

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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2021

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM

TO

Commission File Number 001-39661

**ATEA PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its Charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)  
125 Summer Street  
Boston, MA  
(Address of principal executive offices)

46-0574869  
(I.R.S. Employer  
Identification No.)

02110  
(Zip Code)

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

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

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES  NO

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. YES  NO

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

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

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

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

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.

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

As of June 30, 2021, the aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, based on the last reported sales price for the registrant's common stock, par value \$0.001 per share, on the Nasdaq Global Select Market on such date, was approximately \$1,615,148,024.

The number of shares of Registrant's Common Stock outstanding as of February 25, 2022 was 83,225,591.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2022 Annual Meeting of Stockholders, which the registrant intends to file with the Securities and Exchange Commission within 120 days after the end of the registrant's fiscal year ended December 31, 2021, are incorporated by reference into Part III of this Annual Report on Form 10-K.

Table of Contents

	<u>Page</u>
<a href="#">SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS</a>	ii
<a href="#">SUMMARY RISK FACTORS</a>	iii
<b>PART I</b>	
Item 1. <a href="#">Business</a>	1
Item 1A. <a href="#">Risk Factors</a>	53
Item 1B. <a href="#">Unresolved Staff Comments</a>	121
Item 2. <a href="#">Properties</a>	121
Item 3. <a href="#">Legal Proceedings</a>	121
Item 4. <a href="#">Mine Safety Disclosures</a>	121
<b>PART II</b>	
Item 5. <a href="#">Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</a>	122
Item 6. <a href="#">Reserved</a>	123
Item 7. <a href="#">Management's Discussion and Analysis of Financial Condition and Results of Operations</a>	124
Item 7A. <a href="#">Quantitative and Qualitative Disclosures About Market Risk</a>	137
Item 8. <a href="#">Financial Statements and Supplementary Data</a>	137
Item 9. <a href="#">Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</a>	137
Item 9A. <a href="#">Controls and Procedures</a>	137
Item 9B. <a href="#">Other Information</a>	139
Item 9C. <a href="#">Disclosure Regarding Foreign Jurisdictions that Prevent Inspections</a>	139
<b>PART III</b>	
Item 10. <a href="#">Directors, Executive Officers and Corporate Governance</a>	140
Item 11. <a href="#">Executive Compensation</a>	140
Item 12. <a href="#">Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</a>	140
Item 13. <a href="#">Certain Relationships and Related Transactions, and Director Independence</a>	140
Item 14. <a href="#">Principal Accountant Fees and Services</a>	140
<b>PART IV</b>	
Item 15. <a href="#">Exhibits, Financial Statement Schedules</a>	141
Item 16. <a href="#">Form 10-K Summary</a>	143

## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K 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 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 and needs for additional 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 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 I, Item 1A. "Risk Factors." You should read these 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. These 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 Annual Report on Form 10-K, unless otherwise specified or the context otherwise requires, the terms "we," "our," "us," the "Company" refer to Atea Pharmaceuticals, Inc. and its subsidiary. All brand names or trademarks appearing in this Annual Report on Form 10-K 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 Annual Report on Form 10-K. The principal risks and uncertainties affecting our business include the following:

- There is significant uncertainty around our development of bemnifosbuvir as a potential combination 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 or we are not successful at commercializing bemnifosbuvir.
- The market for therapeutics for the treatment of COVID-19 may be reduced, perhaps significantly, if vaccines are effective and widely accepted.
- Bemnifosbuvir may face significant competition from other treatments for COVID-19 that are currently marketed or are in development.
- The COVID-19 pandemic may materially and adversely affect our business opportunities, clinical trials and financial results.
- We have a limited operating history and no history of successfully developing or commercializing any approved antiviral products, which may make it difficult to evaluate the success of our business to date and to assess the prospects for our future viability.
- We have incurred significant operating expenses since inception. We expect our expenditures will increase for the foreseeable future. We have no products that have generated any commercial revenue and we may never 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 identify and develop a bemnifosbuvir COVID-19 combination product candidate or if these product candidates fail in preclinical or clinical development, do not receive regulatory approval or are not successfully commercialized, 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 the commercialization of any product candidate we develop.
- Clinical development is lengthy and uncertain. 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 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.
- We could be subject to securities class action litigation.

**Item 1. Business.****Overview**

We are a clinical-stage biopharmaceutical company focused on discovering, developing and commercializing antiviral therapeutics to improve the lives of patients suffering from difficult to treat, life-threatening viral infections. Our current focus is on the development of product candidates to treat COVID-19, hepatitis C virus ("HCV"), dengue and respiratory syncytial virus ("RSV").

Utilizing our team's expertise and experience from decades of developing innovative antiviral treatments, we are advancing product candidates that are designed to be potent and selective, including nucleos(t)ide analogs developed as either monotherapy or in combination with other antiviral agents. Each of the nucleos(t)ide analogs we are developing, specifically bemnifosbuvir (AT-527) and AT-752, have been derived from our proprietary nucleotide platform that combines unique nucleotide scaffolds with novel double prodrugs for the purpose of inhibiting the enzymes central to viral replication. We believe that utilizing this double prodrug moiety approach allows us to maximize formation of the active metabolite, potentially resulting in oral antiviral product candidates that are selective for and highly effective at preventing replication of single stranded RNA ("ssRNA") viruses while avoiding toxicity to host cells. We have built, and we plan to continue to build our pipeline of antiviral product candidates by augmenting our nucleos(t)ide platform with other classes of antivirals we believe that may be developed in combination with our nucleos(t)ide product candidates.

**The Nucleos(t)ide Class and Combination Treatments**

Combination therapy utilizing multiple direct acting antivirals with differing mechanisms of action is an established strategy that has been historically successful in treating many life-threatening viral diseases, including human immunodeficiency virus ("HIV"), hepatitis B virus ("HBV") and HCV. Nucleos(t)ide analogs are the backbone of many of these successful combination therapies.

Drug combinations can simultaneously target multiple points in the viral replication cycle and can also combat resistance that may develop over time with use of single agent drugs. Because nucleos(t)ide analogs target highly conserved enzymes responsible for viral replication, these agents have a high barrier to resistance compared to drugs in other antiviral classes. We believe this profile makes nucleos(t)ide analogs well suited for use in combination regimens for the treatment of viral diseases, potentially allowing us to leverage our nucleos(t)ide platform and the differentiated product candidates derived from it as the backbone of potential combination therapy.

**Our Development Pipeline**

The following table summarizes our orally administered antiviral product candidate pipeline. All our product candidates, with the exception of ruzasvir which we in-licensed from MSD International GmbH, an affiliate of Merck & Co, Inc. ("Merck") in December 2021, have been discovered and developed internally at Atea. We have full global rights to commercialize all our product candidates in all indications.

ssRNA VIRUS	THERAPEUTIC INDICATION		PRECLINICAL	PHASE 1	PHASE 2	PHASE 3
Coronaviridae	COVID-19 <sup>1</sup>	Bemifosbuvir (AT-527) Nucleotide*				
	COVID-19	Bemifosbuvir Nucleotide + Protease Inhibitor				
Flaviviridae	Hepatitis C Virus (HCV) <sup>2</sup>	Bemifosbuvir Nucleotide				
	Hepatitis C Virus (HCV)	Ruzasvir** (NS5A inhibitor)				
	Dengue Virus	AT-752 Nucleotide				
Paramyxoviridae	Respiratory Syncytial Virus (RSV)	Product Candidates				

\*Bemifosbuvir is a double prodrug nucleotide analog

\*\* Worldwide exclusive license for all uses from Merck

1. Bemifosbuvir has been evaluated as a monotherapy in Phase 2 clinical trials. *In vitro* combination studies are being conducted to generate data in support of potential clinical combination studies for the treatment of COVID-19.
2. Bemifosbuvir and Ruzasvir have been evaluated in Phase 2 clinical trials are anticipated to be developed as a combination for the treatment of HCV.

