ended September 30, 2022

Research and Development Expenses

Research and development expenses decreased by $38.1 million from $43.0 million for the three months ended September 30, 2021 to $4.9 million for the three months ended September 30, 2022. 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 September 30, 2021 were $25.3 million compared to a credit of $14.5 million recorded for the three months ended September 30, 2022. Partially offsetting the decrease in research and development expenses was an increase of $1.7 million related to salaries and bonuses, benefits

and stock-based compensation expense for our research and development employees and consulting fees and other research and development expenses.

General and Administrative Expenses

General and administrative expenses remained relatively consistent at approximately $11.9 million for the three months ended September 30, 2021 and $11.4 million for the three months ended September 30, 2022.

Interest Income and Other, Net

Interest income and other, net, increased by $4.4 million from less than $0.1 million for the three months ended September 30, 2021 to $4.4 million during the three months ended September 30, 2022. The increase was primarily a result of investing in higher yield marketable securities and higher interest rates.

Income Tax Expense

We recorded a net benefit for income taxes of $3.8 million for the three months ended September 30, 2022 compared to a provision for income taxes of $6.1 million for the three months ended September 30, 2021. The net benefit recorded for the three months ended September 30, 2022 was primarily the result of changes in estimates between our original provision for 2021 income taxes and the actual amounts reflected in the income tax returns as filed. For the three months ended September 30, 2021, we recorded income tax expense related to pre-tax income earned primarily due to amounts received from the Roche License Agreement.

Comparison of the Nine Months Ended September 30, 2022 and 2021

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

	Nine Months Ended September 30,		
	2022	**2021**	**Change**
	(in thousands)		
Collaboration revenue	$ —	$ 159,187	$ (159,187)
Operating expenses:			
Research and development	54,396	109,394	(54,998)
General and administrative	36,355	32,597	3,758
Total operating expenses	90,751	141,991	(51,240)
Income (loss) from operations	(90,751)	17,196	(107,947)
Interest income and other, net	5,560	162	5,398
Income (loss) before income taxes	(85,191)	17,358	(102,549)
Income tax benefit (expense)	3,713	(13,300)	17,013
Net income (loss) and comprehensive income (loss)	$ (81,478)	$ 4,058	$ (85,536)

Revenue

Collaboration revenue for the nine months ended September 30, 2021 was derived from the Roche License Agreement that was executed in October 2020 and terminated in February 2022. As discussed in Note 3 to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q, following receipt in November 2021 of the notice from Roche terminating the agreement, the Company recognized all remaining revenue in 2021. We had no collaboration revenue for the nine months ended September 30, 2022.

Research and Development Expenses

Research and development expenses decreased by $55.0 million from $109.4 million for the nine months ended September 30, 2021 to $54.4 million for the nine months ended September 30, 2022. Research and development expense 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 decreased from the nine months ended September 30, 2021 to the nine months ended September 30, 2022 primarily due to a reduction in the amount of $68.0 million related to our share of costs incurred by Roche including a credit of $14.5 million for the nine months ended September 30, 2022. This reduction was offset by a $5.0 million increase related to costs associated with dengue and HCV development activities. Partially offsetting the decrease in

external research and development expenses was an increase of $8.7 million related to internal expenses, including $3.9 million related to salaries, bonuses, benefits, $3.6 million related to stock-based compensation expense for our research and product development employees and $1.2 million related to consulting fees and other research and development expenses.

General and Administrative Expenses

General and administrative expenses increased by $3.8 million from $32.6 million for the nine months ended September 30, 2021 to $36.4 million for the nine months ended September 30, 2022. The increase in general and administrative expenses was primarily due to an increase in payroll and personnel-related expenses of $3.8 million, including salaries, bonuses, benefits and stock-based compensation expense. In addition, there was an increase of $0.4 million for other general and administrative expenses.

Interest Income and Other, Net

Interest income and other, net, increased by $5.4 million from $0.1 million during the nine months ended September 30, 2021 to $5.5 million for the nine months ended September 30, 2022 primarily as a result of investing in higher yield marketable securities and higher interest rates.

Income Tax Expense

We recorded a net benefit for income taxes of $3.7 million for the nine months ended September 30, 2022 compared to a provision for income taxes of $13.3 million for the nine months ended September 30, 2021. The net benefit recorded for the nine months ended September 30, 2022 was primarily the result of changes in estimates between our original provision for 2021 income taxes and the actual amounts reflected in the income tax returns as filed. For the nine months ended September 30, 2021, we recorded income tax expense related to pre-tax income earned primarily due to amounts received from the Roche License Agreement.

Liquidity and Capital Resources

Sources of Liquidity

As of September 30, 2022, we had cash, cash equivalents and marketable securities of $665.0 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 through at least 2025.

We entered into an open market sales agreement, or the Sales Agreement, with Jeffries, LLC, or Jeffries, 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 Jeffries, acting as sales agent or principal. We have agreed to pay Jeffries a commission of up to 3.0% of the aggregate gross proceeds from each sale of shares, reimburse legal fees and disbursements and provide Jeffries with customary indemnification and contribution rights. As of September 30, 2022, 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 may incur additional general and administrative costs as we continue to operate as a public company.

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 or other arrangements with corporate sources, 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 that product candidate. 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 related to 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:

	Nine Months Ended September 30,	
	2022	**2021**
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ (99,437)	$ (11,582)
Investing activities	(488,898)	—
Financing activities	370	1,323
Net increase (decrease) in cash, cash equivalents and restricted cash	$ (587,965)	$ (10,259)

Cash Flows from Operating Activities

Net cash used in operating activities for the nine months ended 30, 2022 was $99.4 million. Cash used in operating activities was primarily due to net loss of $81.5 million and a net decrease in accounts payable and accrued expenses of $42.5 million, an increase in unbilled accounts receivable of $4.5 million and prepaid expenses of $4.5 million and amortization of premium and discounts on marketable securities of $2.5 million, partially offset by stock-based compensation of $35.1 million.

Net cash used in operating activities for the nine months ended September 30, 2021 was $11.6 million. Cash used in operating activities was primarily due to net income of $4.1 million offset by stock-based compensation of $28.3 million, an increase in accounts payable and accrued expenses of $61.2 million, an increase in other assets of $0.2 million, a decrease in prepaid expenses of $4.3 million and a decrease in deferred revenue of $109.2 million.