## COVID-19

The global pandemic of COVID-19, caused by the rapid spread of the SARS-CoV-2 virus, which was first reported in Wuhan, China on December 1, 2019, has created significant disruption to public health and economic activity worldwide. As of February 21, 2022, there has been reported over 420 million confirmed cases of COVID-19, nearly six million deaths worldwide and lasting health problems, frequently referred to as "Long COVID" in many survivors.

At approximately two years into the pandemic, unprecedented progress has been made with both vaccines and treatment options. Treatment options in the United States, that have either been approved or authorized for emergency use for high-risk patients, include the oral direct acting antivirals Paxlovid™ (nirmatrevir and ritonavir) and molnupiravir, each of which have demonstrated the important impact that easily administered agents can have on preventing disease progression, hospitalization and death. Treatment options also include Veklury® (remdesivir), a direct acting antiviral which is administered through IV infusion, in addition to monoclonal antibodies which are also administered through IV infusion. This progress has, however, been offset by a blend of vaccine hesitancy, vaccine resistance and the emergence of a number of SARS-COV-2 variants, most recently omicron, that have increased transmissibility and the ability to evade neutralizing antibodies.

As a result, substantial need remains for additional treatment options. As COVID-19 becomes endemic with the potential for variant fueled pandemic surges, we believe that this need will continue for years.

As single agent therapeutics become more widely utilized by larger, broader populations during the endemic phase, the potential for development of resistance increases, especially for those agents which do not target highly conserved sites on the SARS-CoV-2 virus. We believe that oral therapies which are practical, convenient and efficient for use in the early stages of disease, have the potential to protect against the development of severe infection and transmission of the virus, and to benefit a wide range of patient populations including patients who are unvaccinated, patients who fail to respond to available vaccines, individuals for whom a vaccine is contraindicated, and vaccinated patients with waning efficacy, which can occur between three to six months after immunization.

We believe that nucleoside analogues are promising candidates for combination therapy development since antiviral activity is expected to remain even in the presence of newly emerging variants. In particular, we believe bemnifosbuvir is a well-suited product candidate for development in COVID-19 combination regimens as it is designed to target not only the highly conserved polymerase, but also the nidovirus RdRp associated nucleotidyltransferase ("NiRAN") function and it has been to be well tolerated in clinical trials completed to date.

As additional oral therapies are developed and are added to the treatment armamentarium, we believe that combination regimens will be needed to cover broad patient populations, as newer variants emerge, and resistance develops with the use of single agents.

#### **Bemnifosbuvir**

Our most advanced product candidate for the treatment of COVID-19 is bemnifosbuvir, an investigational, novel, orally administered guanosine nucleotide analog polymerase inhibitor which we believe could be a preferred backbone for an oral combination regimen. 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. As we anticipate continued rapid emergence and evolution of viral variants together with the potential for viral drug resistance to single agent therapies which could render previously effective monotherapy obsolete, we have prioritized the development of bemnifosbuvir as a potential combination therapy for the treatment of COVID-19.

In 2021, we reported data from two monotherapy Phase 2 clinical trials evaluating bemnifosbuvir for the treatment of COVID-19. One study was conducted in hospitalized adult high-risk patients with moderate COVID-19, while the second was conducted in adult outpatients with mild to moderate disease. Although the Phase 2 clinical trial in adult outpatients did not meet its primary endpoint and the Phase 2 clinical trial in hospitalized patients was closed out prior to completion, there were consistent positive trends in antiviral activity (~0.5 log<sub>10</sub> reductions) observed after dosing with 550 mg BID and 1100 mg BID in sub-groups of patients at high risk for progression. In addition, results from a bronchoalveolar lavage study in healthy subjects showed that bemnifosbuvir was efficiently delivered to the lungs (epithelial lining fluid), the primary site of SARS-CoV-2 infection. We believe the collective results from these studies provide positive human proof-of-concept to support our combination strategy.

To efficiently develop a combination regimen for the treatment of COVID-19, we plan to initially study the combination of bemnifosbuvir with a protease inhibitor. As a class, protease inhibitors have demonstrated antiviral activity in COVID-19 but may be susceptible to resistance if used as a single agent. We have initiated preclinical *in vitro* combination studies of bemnifosbuvir with protease inhibitors to explore antiviral synergy and mitigation of potential viral resistance. Data from ongoing *in vitro* studies is expected in the first half of 2022.

#### **Hepatitis C**

Despite significant recent advances in treatment, HCV remains a global health burden largely owing to the epidemic of injection drug use, and a lack of diagnosis of many of those who have been infected.

#### **Bemnifosbuvir and ruzasvir**

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. As ruzasvir is a Phase 2-ready NS5A inhibitor that has already been evaluated by Merck in over 1200 HCV-infected patients, we have prioritized clinical development of the ruzasvir/bemnifosbuvir combination program over the AT-777/AT-787 programs (AT-777 being our prior lead NS5A inhibitor program which was paused at the outset of the COVID-19 pandemic given industry-wide challenges in conducting clinical studies at that time).

We believe that a combination of bemnifosbuvir and ruzasvir has the potential to offer a differentiated short duration, pan-genotypic protease-sparing regimen for HCV-infected patients with or without cirrhosis. For patients with decompensated cirrhosis, a life-threatening stage of liver disease, we believe that the combination of bemnifosbuvir and ruzasvir may have the potential to treat these patients without the co-administration of ribavirin. In the second half of 2022, we expect to initiate a Phase 2 clinical trial



of the combination of bemnifosbuvir and ruzasvir evaluating the safety and efficacy in HCV-infected patients.

#### **Dengue**

Dengue is a mosquito-borne viral infection that infects up to 400 million people worldwide a year, causing substantial public health and economic burden. Dengue, which is life threatening in severe cases, was traditionally considered a tropical disease, endemic to countries located mostly in the tropical regions of Asia, Latin America, the Pacific, and across Africa. However, in recent decades the incidence of the disease has been spreading globally. While a vaccine to prevent dengue is approved in some countries, it is indicated only for persons with confirmed prior dengue infection and its product label use is highly restricted. Currently there are no antiviral therapies approved by either the U.S. Food and Drug Administration ("FDA") or the European Commission.

#### **AT-752**

To address this unmet medical need, we are developing AT-752, an oral, purine nucleotide prodrug for the treatment of dengue. AT-752 targets and inhibits 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.

In 2021, we initiated and completed a randomized, double-blind, placebo-controlled Phase 1a clinical trial to evaluate the safety and pharmacokinetics ("PK"), of different dosages of AT-752 in healthy adults (n=65). In this first-in-human clinical trial, AT-752 administered as single or multiple ascending doses was well tolerated. No premature discontinuations due to adverse events or serious adverse events were reported and most adverse events were mild. There were no clinically relevant changes in laboratory parameters.

In 2022, we anticipate conducting two studies of AT-752. One will be a human challenge study designed to allow assessment of viral load and viral kinetics in healthy subjects who are challenged with a Dengue Virus-1 Live Virus Human Challenge (DENV-1-LVHC) strain after receiving AT-752 or placebo. This study will be conducted in the United States. We are also preparing to initiate a Phase 2, global randomized double-blind, placebo-controlled trial in adult patients with dengue fever. This proof-of-concept study in patients is designed to evaluate the antiviral activity, safety and PK of multiple doses of AT-752. It will be conducted in areas where dengue is endemic.

#### **RSV**

RSV is a seasonal respiratory virus that is responsible for significant health and economic burden worldwide. RSV is a common virus that causes severe respiratory disease in infants, which often leads to hospitalization. Up to 70% of infants are infected by the age of one and virtually all infants will have been infected by their third year of life. As protective immunity wanes, RSV reinfection in children and adults, is common. While these reinfections tend to be milder, RSV is a well-established cause of significant morbidity and mortality in the elderly, the immunocompromised and other high-risk patients. There is also an increased awareness of the long-term consequences of RSV primary infection that have been linked to prolonged wheezing and an increased risk of developing asthma. There are no approved vaccines. The only approved drugs are ribavirin, which has safety concerns and questionable efficacy and Synagis, a monoclonal antibody which is indicated not for treatment but only for protection against RSV in a high risk pediatric population.

Based on the extensive structure-activity relationship we have identified with our nucleos(t)ide library, we are optimizing the inhibitory potency and selectivity of lead analogs against RSV RdRp. In the second half of 2022, we anticipate nominating a lead candidate and initiating investigational new drug application ("IND")-enabling studies.

#### **Our Team**

Our management team has significant experience discovering, developing and commercializing antiviral therapies for life-threatening viral infections. Our Founder, Chairman, and Chief Executive Officer, Jean-Pierre Sommadossi, Ph.D., has over 30 years of scientific, operational, strategic, and management experience in the biopharmaceutical industry. Dr. Sommadossi has authored over 180 peer-reviewed

publications and holds more than 135 U.S. patents related to antiviral and cancer therapeutics. Dr. Sommadossi was the principal founder of Idenix Pharmaceuticals, Inc. ("Idenix"), which was acquired by Merck in 2014, and a co-founder of Pharmasset, Inc. ("Pharmasset"), which was acquired by Gilead Sciences, Inc. in 2012.

We have assembled an experienced management and scientific team with a track record of success in the field of antiviral drug development, many of whom have worked together previously. Our team has significant expertise in nucleos(t)ide chemistry, biochemistry and virology and has applied that expertise towards the discovery and development of innovative antiviral treatments, including Eпивir, Sovaldi, Tyzeka, Valtrex, Wellferon, Videx, Reyataz, Sustiva, Mavyret, Xofluza, Relenza, Zerit, Zepatier, Epclusa, Harvoni and Veklury. Members of our team have held senior positions at AstraZeneca plc, Merck, GlaxoSmithKline plc, Chiron, Novartis International AG, Biogen, F. Hoffmann La Roche, Abbvie, Bristol Myers Squibb, Shire, Biohaven Pharma, Pharmasset, Idenix, Valeant Pharmaceuticals International, Gilead Sciences, Inc. and Alnylam Pharmaceuticals.

#### **Our Strategy**

Our goal is to become a global leader in the discovery, development, and commercialization of novel antiviral therapies for severe or life-threatening viral infections. We intend to achieve this goal by pursuing the following strategies:

**Deploy our medicinal chemistry expertise and proprietary nucleotide platform against severe ssRNA viruses with high unmet need.** We are developing oral, small molecule antiviral product candidates for the treatment of severe viral diseases. These drug candidates are derived from our proprietary platform complemented by the strategic in license of drug candidates with mechanisms of action different from the drug candidates generated from our platform. Our pipeline includes three programs each at the Phase 2 development stage with drug candidates advancing for the treatment of COVID-19, hepatitis C and dengue fever as well as a preclinical program for RSV. We anticipate multiple value driving milestones over the next 18 months from our three clinical programs.

**Develop bemnifosbuvir (AT-527) as the nucleos(t)ide polymerase preferred backbone for combination therapy for the treatment of COVID-19.** Bemnifosbuvir, is an investigational, orally administered, non-mutagenic, direct-acting antiviral agent that has been evaluated in Phase 2 clinical trials. In these Phase 2 trials, bemnifosbuvir has been generally well tolerated and antiviral activity of bemnifosbuvir was observed in high-risk patients with COVID-19. *In vitro*, bemnifosbuvir has shown potent inhibition of SARS-CoV-2 replication against all major variants of concern or interest that have been evaluated. Historically, the emergence of viral resistance has been a major obstacle to successful antiviral therapy. We believe bemnifosbuvir's mechanism of action, which targets two sites within the RNA-dependent RNA polymerase and results in termination of RNA synthesis and inhibition of NiRAN activity, has the potential create a high barrier to viral resistance. Taken together, we believe that these properties make bemnifosbuvir an ideal candidate for development as a backbone of potential combination regimens for the treatment of COVID-19.

**Advance a potentially best-in-class pan-genotypic regimen of bemnifosbuvir and ruzasvir for HCV.** Despite the availability of DAA oral combination regimens for the treatment of HCV, there remains a large, underserved, HCV patient population which continues to grow in the United States. A large portion of this increase in incidence is attributable to the opioid crisis, IV drug use and HCV reinfection, especially among younger adults. Additionally, improved therapies may eliminate the need for ribavirin in patients suffering from decompensated cirrhosis. Clinical studies of ruzasvir conducted by Merck and clinical studies of bemnifosbuvir conducted by us each demonstrated potent antiviral activity in HCV-infected patients as well as favorable tolerability. *In vitro* synergy of the combination of bemnifosbuvir and ruzasvir in inhibiting HCV replication has also been observed. We believe that the combination of bemnifosbuvir and ruzasvir, if successfully developed and approved, has the potential to benefit the populations of HCV-infected patients increasing in the United States and globally, including, in particular, those who are most difficult to treat.

**Develop AT-752 as the potential first oral antiviral treatment for dengue fever.** Dengue virus infects approximately 400 million people each year and there are no approved oral antiviral treatments available. AT-752 is a purine nucleotide prodrug product candidate derived from our proprietary nucleotide platform.

Peer-reviewed published data showed potent *in vitro* activity against all serotypes tested and demonstrated antiviral activity in an animal models. The safety, tolerability and PK of AT-752 has been evaluated in a completed Phase 1 study in healthy subjects. These data support the continued evaluation of AT-752 in Phase 2 studies in dengue-infected patients. We believe that AT-752, if approved, has the potential to become the first pharmaceutical for the treatment and prophylaxis of dengue fever.