Cash Flows from Investing Activities

Cash used in investing activities for the nine months ended September 30, 2022 was $488.9 million and consisted of purchases of fixed assets of $1.9 million and purchases of marketable securities of $487.0 million.

There were no cash flows from investing activities for the nine months ended September 30, 2021.

Cash Flows from Financing Activities

Net cash provided by financing activities was $0.4 million for the nine months ended September 30, 2022 and consisted of proceeds from the exercise of stock options and shares purchased under the Company's ESPP.

Net cash provided by financing activities was $1.3 million for the nine months ended September 30, 2021 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 nine months ended September 30, 2022 from those previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2021.

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 cancelation consist only of payments for services provided and expenses incurred up to the date of cancelation.

Critical Accounting Policies and Estimates

Our financial statements have been prepared in accordance with 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, 2021. 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 nine months ended September 30, 2022, there were no material changes to our critical accounting policies from those discussed in our Annual Report on Form 10-K except for as noted below.

Cash and Cash Equivalents

We consider all highly-liquid investments with an original maturity, or a remaining maturity at the time of purchase, of three months or less to be cash equivalents. Our cash equivalents include money market funds and commercial paper, which are highly liquid and have strong credit ratings. These investments are subject to minimal credit and market risks. Cash and cash equivalents are stated at cost, which approximates market value.

Marketable Securities

Our investment strategy is focused on capital preservation. We invest in instruments that meet the credit quality standards outlined in our investment policy. Marketable securities consist of investments with maturities greater than three months. Marketable securities include U.S. treasury obligations, U.S. agency obligations, corporate debt, commercial paper and asset-backed securities. We classify all of our marketable securities as available-for-sale. Accordingly, these investments are recorded at fair value. Unrealized gains and losses are recorded as a component of other comprehensive income within stockholders’ equity. Amortization and accretion of discounts and premiums are recorded as interest income.

Fair Value Measurements

Fair value is defined as the price that would be received upon sale of an asset or paid to transfer a liability between market participants at measurement dates. ASC 820, *Fair Value Measurement,* establishes a three-level valuation hierarchy for instruments measured at fair value. The hierarchy is based on the transparency of inputs to the valuation of an asset or liability as of the measurement date. The three levels are defined as follows:
Level 1—Inputs to the valuation methodology are quoted prices (unadjusted) for identical assets or liabilities in active markets.
Level 2—Inputs to the valuation methodology include quoted prices for similar assets and liabilities in active markets, and inputs that are observable for the asset or liability, either directly or indirectly, for substantially the full term of the financial instrument.
Level 3—Inputs to the valuation methodology are unobservable and significant to the fair value measurement.

Concentration of Credit Risk and Off-balance Sheet Risk

Financial instruments that potentially subject the Company to concentrations of credit risk primarily consist of cash equivalents and marketable securities. Under its investment policy, the Company limits amounts invested in such securities by credit rating, maturity, industry group, investment type and issuer, except for securities issued by the U.S. government. The Company does not believe that it is subject to any significant concentrations of credit risk from these financial instruments. The Company has no financial instruments with off-balance sheet risk, such as foreign exchange contracts, option contracts, or other foreign hedging arrangements.

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.

Recent Accounting Pronouncements

See the section titled "Summary of Significant Accounting Policies—Recent Accounting Pronouncements" in Note 2 to our unaudited condensed consolidated financial statements included in this Quarterly Report on Form 10-Q for additional information.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Sensitivity

The market risk inherent in our financial instruments and in our financial position represents the potential loss arising from adverse changes in interest rates or exchange rates. As of September 30, 2022, we had cash, cash equivalents and marketable securities of $665.0 million, consisting of interest-bearing money market funds for which the fair value would be affected by changes in the general level of U.S. 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 September 30, 2022, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended September 30, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

We are not subject to any material legal proceedings.

Item 1A. Risk Factors.

You should carefully consider the risks and uncertainties described below, as well as the other information in this Quarterly Report on Form 10-Q, including our unaudited condensed consolidated financial statements and the related notes and "Management's Discussion and Analysis of 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.

Risks Related to COVID-19

There is significant uncertainty around our development of bemnifosbuvir as a potential treatment for COVID-19.

Our development of bemnifosbuvir for the treatment of COVID-19 is in its early stages, and we may not be successful in our development of bemnifosbuvir as a potential treatment for COVID-19. In October 2020, we entered into a license agreement (as amended, the "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 bemnifosbuvir, outside of the United States (other than for certain HCV uses). Together with Roche, in April 2021, we initiated a randomized, double blind, multi-center, placebo-controlled Phase 3 clinical trial to study bemnifosbuvir in adult and adolescent patients with mild or moderate COVID-19 in the outpatient setting ("MORNINGSKY") and we subsequently initiated a Phase 3 six month follow-up study ("MEADOWSPRING") to assess the impact of bemnifosbuvir treatment on long-term sequelae of COVID-19 in the patients previously enrolled in MORNINGSKY. The Phase 3 clinical trials were begun while two Phase 2 clinical trials evaluating bemnifosbuvir in patients with COVID1-19 were ongoing. One of these Phase 2 clinical trials enrolled hospitalized patients and the other Phase 2 clinical trial (MOONSONG) 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 study to conduct prespecified statistical analyses. In January 2022 we determined to close out the Phase 2 clinical trial in hospitalized patients.

In May 2022, we reported topline results from the MORNINGSKY trial and the final analysis of data from the Phase 2 clinical trial in high-risk hospitalized patients.

In the topline analysis of data from the MORNINGSKY trial, the primary endpoint, time to symptom alleviation, was not achieved. However, a 71% reduction in hospitalization (2.9% versus 10%) was observed (p=0.047, unadjusted, exploratory) in the bemnifosbuvir arm (n=137) versus placebo (n=70). There were no deaths in the MORNINGSKY trial.