**Leverage the drug discovery and development experience of our team.** We believe that building a successful antiviral-focused company requires very specific expertise in the areas of identification of unmet patient needs, medicinal chemistry, drug discovery, preclinical and clinical development, and regulatory affairs. We have assembled and are utilizing the expertise and experience of a team with a demonstrated track record of efficiently and successfully discovering, developing and obtaining global regulatory approval for innovative antiviral therapeutics.

**Maximize the value of our product candidates.** We generally intend to retain global commercialization rights to our product candidates, which we believe will allow us to retain the greatest potential value of our product portfolio. However, we may opportunistically enter into license agreements or collaborations where we believe there is an opportunity, particularly outside the United States, to maximize the value and accelerate the development of our product candidates and potential commercialization of any products. Currently, we plan to establish our own commercial organization in the United States, and we may build additional commercial organizations in other selected markets for any of our product candidates that are approved.

**Maintain our scientifically rigorous approach and culture of tireless commitment to patients.** The patients we seek to treat suffer from life-threatening viral infections for which there are no approved therapies or where there may be an opportunity to improve upon existing therapies. Members of our team, who have dedicated their lives to discovering, developing, and commercializing novel antiviral therapies for severe or life-threatening viral infections, are bringing this commitment and scientific rigor to our efforts to discover, develop and commercialize innovative and differentiated products for patients suffering from COVID-19, HCV, dengue and RSV.

## Antiviral Therapy

### Background on viruses

Viruses are cellular parasites that can only replicate using a host cell's replication processes, as viruses lack the machinery required to survive and replicate on their own. Unlike living organisms that use DNA as the basis for their genetic material, viruses can use either DNA or RNA. Approximately 70% of all viruses are RNA viruses.

Viruses have two primary components: nucleic acid (single or double stranded RNA or DNA) and a protective shell (the capsid). Some viruses may also have a lipid bilayer (the envelope) surrounding the capsid, an additional membrane derived from host cell membranes that contains viral proteins.

The viral replication process begins when a virus attaches itself to a specific receptor site on the host-cell membrane through attachment proteins. The replication mechanism is dependent upon whether the virus is an RNA or DNA virus. Most DNA viruses use host cell proteins and enzymes to make additional DNA that is used to copy the viral genome or is transcribed to messenger RNA ("mRNA"). RNA viruses use their RNA as a template for synthesis of viral genomic RNA and mRNAs. The mRNAs encode both nonstructural proteins responsible for viral replication and transcription and structural proteins responsible for viral assembly. Finally, the newly created virus particles ("virions"), are released from the host cell in order to repeat the infection and replication cycle. RNA viruses can be particularly challenging to treat, as the error rates around the viral RNA polymerase directed RNA synthesis cause high mutation rates during reproduction, creating variants and resistance challenges for antiviral therapies.

### Background of ssRNA viruses

RNA viruses can be single stranded (ssRNA) viruses or double-stranded (dsRNA), viruses, depending on the type of RNA used as the genetic material. A virus encased within a lipid bilayer is known as an enveloped virus, while a virus without this bilayer is called a non-enveloped virus. Enveloped ssRNA viruses are the more prevalent cause of severe human viral diseases. Studies from the last decade have

placed RNA viruses as primary etiological agents of many emerging human pathogens, representing up to 50% of all emerging infectious diseases. Types of enveloped and non-enveloped ssRNA viruses and some of the diseases they cause are shown in the table below, with the types of ssRNA viruses that we are currently targeting with our product candidates highlighted in yellow.

Enveloped ssRNA viruses	
<b>Coronaviridae</b> - MERS - SARS - SARS-CoV-2	<b>Flaviviridae</b> - HCV, Dengue, West Nile, Zika, Yellow Fever, Japanese Encephalitis
<b>Paramyxoviridae</b> - RSV - Mumps	<b>Retroviridae</b> - HIV - Human T-Cell Leukemia Virus
<b>Bunyaviridae</b> - La Crosse encephalitis - Crimean-Congo hemorrhagic fever - Hantavirus pulmonary syndrome - Rift Valley fever	<b>Togaviridae</b> - Alphavirus - EEE, Venezuelan equine encephalitis, chikungunya
<b>Orthomyxoviridae</b> - H1N1 - Avian H7N9	<b>Rhabdoviridae</b> - Rabies encephalitis
<b>Arenaviridae</b> - Lymphocytic choriomeningitis virus (LCMV) - St. Louis Encephalitis, aseptic meningitis, Lassa Fever	<b>Filoviridae</b> - Ebola - Marburg
Non-enveloped ssRNA viruses	
<b>Picornaviridae</b> - Rhinovirus - Enterovirus	<b>Reoviridae</b> - Rotavirus (GI disorders)
<b>Caliciviridae</b> - Gastroenteritis	<b>Birnaviridae</b> - Not a human pathogen

Over the last 40 years, a great deal of progress has been made in the treatment of some of the most severe viral infections. However, many highly pathogenic ssRNA viruses, including dengue virus and newly emerging viruses such as SARS-CoV-2 and its evolving variants, continue to cause severe viral diseases which still remain inadequately treated or not treated at all.

#### Viral polymerase as an antiviral target

From the discovery and approval of the first antiviral drug in 1963, there have been more than 100 antiviral drugs approved in the United States for the treatment of nine different human viral diseases. A historical challenge with the treatment of intracellular viruses has been selectivity or discovering drug targets that can completely inhibit viral replication without harming the host cells, leading to toxic side effects. Advances in technology and high throughput screening in recent years have driven the discovery of more selective antiviral product candidates. The viral polymerase, which is the single protein present in all RNA viruses, is a key enzyme in the replication of viruses, making for an ideal drug target as its core structural features are highly conserved across different viruses. There are four types of viral polymerase, depending upon the virus and its genomic makeup:

- RNA-dependent RNA polymerase ("RdRp"): All ssRNA viruses, including SARS-CoV-2 and HCV, depend on the RdRp, encoded in the viral genome, for replication and transcription. Since these enzymes are not present in the host cell, this facilitates the design of selective inhibitors of viral replication, which target viral but not host cell polymerases.
- DNA-dependent DNA polymerase ("DdDP"): DdDP is used by DNA viruses to replicate their genome.
- RNA-dependent DNA polymerase ("reverse transcriptase"): Reverse transcriptase is used by certain DNA or RNA viruses, such as HBV and HIV-1, to replicate their genomes.
- DNA-dependent RNA polymerase ("DdRP"): DdRP is used by DNA viruses to transcribe mRNA from DNA templates during replication.

As viral RNA polymerase-based synthesis does not occur in human host cells, antiviral drug development for RNA viruses focuses on identifying selective drug-like molecules that target viral RNA polymerase. Advances in technology have enabled intensive structural and functional studies of viral RNA polymerase

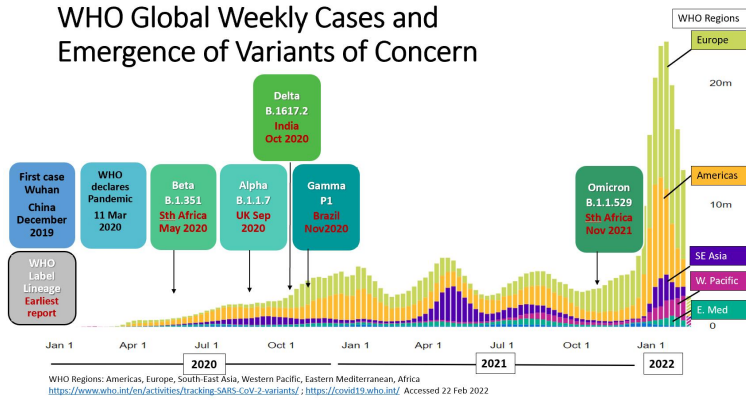
including the identification in the case of SARS-CoV-2 of nidovirus RdRp associated nucleotidyltransferase ("NiRAN"), and have opened avenues for the development of new and more effective antiviral therapies.

### Viral resistance and variants

A major obstacle to antiviral therapy is viral resistance. Resistance is a function of a virus' ability to genetically mutate, which, in the case of RNA viruses, is substantially higher than DNA viruses, as most RdRp lack proofreading abilities. The rate of mutation of RNA viruses can occur at six orders of magnitude greater than the rate of mutation of host cells. The ability of viruses to evolve makes the design of ssRNA-directed therapies challenging, as these viral strains continue to mutate and become more resistant to certain antiviral therapies over time. Since all the enzymes involved in the metabolic pathways of bemnifosbuvir and AT-752 to their active triphosphate are designed to be essentially ubiquitous host cell enzymes and not virally encoded proteins, we believe that the high rate of viral mutation does not affect the activation of the prodrug.

Another consequence of viral mutations is the emergence of new variants. For example, each year the genetic mutations accumulated in the influenza virus cause antigen drift that could significantly impact immune recognition, thus the flu vaccines have to be reviewed and updated. SARS-CoV-2, despite the fact that it does have a proof-reading function with the nsp14 exonuclease, has proven to be able to mutate quickly as well. More than six million SARS-CoV-2 variants have been identified since fall 2020, including alpha (B.1.1.7) in the U.K., beta (B.1.351) in South Africa, gamma (P.1) in Brazil, delta (B.1.617.2) in India, and omicron (B.1.1.529) in South Africa.

## WHO Global Weekly Cases and Emergence of Variants of Concern



A number of these variants have been designated by WHO and CDC as Variants of Concern (VOC) or Variants of Interest (VOI) because there is evidence of increased transmissibility, more severe disease, reduced effectiveness of vaccines or antibodies, or diagnostic detection failures. For example, it is estimated that the effectiveness of mRNA vaccines is reduced by >50% for the omicron variant vs. delta variant without a booster. The neutralizing activity of bamlanivimab, etesevimab, casirivimab and imdevimab, monoclonal antibodies authorized for treatment of high risk COVID-19 patients, was reduced by >500 fold against omicron, the most recent prevalent variant, rendering those monoclonal antibodies ineffective. Given the mutagenic nature of the virus, we expect that the evolution of the virus will continue with more variants emerging and presenting new and varied health challenges.

### **Nucleos(t)ide analogs and prodrugs**

Nucleic acids (DNA and RNA), which comprise human and viral genetic material, are composed of natural chemical compounds termed nucleosides and nucleotides. Nucleos(t)ide analogs, which are synthetic compounds that mimic the structure of naturally occurring nucleosides and nucleotides, target the viral polymerase directly so that it mistakenly incorporates these analogs into nascent nucleic acids, causing inhibition of viral replication. Nucleos(t)ide analogs, compared to other classes of antiviral therapies, have a high barrier to viral resistance due to the conservation of the structure of the polymerase that is required to produce viable virions.

Prodrugs of nucleos(t)ide analogs have become the backbone of single-drug and combination-drug therapies to treat life threatening viral infections, including HIV, HBV, and HCV. Prodrugs are employed to bypass rate limiting activation steps and to improve the oral bioavailability and permeation of cell membranes by the nucleos(t)ide analog.

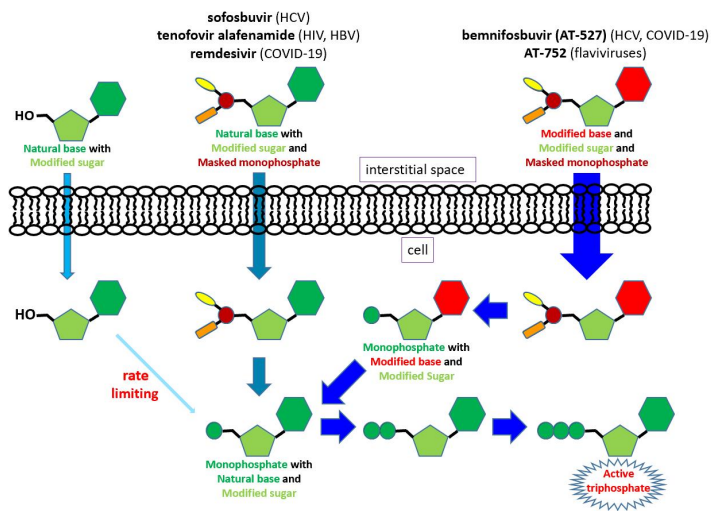
#### **Our Nucleotide Prodrug Platform**

Leveraging our deep understanding of antiviral drug development, nucleos(t)ide chemistry, biochemistry and virology, we have built a proprietary purine nucleotide prodrug platform to develop novel treatments for life threatening diseases caused by ssRNA viral infections.

Our proprietary nucleotide prodrug platform, as illustrated below, is comprised of the following critical components:

- specific modifications at the 6-position of the purine base, acting as a prodrug, are designed to prevent the toxic effects of other such modifications and enhance cell membrane permeability, resulting in an intermediate metabolite that maximizes formation of the triphosphate active metabolite in cells;
- stereospecific phosphoramidate, acting as a prodrug, designed to bypass the first rate-limiting phosphorylation enzyme in the intracellular activation pathway;
- specific modifications in the sugar moiety of the purine nucleotide scaffold, producing potent antiviral activity with a high degree of selectivity; and
- highly specific salt form to enhance solubility and drug bioavailability.

## Atea's purine nucleotide prodrug platform



We believe that product candidates derived from our platform, which combines unique purine nucleotide scaffolds with a novel double prodrug strategy, have the following potential advantageous characteristics and features:

- enhanced antiviral activity and selectivity, as well as well-established pharmacology and animal models to predict clinical activity;
- favorable safety profile;
- convenience of oral administration; and
- efficient, predictable, scalable, and reproducible manufacturing, as well as long shelf life for potential stockpiling.

### Development Programs

#### Bemnifosbuvir for the treatment of COVID-19

Although vaccines have an important role in improving a patient's chance of having a milder form of disease and mitigating the COVID-19 pandemic, as COVID-19 becomes endemic we believe that there will be a continuing need for novel, orally available treatment options, to stay ahead of both increasingly infectious variants and the potential resistance to currently available single agent oral therapies which may emerge in the future.

While effective vaccines are available, global adoption, access and utilization of vaccines remains limited. In addition, breakthrough infection can occur because the current vaccines are not 100% effective and variants have had an impact on their efficacy. With the continuing prevalence of COVID-19 globally, there is heightened risk of a further mutation of the virus that could evade one or more of the current

vaccines and monoclonal antibody treatments. Thus, we believe there is an urgent need for effective, safe, oral, antiviral treatments.