Final clinical results reported from the Phase 2 study in high-risk hospitalized patients (n=83) showed that the overall rate of disease progression was low, which we believe had an impact on the ability to assess the primary endpoint of progression of respiratory insufficiency (PRI) rate. More specifically, these results, suggest potential clinical benefit showing a 7.5% PRI rate for bemnifosbuvir 550 mg BID versus a 10% PRI rate for placebo (primary endpoint). There were three deaths in the study, no deaths were reported with patients treated with bemnifosbuvir versus three deaths reported with placebo. Final virology results (secondary endpoint) were consistent with previously reported interim data from this study. Bemnifosbuvir was generally well tolerated with no drug related serious adverse events and no adverse events leading to treatment discontinuation.

Given these results, we are advancing the development of bemnifosbuvir for the treatment of COVID-19 in high risk non-hospitalized patients pursuing both a mono- and combination strategy. We have designed and are currently engaged in activities to initiate a global, randomized, double blind placebo controlled Phase 3 clinical

known as SUNRISE-3. We are also engaged in the discovery of a proprietary protease inhibitor that could potentially be combined with bemnifosbuvir for the treatment of COVID-19. We do not know if either of these approaches will be successful.

While, we have begun to internally develop a potential protease inhibitor to evaluate in combination with bemnifosbuvir, these efforts 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. 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 risks, including the potential requirement to sufficiently demonstrate the effect, if any, of each constituent component of the combination regimen to the satisfaction of the United States Food and Drug Administration ("FDA") or other regulatory authorities.

We have committed and plan to continue to commit significant financial and personnel resources to the development of bemnifosbuvir as a mono- and combination therapy 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 will 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 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 the 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 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 pandemic were to dissipate, whether due to a significant 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 treatment decreases before or soon after commercialization of a bemnifosbuvir COV19 product candidate, if successfully developed and approved, our business could 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 are developing 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.

For example, in November 2021, Lagevrio™, or molnupiravir, an orally administered direct-acting antiviral, being developed by Merck and Ridgeback Biotherapeutics ("Ridgeback") for the treatment of adults with mild to moderate COVID-19 in the outpatient setting received conditional marketing authorization for use from the health authorities in the United Kingdom. In December 2021, the FDA issued an emergency use authorization for Lagevrio for the treatment of mild-to-moderate COVID-19 in certain adults who are at high-risk for progression to severe COVID-19, including hospitalization or death. Merck and Ridgeback have obtained similar authorizations from numerous other global health authorities. In December 2021, the FDA issued an emergency use authorization for Paxlovid™, an orally administered direct-acting antiviral being developed by Pfizer Inc. ("Pfizer") consisting of nirmatrelvir, a protease inhibitor, and ritonavir, for the treatment of adults with mild to moderate COVID-19 in the outpatient setting. In January 2022, the European Medicines Agency recommended conditional marketing authorization for Paxlovid.

Other products for the treatment of COVID-19 are currently authorized for use or approved by health regulatory authorities in numerous countries throughout the world. These products include the antiviral drug Veklury® (remdesivir), a direct acting antiviral marketed by Gilead Sciences, Inc. for the treatment of COVID-19 for certain patients requiring hospitalization.

In addition to therapeutics, vaccines indicated for active immunization to prevent COVID-19 have been approved or authorized for emergency use by the FDA. Vaccine manufacturers, including Pfizer and BioNTech and Moderna, Inc. ("Moderna") have also created, developed and received regulatory authorization in a number of jurisdictions for the use of vaccine "boosters," which are intended to extend the immunizing effect initiated with the administration of the initial vaccine regimen.

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., Gilead Sciences, Inc., Shionogi & Co., Ltd., Aligos Therapeutics, Inc., Pardes Biosciences, Inc., Ascletis pharma, Inc., and others in Asia.

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 at a lower cost, or is more successful at commercializing an approved treatment, even if a bemnifosbuvir COV19 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.

The COVID-19 pandemic may materially and adversely affect our business and financial results.

The global emergence of variants and subvariants of SARS-CoV-2, including the Delta and Omicron variant and subvariants such as BA.2 and BA.2.12.1, BA.4, BA.5, and more recently BA.4.6, BA.2.75.2, BQ.1 and BQ.1.1 has resulted in an increasing number of infections, including breakthrough infections in persons who have been vaccinated against the infection. In the United States, travel bans and government stay-at-home orders in response to the initial outbreak caused widespread disruption in business operations and economic activity. Governmental authorities around the world implemented measures to reduce the spread of COVID-19. These measures, including suggested or mandated "shelter-in-place" orders, adversely affected workforces, customers, consumer sentiment, economies, and financial markets, and, along with decreased consumer spending, contributed to an economic downturn in the United States. Future resurgences in cases may result in renewal of measures, many of which are currently relaxed, that are intended to reduce the spread of COVID-19. In response to the public health directives and orders and to help minimize the risk of COVID-19 for our employees, we have taken precautionary measures, including implementing work-from-home policies for all our employees. Many of our third-party collaborators, such as our CMOs, clinical research organizations ("CROs"), suppliers and others, have taken similar precautionary measures. At times during the pandemic, these measures have disrupted our business and delayed certain of our clinical programs and timelines. For example, our Phase 1/2a clinical trial in patients with hepatitis C virus ("HCV") was paused when clinical trial sites closed due to COVID-19 precautions by the countries and medical facilities where the trial was to be conducted

The impact to our operations due to elongation or resurgence of the COVID-19 pandemic could be severe and could negatively affect our business, financial condition and results of operations. To the extent the COVID-19 pandemic 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, such as those relating to our clinical trial timelines, our ability to enroll subjects for clinical trials and obtain materials that are required for the manufacture of our product candidates, and our ability to raise capital.

The COVID-19 pandemic or other public health crises may materially and adversely affect our clinical trials.

As a result of the COVID-19 pandemic or 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 COVID-19 pandemic or other 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 symptoms, progression, and transmission of COVID-19 resulting from infection with a particular variant, as evidenced with Delta or Omicron variants differ in multiple ways including severity of symptoms and rate of transmissibility. This rapid and continuing emergence of variants and the evolution of disease manifestation presents additional challenges for the conduct of our clinical trials in COVID-19 patients. For example, COVID-19 patients have presented with a wide range of symptoms and side effects, which may make it more difficult for clinical trial investigators to determine whether any adverse events observed in our clinical trials are related to bemnifosbuvir or are consistent with the underlying disease. Any increase in the severity or incidence of adverse events deemed to be related to bemnifosbuvir or any combination regimen we seek to develop could delay or prevent its regulatory approval, which could have a material adverse effect on our business, financial condition and results of operations. In addition, efficacy and antiviral results from a COVID-19 clinical trial may be affected by, among other things, which variant or variants causes the infection and evolving immunization status of the patients enrolling in the clinical trial, resulting in response rates that may also be variable over time as the pandemic progresses.

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 arrange for 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 2021.

In connection with our development of a combination bemnifosbuvir COV19 product, we expect to be required to conduct earlier-stage trials before we can advance to any late- or pivotal-stage clinical trials, and therefore will require additional time and resources, including the resources required to discover or acquire a product or product candidate that we can evaluate in combination with bemnifosbuvir. 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. For example, the decision by Roche to terminate the Roche License Agreement also terminated Roche's obligation, after February 10, 2022, the effective date of the termination of the Roche License Agreement, to share with us costs associated with the development of bemnifosbuvir for the treatment of COVID-19.

Additionally, as a further result of the termination of the Roche License Agreement, we will not receive any other revenue from Roche beyond the upfront payment we received in 2020 and the milestone payment we received in 2021. 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 and we do not expect to maintain profitability in 2022 and for the foreseeable future.

We have incurred significant operating expenses since our inception. For the nine months ended September 30, 2022 and the year ended December 31, 2021, our operating expenses were $90.8 million and $213.0 million, respectively. In 2021, as a result of the termination by Roche of the Roche License Agreement, which resulted in the recognition of revenue for accounting purposes associated with the deferred revenue balance associated with upfront payment and the milestone payment we received from Roche, we recorded operating income for the year ended December 31, 2021. For the nine months ended September 30, 2022, we have not recorded any operating income and do not expect to realize operating income in 2022 or for the foreseeable future.

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 in the remainder of 2022 and 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 United States or abroad, respectively, we must submit to the FDA a New Drug Application ("NDA") or similar application to the foreign regulatory authority demonstrating to the FDA's or foreign regulatory authority's satisfaction that the product candidate is safe and effective for its intended use(s). This demonstration requires significant research and extensive data from 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 our Phase 3 SUNRISE-3 clinical trial we expect our expenses will increase substantially. Additionally, our expenses will also increase substantially if or as we:

- initiate clinical trials of a bemnifosbuvir combination regimen for the treatment of patients with COVID-19;
- advance the development of our other product candidates, including the ongoing clinical development of AT-752 for the treatment and prevention of dengue, our planned clinical development of bemnifosbuvir in combination with ruzasvir for the treatment of HCV, and the preclinical development of potential other product candidates, including for the treatment of RSV;
- 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, 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 and any future in-license agreements relating to other product candidates; and
- incur additional 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 incur operating expenses and use cash for operating activities for the foreseeable future. These operating expenses and use of cash have had, and will continue to have, an adverse effect on our working capital. Additionally, we expect to incur operating losses in foreseeable future periods.

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 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 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 to in connection with the conduct of the Phase 3 SUNRISE-3 clinical trial. Additionally, we anticipate to incur substantial expenses in connection with the clinical development of a combination bemnifosbuvir COV19 product candidate and, the combination of bemnifosbuvir and ruzasvir for the treatment of HCV and AT-752 for the treatment of dengue. Additionally, we expect to incur significant expenses in the future in connection with clinical trials for other product candidates and in our efforts to identify new product candidates, through internal discovery efforts or through acquisition or licensing.

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 may divert the time and attention of our management from day-to-day activities and harm our product candidate development efforts.

Based on our current operating plan, we believe that our cash and cash equivalents as of September 30, 2022 will be sufficient to fund our operating expenses and capital expenditure requirements through at least 2025. 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.

Our future capital requirements depend on many factors, including but not limited to:

- 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 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 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 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 in connection with 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.

We cannot be certain that additional funding will be available on acceptable terms, or at all. The COVID-19 pandemic, including the evolution of new and existing variants of COVID-19, and geopolitical events, including civil or political unrest (such as the ongoing war between Ukraine and Russia), have resulted in a 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.

Due to the recognition of revenue for accounting purposes of certain payments we received under the terminated Roche License Agreement, we recognized operating income for the year ended December 31, 2021, however, our ability to achieve and sustain future profitability depends upon our ability to generate revenue from product sales. Other than from the Roche License Agreement, we have not generated any revenue and 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:

- timely initiation and completion of our Phase 3 SUNRISE-3 clinical trial, other clinical trials of our bemnifosbuvir COV19 product candidates, bemnifosbuvir and ruzasvir, and AT-752, our preclinical studies and other future clinical trials, which may be significantly slower or more costly than we currently anticipate and will depend substantially upon the performance of third-party contractors;
- our ability to complete additional investigational new drug application (“IND”) enabling studies and successfully submit INDs or comparable applications to allow us to initiate clinical trials for our 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, perceived advantages and relative cost, convenience and efficacy of any bemnifosbuvir COV19 product, 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 utilize or adopt any of our product candidates or future product candidates as potential antiviral therapies;
- our ability and the ability of third parties with whom we contract to manufacture adequate clinical and commercial supplies of our product candidates or any 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 United States;

- our ability to successfully develop a commercial strategy and thereafter commercialize our product candidates or any future product candidates in the United States and internationally, if licensed 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.

We utilized federal and state net operating loss carryforwards ("NOLs") of approximately $52.8 million and $52.6 million, respectively, during the year ending December 31, 2021. We utilized federal and state research and development credit carryforwards of $0.7 million and $0.3 million, respectively during the year ended December 31, 2021.