Paxlovid™ and molnupiravir have provided important evidence regarding the impact that easily administered oral direct acting antivirals can have on preventing disease progression, hospitalization and death. As additional oral therapies are developed and are added to the treatment armamentarium, we believe that combination regimens will be needed to cover broader patient populations, as newer variants emerge, and resistance develops with the use of single agents alone.

We believe that nucleoside analogues are well suited to serve as the backbone of a combination regimen since antiviral activity is expected to remain even in the presence of newly emerging variants. More specifically, we believe bemnifosbuvir is a particularly well-suited product candidate for development in COVID-19 combination regimens as it been shown to inhibit the highly conserved viral RNA polymerase at both the NiRAN and RdRp functional domains and has been generally well tolerated in clinical trials conducted to date.

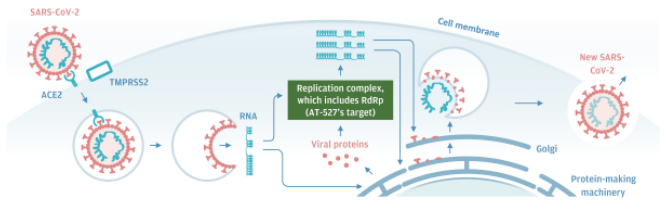
## SARS-CoV-2

### Background

SARS-CoV-2 is a coronavirus, belonging to the Coronaviridae family, and is an enveloped virus with a positive sense ssRNA genome which encodes 29 viral proteins. It is one of six other human coronaviruses that exist, with four responsible for one third of common cold infections.

SARS-CoV-2 is structurally similar to two other life-threatening coronaviruses: SARS-CoV and Middle East Respiratory Syndrome coronavirus ("MERS-CoV-1").

SARS-CoV-2 is a spherical virus that carries four different structural proteins: spike protein, envelope protein, membrane glycoprotein and nucleocapsid protein. As shown in the illustration below, the infection cycle begins when the spike proteins bind to the angiotensin-converting enzyme 2 cellular receptor ("ACE2"), on the surface of the target cells. A second cell surface protein, transmembrane serine protease 2 ("TMPRSS2"), enables the virion to enter the cell, where it releases its RNA. Some of this RNA is translated into new proteins using the host cell's machinery—these proteins include the four structural proteins, as well as a number of non-structural proteins ("nsps"), that form the replication complex. Within this complex, RdRps catalyze the synthesis of the approximately 30,000-nucleotide RNA viral genome. The proteins and RNA are then assembled into a new virion in the Golgi and released through exocytosis.



## COVID-19

An epidemic of cases with unexplained lower respiratory tract infections was first detected in Wuhan, the largest metropolitan area in China's Hubei province, and was reported to the World Health Organization ("WHO") Country Office in China on 31 December 2019. The WHO subsequently declared a pandemic on 11 March 2020. This infectious disease, named coronavirus disease 2019 (COVID-19) by the WHO, is caused by the novel coronavirus strain SARS coronavirus-2 (SARS-CoV-2).

Infection with SARS-CoV-2 may be asymptomatic or it may cause a wide spectrum of illness ranging from a mild upper respiratory tract infection to severe life-threatening sepsis and multiorgan failure. Commonly reported symptoms include fever, cough, shortness of breath, loss of taste or smell, sore throat, fatigue,



headaches, muscle aches, and gastrointestinal (GI) disturbance. Symptoms typically last two to three weeks, but many patients continue to experience symptoms for many weeks or develop new symptoms, which is now recognized as the post-acute COVID-19 syndrome, or Long COVID. Approximately 10% of non-hospitalized adult patients with COVID-19 report symptoms three months later, and up to 89% of hospitalized patients continue to experience symptoms two months after the onset of their illness. COVID-19 affects people of all ages; however, people who are immunocompromised, elderly, or have certain underlying medical conditions (e.g., chronic heart, lung, and kidney disease; diabetes, obesity, and cancer) are at increased risk of poor outcomes.

#### **Current vaccine and treatment landscape**

Several vaccines are approved or authorized for emergency use and additional vaccines are being developed to prevent infection and to create herd immunity, with the aim of preventing disease and reducing the amount of virus circulating within the community. In December 2020, the FDA granted emergency use authorization ("EUA") for vaccines from Pfizer Inc. and BioNTech and Moderna, Inc., each of which announced clinical trial results showing that their respective vaccine candidate was found to be more than 90% effective in preventing COVID-19 during such trials. In February 2021, the FDA granted EUA to a vaccine developed by Janssen Pharmaceutical Company. In August 2021, the vaccine from Pfizer Inc. and BioNTech received full FDA approval. In January 2022, the vaccine from Moderna, Inc. received full FDA approval. In addition to the vaccines authorized for use in the United States, at least five other vaccines have been distributed worldwide. Furthermore, in December of 2021, the FDA granted EUA to the monoclonal antibody combination of tixagevimab and cilgavimab for pre-exposure prophylaxis of COVID-19 in immunocompromised patients and those unable to receive any of the available COVID vaccines.

Antiviral therapies are complementary to vaccines, and preventative therapies. We anticipate that antivirals will continue to be essential because of uncertainties around the level of immunity that the existing options will be able to generate, the durability of such immunity and the emergence of new variants of the virus that could change and potentially lessen the effectiveness of vaccines. In November 2021, molnupiravir, an orally administered direct-acting antiviral being developed by Merck and Ridgeback Biotherapeutics for the treatment of adults with mild to moderate COVID-19 in the outpatient setting, received conditional authorization for use from the health authorities in the United Kingdom. In December 2021, the FDA issued an EUA for molnupiravir. Merck and Ridgeback are currently seeking similar authorizations from numerous other global health authorities. In December 2021, the FDA issued an EUA for Pfizer's Paxlovid, an orally administered direct-acting antiviral 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 and the FDA expanded the EUA of remdesivir, an intravenous antiviral that is a RdRp inhibitor, to include the treatment of outpatients at high risk of progression to severe COVID-19 illness.

Other products for the treatment of COVID-19 are currently authorized for emergency use or approved by health regulatory authorities in numerous countries throughout the world. These products include sotrovimab, (VIR Biotechnology, Inc. and GlaxoSmithKline) and bebtelovimab (Eli Lilly), both are monoclonal antibodies for the treatment of high-risk adults and adolescents with mild to moderate COVID-19. Antibody therapies, including those that are currently authorized for emergency use as well as those in development, may have application in prevention as well as treatment. However, the antibodies currently in use and in development require parenteral administration and are historically more complex than small molecules to manufacture. We believe that these two factors will impact and limit the use of antibodies for the treatment of patients, particularly outpatients with COVID-19. In addition, the effectiveness of monoclonal antibody therapies has been adversely effected by different SARS-CoV-2 variant strains. Recently both monoclonal antibody combination therapies of bamlanivimab/etesevimab and casirivimab/imdevimab have effectively lost authorization in the United States due to lack of susceptibility to the omicron (B.1.1.529) strain.

In addition to our antiviral candidate, bemnifosbuvir, other antiviral drug candidates are currently in development. These include, without limitation, GS-5245, an oral remdesivir prodrug which is expected to soon be in Phase 1 being developed by Gilead Sciences, Inc., S-217622, an oral protease inhibitor being developed by Shionogi & Co., Ltd, EDP-235, an oral protease inhibitor in a first in human study

being developed by Enanta Pharmaceuticals, Inc., and numerous other protease inhibitors that are still early in their development.