In general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the "Code"), a corporation that undergoes an "ownership change," generally defined as a greater than 50% change by value in its equity ownership over a three-year period, is subject to 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 fiscal year 2021, we have completed a Section 382 study, the results of which indicated that no ownership shift occurred during such 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 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, 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. Such a delay, suspension or termination 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 bemnifosbuvir COV19 product candidates. If we are not successful in developing a bemnifosbuvir 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 bemnifosbuvir and ruzasvir for the treatment of HCV, and AT-752 for the treatment of dengue, each of 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 one or more bemnifosbuvir COV19 product candidates and to develop, obtain regulatory approval for and successfully commercialize the combination of bemnifosbuvir and ruzasvir for the treatment of HCV and AT-752 for the treatment of dengue. 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 bemnifosbuvir COV19 product candidate. Among other things, this effort will require the successful completion of our Phase 3 SUNRISE-3 clinical trial 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 bemnifosbuvir for the treatment of COVID-19. COVID-19, while currently a global pandemic, is unpredictable and therapies, including any bemnifosbuvir COV19 product candidate, may be adversely impacted up to the point of obsolescence by the emergence of new variants or subvariants. 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 bemnifosbuvir and ruzasvir for the treatment of HCV and AT-752 for the treatment and prevention of dengue, each of 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. For example, each of a prior Phase 2 clinical trial and the Phase 3 MORNINGSKY clinical trial evaluating bemnifosbuvir for the treatment of COVID-19 in outpatients failed to meet its primary endpoint in the overall study population. Further, our development of any product candidate may be delayed, 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 our product candidates will be consistent with the results observed in clinical trials or in the case of a bemnifosbuvir 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 our most advanced product candidates or in developing our bemnifosbuvir COV19 product candidate, 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 United States 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. 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 United States 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 or our collaborators 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 or our collaborators 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 COV19 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, 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 our Phase 3 SUNRISE-3 clinical trial or any of our other 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 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 institutional review board ("IRB") or ethics committee approval at each clinical trial site;
- delays in recruiting, screening and enrolling suitable 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 practice requirements ("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;
- clinical sites deviating from 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, disruptions caused by the COVID-19 pandemic 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 availability of an increasing number of therapeutic options, may impact the initiation or successful completion of our Phase 3 SUNRISE-3 clinical trial and our other COVID-19-related clinical trials.

Any inability to successfully initiate or complete our Phase 3 SUNRISE-3 clinical trial or our other ongoing and planned clinical trials 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 data safety monitoring board (“DSMB”) for such trial, or by the FDA or any other regulatory authority, or if the IRBs of the institutions in 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 with our dengue clinical trials, are planning to do for the Phase 3 SUNRISE-3 clinical trial and otherwise expect to continue doing for our 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 Clinical Trials Regulation ("CTR") which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. While the Clinical Trials Directive required a separate clinical trial application ("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. Additionally, sponsors may still choose to submit a CTA under either the Clinical Trials Directive or the CTR until January 31, 2023 and, if authorized, those will be governed by the Clinical Trials Directive until January 31, 2025. By that date, all ongoing trials will become subject to the provisions of the CTR. 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 United Kingdom ("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 will be closely watched and will determine whether the UK chooses to align with the regulation or diverge from it to maintain regulatory flexibility. A decision by the UK not to closely align its regulations with the new approach that will be adopted in the EU may have an effect on the cost of conducting clinical trials in the UK as opposed to other countries and/or make it harder to seek a marketing authorization in the EU for our product candidates on the basis of clinical trials conducted in the UK.
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 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 planning to develop combination therapies for the treatment of COVID-19 and HCV. 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 COVID-19 patients, in addition to our development of bemnifosbuvir as a monotherapy, we anticipate to develop a combination product consisting of bemnifosbuvir and a protease inhibitor that is currently the subject of internal discovery efforts. For the treatment of HCV, we are currently pursuing development of bemnifosbuvir in combination with ruzasvir, a product candidate that has not yet been approved for marketing by the FDA or similar foreign regulatory authorities. 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 of, 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;
- 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 new 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 will reduce the number and types of patients available to us because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites.

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

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.

We have received Fast Track Designation for AT-752 for the treatment of dengue infection and may seek such designation for certain of our other product candidates.

If a product candidate is intended for the treatment of a serious or life-threatening condition and the product candidate demonstrates the potential to address unmet medical needs for such condition, the product candidate sponsor may apply for Fast Track Designation. The sponsor of a product candidate that has received Fast Track Designation may have opportunities for more frequent interactions with the FDA review team during product development and, once a New Drug Application ("NDA") is submitted, the NDA may be eligible for priority review. An NDA for a Fast Track 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, including our COVID-19 product candidate, but cannot assure you that the FDA would decide to grant it. Even if we do receive 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 United States, 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 United States for our product candidates. The acceptance of study data from clinical trials conducted outside the U.S. 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 U.S., the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. 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, the FDA will not accept the data as support for an application for marketing approval unless the study is well-designed and well-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 U.S. 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 United States, 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;
- 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. The process by which we identify 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 COV19 product candidates, bemnifosbuvir in combination with ruzasvir for the treatment of HCV and AT-752 for the treatment and prevention of dengue, and as such, we may forgo or delay pursuit of opportunities with other future product candidates that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and other future product candidates for specific indications may not yield any commercially viable future product candidates. If we do not accurately evaluate the commercial potential or target market for a particular 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 United States. 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 expedited approval.

We are developing certain product candidates for the treatment of serious and life-threatening 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, additional post-approval 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 post-approval studies fail to verify the drug's predicted clinical benefit, the FDA may withdraw its approval of the drug on an expedited basis.

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.

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 United States 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. Our development programs are early-stage and 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 United States 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. A proposal for revision of several legislative instruments related to medicinal products (potentially revising the duration of regulatory exclusivity, eligibility for expedited pathways, etc.) is expected to be adopted by the European Commission by the end of 2022. The proposed revisions, once they are agreed and adopted by the European Parliament and European Council (not expected before the end of 2024) 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 bemnifosbuvir COV19 product candidate 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 bemnifosbuvir COV19 product candidates. The FDA has the authority to issue an EUA only under certain circumstances, such as during a public health emergency, pursuant to a declaration by the Secretary of the Department of Health and Human Services, or HHS, that an emergency exists 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 exist justifying authorization of drugs and biologics during the COVID-19 pandemic, subject to the terms of any EUA that is 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 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 bemnifosbuvir COV19 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.

In addition, the authorization to market products under an EUA is limited to the period of time the EUA declaration is in effect, and the FDA can revoke an EUA in certain circumstances. 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.

Therefore, even if, upon presentation of the data from our Phase 3 SUNRISE-3 clinical trial and other COVID-19 clinical trials, we should obtain an EUA or other emergency authorizations for a bemnifosbuvir COV19 product candidate, 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 United States, which would limit our ability to realize their full market potential.

In order to market any products outside of the United States, 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 U.S., 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 U.S. 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, in March 2020, the FDA temporarily postponed routine surveillance inspections of domestic and foreign manufacturing facilities. Subsequently, in July 2020, the FDA resumed certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA utilized this risk-based assessment system to assist in determining when and where it was safest to conduct prioritized domestic inspections. Additionally, on April 15, 2021, the FDA issued a guidance document in which the FDA described its plans to conduct voluntary remote interactive evaluations of certain drug manufacturing facilities and clinical research sites, among other facilities. According to the guidance, the FDA may request such remote interactive evaluations where the FDA determines that remote evaluation would be appropriate based on mission needs and travel limitations. In July 2021, the FDA resumed standard inspectional operations of domestic facilities. More recently, 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. Regulatory authorities outside the United States 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 judgement 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 may 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, 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.

Risks Related to Healthcare Laws and Other Legal Compliance Matters

We will be 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 the U.S. Department of Health and Human Services, the U.S. Department of Justice, state and local governments, and their respective equivalents outside of the United States. 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 United States regulation.

Government regulation substantially increases the cost and risk of researching, developing, manufacturing and 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 preclinical studies and 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 United States, 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 products in development, 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 U.S. 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 new 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 new 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 U.S. 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 United States 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, President Biden signed the American Rescue Plan Act of 2021 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.

Most significantly, on August 16, 2022, President Biden signed the IRA into law. This statute marks the most significant action by Congress with respect to the pharmaceutical industry since adoption of the ACA in 2010. 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, and while the impact of the IRA on the pharmaceutical industry and our business cannot yet be fully determined, it is likely to be significant.

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 U.S. 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. We expect that additional U.S. federal healthcare reform measures will be

adopted in the future, any of which could limit the amounts that the U.S. 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 United States 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 United States 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 United States, 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 United States, 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 United States 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 United States 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 U.S. 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 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 investigators, 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, market, sell and distribute our product candidates, if approved. Such laws include but are not limited to:

- the U.S. 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 U.S. 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 U.S. federal civil and criminal false claims laws, including the civil False Claims Act (the "FCA"), which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the U.S. 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 U.S. 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 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 U.S. 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 U.S. 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 U.S. federal Food, Drug and Cosmetic Act ("FDCA"), which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- the U.S. 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;

- 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;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- analogous U.S. 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 U.S. 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 United States and globally, and existing ones are being updated and strengthened. For example, on June 28, 2018, California enacted the California Consumer Privacy Act (the "CCPA"), which took effect on January 1, 2020. The CCPA 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") recently passed in California. The CPRA significantly amends the CCPA and will impose 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 will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, 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 United States. 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, financial condition and results of operations, including but 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.

The privacy laws in the EU have been significantly reformed in recent years. On May 25, 2018, the EU General Data Protection Regulation ("GDPR") entered into force and became directly applicable in all EU member states. The GDPR and related implementing laws in individual EU member states govern the collection and use of personal 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). The GDPR rules are also applicable in the European Economic Area (“EEA”), which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland. The GDPR implements more stringent operational requirements than its predecessor legislation. For example, the GDPR requires us to make more detailed disclosures to data subjects, requires disclosure of the legal basis on which we can process personal data, makes it harder for us to obtain valid consent for collecting and processing personal data, requires the appointment of data protection officers when sensitive personal data, such as health data, is processed on a large scale, provides more robust rights for data subjects, introduces mandatory data breach notification through the EU, imposes additional obligations on us when contracting with service providers and requires us to adopt appropriate privacy governance, including policies, procedures, training and data audit. The GDPR provides that EU member states may establish their own laws and regulations limiting the processing of personal data, including genetic, biometric or health data, which could limit our ability to use and share personal data or could cause our costs to increase. Violations of the GDPR can lead to potential fines of up to €20 million or 4% of the annual global revenues of the noncompliant undertaking. 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 United States, and the efficacy and longevity of current transfer mechanisms between the EU and the United States remains uncertain. For example, in 2016, the EU and United States agreed to a transfer framework for data transferred from the EU to the United States, called the Privacy Shield, but in July 2020 the Court of Justice of the EU (“CJEU”) limited how organizations could lawfully transfer personal data from the EEA to the United States by invalidating the Privacy Shield for purposes of international transfers and imposing further restrictions on use of the standard contractual clauses (“SCCs”). While the CJEU upheld the adequacy of the SCCs, it made clear that reliance on them alone may not necessarily be sufficient in all circumstances. Use of the SCCs must now be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, in particular applicable surveillance laws and rights of individuals and additional measures and/or contractual provisions may need to be put in place, however, the nature of these additional measures is currently uncertain. The CJEU went on to state that if a competent supervisory authority believes that the SCCs cannot be complied with in the destination country and the required level of protection cannot be secured by other means, such supervisory authority is under an obligation to suspend or prohibit that transfer. The European Commission issued revised SCCs on June 4, 2021 to account for the decision of the CJEU and recommendations made by the European Data Protection Board. The revised SCCs must be used for relevant new data transfers since September 27, 2021; existing standard contractual clauses arrangements must be migrated to the revised clauses by December 27, 2022. There is some uncertainty around whether the revised clauses can be used for all types of data transfers, particularly whether they can be relied on for data transfers to non-EEA entities subject to the GDPR. The revised SCCs apply only to the transfer of personal data outside of the EEA and not the UK; the

UK's Information Commissioner's Office has published new data standard contracts for transfers from the UK under the UK GDPR. This new documentation will be mandatory for relevant data transfers beginning on September 21, 2022, existing standard contractual clauses arrangements must be mitigated to the new documentation by March 21, 2024. This and other recent developments are likely to require us to review and amend the legal mechanisms by which we make and/ or receive personal data transfers to and in the United States. 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, we are subject to the GDPR and also the UK GDPR, which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The European Commission has adopted an adequacy decision in favor of the UK, enabling data transfers from EU member states to the UK without additional safeguards. However, the UK adequacy decision will automatically expire in June 2025 unless the European Commission re-assesses and renews/ extends that decision. In September 2021, the UK government launched a consultation on its proposals for wide-ranging reform of UK data protection laws following Brexit and the response to this consultation was published in June 2022. There is a risk that any material changes which are made to the UK data protection regime could result in the European Commission reviewing the UK adequacy decision, and the UK losing its adequacy decision if the European Commission deems the UK to no longer provide adequate protection for personal data. The relationship between the UK and the EU in relation to certain aspects of data protection law remains unclear, and it is unclear how UK data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the UK will be regulated in the long term. In addition, we may be the subject of litigation and/or adverse publicity, which could adversely affect our business, results of operations and financial condition.