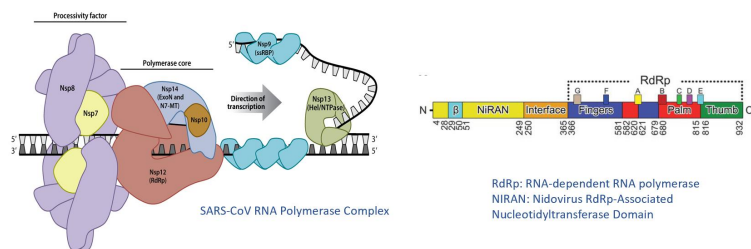
In addition to treatments directed at the virus, there are other immunomodulatory therapies such as interleukin-6 inhibitors, steroids, JAK inhibitors, and anti-tumor necrosis factor antibodies which are being developed to treat the host inflammatory response to the disease.

#### Our approach

We are developing bemnifosbuvir, an investigational, orally administered, novel antiviral product candidate, for the treatment of COVID-19. As drug products comprised of single agents are more widely utilized by larger, broader populations of patients over time, we believe that resistance to these single agents will develop, especially for those agents which do not target highly conserved sites on the SARS-CoV-2 virus. Therefore, we anticipate that future treatments for COVID-19 will preferentially consist of combination regimens including multiple drugs, with differing/complementary mechanisms of action (simultaneously targeting multiple points in the viral replication cycle) and a high barrier to resistance. As bemnifosbuvir uniquely inhibits the highly conserved viral RNA polymerase at both the NiRAN and RdRp functional domains, our development strategy is to evaluate bemnifosbuvir as part of nucleos(t)ide-based combination regimens.

#### Targeting SARS-CoV-2 NiRAN/RdRp to treat COVID-19

The RNA polymerase complex of SARS-CoV and SARS-CoV-2 supports the transcription and replication of their approximately 30,000-nucleotide viral RNA genomes. It is the largest and most complex RNA synthesis machinery among RNA viruses. As shown in the illustration below, the multi-subunit SARS-CoV polymerase complex is composed of a number of nsp including viral RdRp (nsp12), processivity factors (nsp7, nsp8), a proofreading exonuclease, a N7-methyl transferase (nsp14), and a helicase (nsp13). The nsp12 protein contains two domains, a RdRp core, which is the catalytic subunit incorporating ribonucleotides into RNA templates, and a N-terminal NiRAN domain, the function of which was previously unknown.



#### SARS-CoV RNA Polymerase

We have investigated the mechanism by which SARS-CoV initiates viral RNA synthesis and have discovered that there are two distinct pathways: one protein-primed and mediated by the NiRAN through the UMPylation of nsp8, and the other through de novo synthesis of dinucleotide primers in a NiRAN-independent manner. Importantly, both functions can be inhibited by AT-9010, the active triphosphate metabolite of bemnifosbuvir. Furthermore, we have obtained a 2.98 Å cryo-EM quaternary structure of nsp12/7/8/RNA/AT-9100, which confirms that AT-9010 not only bound to the NiRAN active site but also was incorporated by the RdRp and functions as a chain terminator. We believe this unique dual mechanism of bemnifosbuvir creates a potentially higher barrier to resistance compared to other direct acting antiviral inhibitors.

Since bemnifosbuvir targets viral RNA polymerase, a highly conserved enzyme critical to viral replication and transcription, we expect it will maintain its antiviral activity even against the recently emerged variants with mutations in the spike (S) protein responsible for the receptor recognition and host cell membrane fusion process. COVID-19 variants have affected the effectiveness of vaccines and monoclonal antibodies due to the mutations in the viral spike protein and future variants may also impact the effectiveness of vaccines and monoclonal antibodies.

#### Potent *in vitro* inhibition of SARS-CoV-2 replication across variants

We assessed the *in vitro* potency of AT-511 (free base of bemnifosbuvir) against SARS-CoV-2 variants of concern/interest. The data from these studies are summarized in the table below showing that AT-511 maintained its potency against all major variants of concern or interest tested. These data support the key mechanistic advantage of the compound, which targets the highly conserved viral RNA polymerase.

Variant	Lineage	Strain	Relative Potency* AT-511 EC <sub>50</sub> [Variants/USA-WA-1]
Original	A	USA-WA1/2020	1
Alpha	B.1.1.7	England/ 204820464/2020	2.8 (n=3)
Gamma	P.1	Japan/TY7-503/2021	3.2 (n=3)
Epsilon	B.1.427	USA/CA/ VRLC009/2021	1.0 (n=2)
Delta	B.1.617.2	USA/PHC658/2021	1.2 (n=3)
Omicron	B.1.1.529	USA/MD-HP20874/2021**	In process

\*Determined side-by-side in the same assay

EC<sub>50</sub> differences between variants were within *in vitro* assay variations

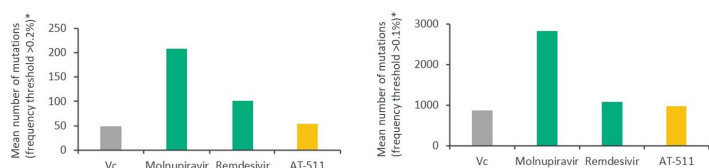
\*\*No new mutation in RNA polymerase of Omicron as compared with other variants

#### Non-mutagenic

Results from non-clinical studies indicate that bemnifosbuvir is non-mutagenic and non-teratogenic and it has shown no reproductive toxicity.

More specifically, analysis of SARS-CoV-2 infected Huh7.5 cells treated with AT-511 (the free base of bemnifosbuvir) by next generation sequencing (NGS) showed that bemnifosbuvir was not a mutagen (which is consistent with the lack of genotoxicity observed in the preclinical *in vitro* and *in vivo* studies) and did not introduce mutations in the viral genome.

Number of mutations in SARS-CoV-2 genome in Huh7.5 cells treated with 5 uM drug for 48h vs. untreated virus control (Vc)



\*Frequency threshold defined as presence of mutation in 0.2% or 0.1% of NGS reads

In addition to the standard battery of safety pharmacology and repeat dose toxicity studies, which showed no adverse effects of bemnifosbuvir treatment in rats and non-human primates at respective doses up to 650 and 1000 mg/kg/day for 13 weeks, new completed preclinical studies have demonstrated that

bemnifosbuvir did not affect male or female fertility in treated rats, did not affect early embryo-fetal development in treated pregnant rats or rabbits, and did not affect the pre- or post-natal development, reproductive capability, or behavioral assessments of the offspring of rats treated prior to and during mating (males) and prior to mating through pregnancy and lactation (females).

#### **Multi-Pronged Approach to identification of protease inhibitor for combination therapy with bemnifosbuvir**

To accelerate the development of a combination regimen for the treatment of COVID-19, we plan to initially study the combination of bemnifosbuvir with a protease inhibitor. Although protease inhibitors as a class may be susceptible to resistance if used as a single agent, they have demonstrated antiviral activity in COVID-19. We have initiated preclinical *in vitro* combination studies of bemnifosbuvir with protease inhibitors to explore potential antiviral synergy and mitigation of potential viral resistance.