In addition, the EU has also proposed a Regulation on Privacy and Electronic Communications, or ePrivacy regulation, which, if adopted, would impose new obligations on the use of personal data in the context of electronic communications, particularly with respect to online tracking technologies and direct marketing.

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 U.S., 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 (the "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.

In addition, 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 United States may implicate international data protection laws, including the UK GDPR, GDPR and legislation of the EU member states implementing it. For example, 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 that enables European patients to have the opportunity to access information about clinical trials.

Our activities outside the United States 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 United States 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.

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;
- comparable foreign regulatory approvals of product candidates;
- 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, 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 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 treatments and, in some cases, vaccines for COVID-19, HCV, dengue and RSV. There are several vaccines approved or authorized for use for COVID-19 and there are therapeutics available for the treatment of COVID-19 including two authorized oral antiviral therapies authorized for emergency use for high risk COVID-19 patients. There are also several drugs including oral antivirals, approved for the treatment of HCV, an approved vaccine for dengue and an approved drug for the treatment of RSV. Our product candidates are intended 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 United States, 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 United States, 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 United States. 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 United States, 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 United States, the reimbursement for our product candidates may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and third-party payors in the United States 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, during the pendency of the public health emergency declared by the Secretary of HHS in March 2020 at the outset of the COVID-19 pandemic, the U.S. federal government has been a primary purchaser of therapeutics for the treatment of COVID-19. Even if we succeed in developing a bemnifosbuvir COV19 product candidate, we may not be able to compete effectively if such product does not satisfy government procurement requirements and our future results of operations may be adversely impacted if government procurement needs for such products decline due to over-saturated supply, reduced patient demand or reduced appropriations for such purchases. Additionally, it is uncertain for how long the U.S. federal government will remain a primary purchaser of COVID-19 therapeutics. Recently, there have been announcements regarding the intention of the U.S. federal government to transition the procurement and distribution of COVID-19 therapeutics, vaccines and diagnostic tests to the commercial market. 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 U.S. federal government COVID-19 response. The effects of such a transition from U.S. federal government procurement and distribution to commercial market channels are many and will likely include discontinuation of free or heavily subsidized access by U.S. persons to COVID-19 therapeutics, vaccines and diagnostics. 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 United States 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 any product launch, which would adversely impact the commercialization of our product candidate, if approved. Additionally, if the commercial launch of our product candidate 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 United States. 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 U.S. 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 Southeast Asia where dengue fever is endemic. Many U.S.-based biotechnology companies have found the process of marketing their own 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 United States. 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 United States 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 and our research activities, preclinical and clinical 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. For example, in 2022, we began to manufacture ruzasvir, the product candidate we licensed in December 2021 from Merck. Until such time, if ever, as we have successfully manufactured a sufficient quantity of ruzasvir clinical trial material, we will be unable initiate patient enrollment in the planned HCV clinical trials of the combination of bemnifosbuvir and ruzasvir.

We expect to rely on third-party manufacturers for the commercial supply of any of our product candidates for which we obtain marketing approval, if any.

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 clinical trial interruptions, 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 AT-752 and 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 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 a natural disaster, 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 United States. 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 market our product candidates, if approved. 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, 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, 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 manufacturing of bemnifosbuvir, AT-752 or ruzasvir or any of our other product candidates. For AT-752 and 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 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 United States 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 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 United States. 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 candidate;
- 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 granted to Roche an exclusive license related to bemnifosbuvir for certain development rights and commercialization rights outside of the United States 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 at a premium. 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 U.S. 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 and biological 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 United States and in the countries in which they operate governing the use, manufacture, storage, handling and disposal of medical and 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 medical or 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 medical and biological or 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, AT-281 (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 United States 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 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 United States 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 United States 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 U.S. 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 United States 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 United States, including the Leahy-Smith America Invents Act of 2011, (the “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 U.S. patent law, including provisions that affect the way patent applications are prosecuted and also affect patent litigation. Under the Leahy-Smith Act, the United States 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 United States 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 U.S. Patent and Trademark Office, (the "USPTO").

The Leahy-Smith Act created for the first time new procedures to challenge issued patents in the United States, 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 U.S. patents in lawsuits in U.S. 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 U.S. 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 United States, involving patent and other intellectual property rights in the pharmaceutical industry, including patent infringement lawsuits, interferences, oppositions, re-examination, and post-grant and inter partes review proceedings before the USPTO and similar proceedings in foreign jurisdictions, such as oppositions before the European Patent Office, (the "EPO"). Numerous U.S. 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

U.S. 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 U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. 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 COVID19 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 bemnifosbuvir 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 U.S. Patent Office issued a patent to us covering the composition of matter of bemnifosbuvir. However, other than the foregoing issued U.S. 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 United States, 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 United States to the patent litigation process of the Hatch-Waxman Act, as currently amended, which allows a generic company to submit an Abbreviated New Drug Application, ("ANDA") to the FDA to obtain approval to sell our drug using bioequivalence data only. Under the Hatch-Waxman Act, we will have the opportunity to list our patents that cover our drug product or its method of use in the FDA's compendium of "Approved Drug Products with Therapeutic Equivalence Evaluation," sometimes referred to as the FDA's Orange Book.

Currently, in the United States, 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 U.S. 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 United States, 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 United States 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 United States 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 United States, 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 United States, 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, (the "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 United States, 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 United States 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 United States 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-U.S. 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 United States. 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 United States and Europe do not afford intellectual property protection to the same extent as the laws of the United States 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 (the "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 United States 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 (the "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 U.S. 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 United States 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 United States 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 United States, other U.S. 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 could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our product candidates 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 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 consultants or find other competent outside contractors 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 consultants and contractors, or we are not able to effectively build out new 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 November 1, 2022, we had 68 full-time employees. Our focus on the clinical development of product candidates in three 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 executive management and directors. 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 our officers or directors could delay or prevent the successful enrollment and completion of our clinical trials. We do not carry key person life insurance on any officers or directors. In general, the employment arrangements that we have with our executive officers do not prevent them from terminating their employment with us at any time.

In addition, our future success and growth will depend in part on the continued service of our directors, employees and management personnel and our ability to identify, hire and retain additional personnel. If we lose one or more of our executive officers or key employees, our ability to implement our business strategy successfully could be seriously harmed. Furthermore, replacing 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 develop, gain regulatory approval of and commercialize product candidates 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 appreciated 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 the market price of our common stock. Our future success also depends on our ability to continue to attract and retain additional executive officers and other key employees.

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 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 current conflict between Ukraine and Russia has created extreme volatility in the capital markets and is expected to have further global economic consequences. 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. Political unrest, such as the current situation with Ukraine and Russia, may also cause volatility and disruption in the global economy. 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 United Kingdom's withdrawal from the European Union may have a negative effect on global economic conditions, financial markets, and our business, which could reduce our share price.

The UK left the EU on January 31, 2020, following which existing EU legislation continued to apply in the UK during a transition period under the terms of the EU-UK Withdrawal Agreement. The transition period, which ended on December 31, 2020, maintained access to the EU single market and to global trade deals negotiated by the EU on behalf of its members. The transition period provided time for the UK and EU to negotiate a framework for partnership for the future, which was then crystallized in the Trade and Cooperation Agreement ("TCA") and became effective on the January 1, 2021. While agreement on the terms of the TCA has avoided a "no deal" Brexit scenario, and provides in principle for quota and tariff free trading of goods, it is nevertheless expected that the TCA will result in the creation of non-tariff barriers (such as increased shipping and regulatory costs and complexities) to the trade in goods between the UK and EU. Further, the TCA does not provide for the continued free movement of services between the UK and EU and also grants each of the UK and EU the ability, in certain circumstances, to unilaterally impose tariffs on one another. The TCA does provide for the mutual recognition of GMP inspections of manufacturing facilities for medicinal products and cGMP documents issued. However, it is important to note that significant regulatory gaps still exist and the TCA does not contain wholesale mutual recognition of UK and EU pharmaceutical regulations and product standards between the parties, for example, in relation to batch testing and pharmacovigilance, which remain subject to further discussions.

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. EU laws which have been transposed into UK law through secondary legislation continue to be applicable as "retained EU law". However, new legislation will not be applicable. The UK government has passed a new 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 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. There is a possibility that over time, national laws will be amended and that consequently the regulatory framework in Great Britain will diverge from that of 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 U.S. 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 September 30, 2022. 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,

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 will be 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 target preclinical studies or clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline as it did following the downgrades by covering analysts in the fourth quarter of 2021. This included certain downgrades after we reported on the data from the Phase 2 MOONSONG clinical trial, which failed to meet the primary study endpoint in the overall patient population and other events. 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 United States 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 United States and other jurisdictions may impact our ability to protect our patents.

The U.S. Supreme Court has issued opinions in patent cases in the last few years that many consider may weaken patent protection in the United States, 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 United States 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 U.S. Congress, the U.S. 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 United States 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 business prospects could be substantially harmed. For example, we have been notified that a pre-grant opposition has been filed with the Controller General Patents, Design, and Trademarks at the Indian Patient 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. If so, uncertainties resulting from the initiation and continuation of such proceedings could have a material adverse effect on our ability to compete in the marketplace. 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. 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 customers 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 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. 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.

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 our customers or 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. We believe this risk is especially relevant for us given our significant stock price volatility in 2021.

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 with closing prices in 2021 ranging from a high of $88.44 on February 8, 2021 to a low of $7.67 on November 23, 2021 and in 2022, to a low of $5.18 on October 19, 2022.

The stock market in general, The Nasdaq Global Select Market 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 United States and other countries;
- development of third-party product candidates that may address our markets and make our product candidates less attractive;
- changes in physician, hospital or healthcare provider practices that may make our product candidates less useful;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- our failure to commercialize our product candidates;

- announcements by us, our partners or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- developments or disputes concerning patent applications, issued patents or other intellectual property or proprietary rights;
- the recruitment or departure of key scientific or management personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- changes in accounting practices;
- the trading volume of our common stock;
- our cash and cash equivalents 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.

We have incurred and may continue to incur increased costs as a result of operating as a public company, and our management has been and will continue to be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, we are incurring significant legal, accounting and other expenses that we did not incur before we became a public company in October 2020. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Global Select Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel are devoting a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have and will continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, these rules and regulations have made it more difficult and more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified members of our board of directors.

We will continue to monitor these rules and regulations and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 ("Section 404"), we are required to furnish a report by our management on our internal control over financial reporting in our Annual Report on Form 10-K. In addition, we are required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. At such time, 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 achieve compliance with Section 404 within the prescribed period, we are engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we 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. 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. We may discover significant deficiencies or material weaknesses in our internal control over financial reporting, which we may not successfully remediate on a timely basis or at all. Any failure to remediate any significant deficiencies or material weaknesses identified by us or to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations or result in material misstatements in our financial statements. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

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, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 for the year ending December 31, 2022. 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 being a public company, 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. Testing and maintaining internal control can divert our management's attention from other matters that are also important to the operation of our business. In addition, 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 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				Filed/ Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
3.1	Restated Certificate of Incorporation.	8-K	001-39661	3.1	11/5/2020	
3.2	Amended and Restated Bylaws.	8-K	001-39661	3.2	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: November 7, 2022

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

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

Date: November 7, 2022

By: /s/ Andrea Corcoran

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

Exhibit 31.1

CERTIFICATION

I, Jean-Pierre Sommadossi, certify that:

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

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Date: November 7, 2022

By: /s/ Jean-Pierre Sommadossi

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

Exhibit 31.2

CERTIFICATION

I, Andrea Corcoran, certify that:

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

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Date: November 7, 2022

By: /s/ Andrea Corcoran

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

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Atea Pharmaceuticals, Inc. (the "Company") for the period ended September 30, 2022 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: November 7, 2022

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

Exhibit 32.2

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

In connection with the Quarterly Report on Form 10-Q of Atea Pharmaceuticals, Inc. (the "Company") for the period ended September 30, 2022 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: November 7, 2022

By: /s/ Andrea Corcoran

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