We are pursuing a multi-pronged approach to identification of a protease inhibitor that, together with bemnifosbuvir as the nucleos(t)ide polymerase inhibitor component, is intended to be a highly effective oral combination therapy that provides a high barrier to viral resistance for use in broad patient populations. We have recently begun efforts to discover and select a protease inhibitor lead candidate, leveraging our expertise in medicinal chemistry, molecular virology, pharmacology, drug metabolism/pharmacokinetics, and toxicology. In parallel, we are, through our business development efforts, evaluating opportunities to in-license a late stage preclinical or early stage clinical protease inhibitor product candidate to accelerate initiation of clinical development of a proprietary combination regimen.

#### **Clinical development history**

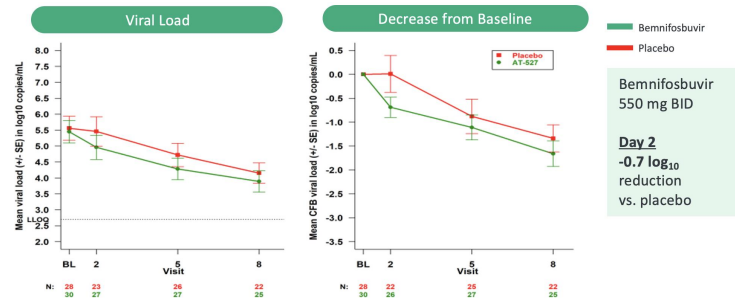
At the outset of the COVID-19 pandemic, we initiated our COVID-19 program with a global Phase 2 clinical trial of bemnifosbuvir in hospitalized patients. The initiation of the global Phase 2 clinical in hospitalized patients was followed by the initiation, together with our former collaborator, F. Hoffmann-LaRoche Ltd. and Genentech, Inc. (together, "Roche"), of a Phase 2 outpatient clinical trial (MOONSONG), a Phase 3 outpatient clinical trial (MORNINGSKY) and a Phase 3 six-month follow-up study (MEADOWSPRING) for patients that had been enrolled in MORNINGSKY. These patient studies, with additional supporting Phase 1 and clinical pharmacology studies conducted in healthy subjects, were intended to support the development of bemnifosbuvir for the treatment of COVID-19 as a monotherapy, or single agent product.

Following the availability of orally available COVID-19 treatment options in November 2021 in the United States and certain other countries, the standard of care for the treatment of COVID-19 in outpatients changed. As additional oral therapies are developed and are added to the treatment armamentarium, we believe that combination regimens will be needed to cover broader patient populations, as newer variants emerge, and resistance develops with the use of single agents alone. In anticipation of this future need, we prioritized our clinical development strategy in January 2022 to focus on the development of a bemnifosbuvir combination regimen. We anticipate that this proposed regimen will be comprised of bemnifosbuvir and a protease inhibitor, which is the drug class of Paxlovid™, one of the currently available oral treatment options. In addition to lowering the possibility of emergence of viral resistance, combination therapies often result in additive or synergistic antiviral activity (i.e. resulting in greater activity than either of the single agents alone).

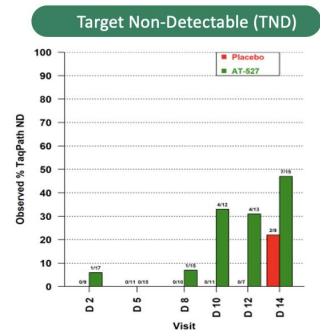
Together with Roche, we completed the Phase 2 outpatient (MOONSONG) clinical trial in October 2022 and we closed out each of the Phase 3 MORNINGSKY and MEADOWSPRING clinical trials in December 2021 and February 2022, respectively. We closed out our Phase 2 hospitalized patient clinical trial in January 2022. We intend to leverage the key clinical data obtained in the program to date, described below, to support our combination strategy.

**Global Phase 2 study in hospitalized patients with COVID-19.** This study was a randomized, double-blind, placebo-controlled, study that evaluated bemnifosbuvir in patients with moderate COVID-19 versus placebo. An interim analysis was conducted (data cut as of May 2021) which included data from 70 hospitalized, high-risk patients with COVID-19 of which data from 62 patients were evaluable for virology analysis. Based on the interim analysis, after bemnifosbuvir 550 mg BID dosing for five days, rapid reduction in viral load levels were observed. At Day 2, patients receiving bemnifosbuvir experienced a 0.7

log<sub>10</sub> greater mean reduction from baseline viral load versus placebo. A sustained difference in viral load reduction was maintained through Day 8.



Bemnifosbuvir's SARS-CoV-2 antiviral activity was also observed in patients with baseline viral loads above the median of 5.26 log<sub>10</sub> as compared to placebo. In this subset, those in the bemnifosbuvir arm achieved SARS-CoV-2 clearance as early as Day 2 (in 6% of patients), Day 8 (in 7% of patients), Day 10 (in 33% of patients), and Day 12 (in 31% of patients) compared to 0% of patients in the placebo arm at the same timepoints. By Day 14 (last viral sampling study day) approximately 47% of patients in the bemnifosbuvir arm and 22% in the placebo arm had no detectable RNA virus.



After dosing with 550 mg BID for five days, bemnifosbuvir was generally well tolerated and there were no drug-related serious adverse events. Non-serious adverse events were equally distributed across treatment arms. Most were mild-to-moderate in severity and assessed as not related to the study drug.

After the interim analysis described above, we amended this placebo-controlled study to explore higher doses of bemnifosbuvir, specifically 1100 mg BID over five days. In January 2022, we closed out the study to prioritize development of a combination regimen.

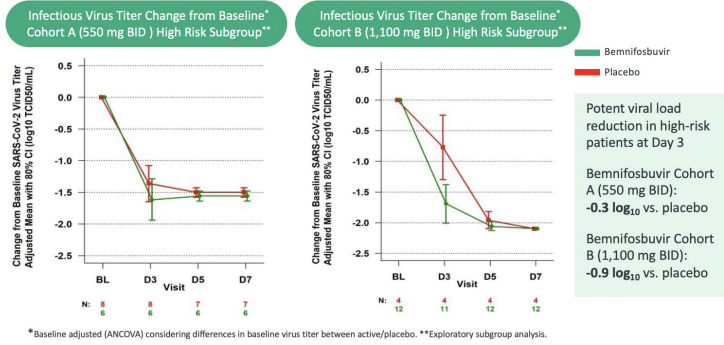
**Global Phase 2 MOONSONG trial:** This study was a randomized, double-blind, multi-center, placebo-controlled trial, that evaluated the antiviral activity, safety and pharmacokinetics of sequential doses of

bemnifosbuvir 550 mg (Cohort A, n=30) and 1,100 mg (Cohort B, n=30) with BID dosing in adult outpatients with mild or moderate COVID-19 versus placebo (n=40). Treatment with bemnifosbuvir in this study did not meet the primary endpoint of showing a reduction in SARS-CoV-2 viral load in the overall population of patients compared to placebo, of whom approximately two thirds were low-risk with mild symptoms. However, in high-risk patients with underlying health conditions, a reduction of viral load of approximately 0.5 log<sub>10</sub> at Day 7 was observed with administration of 550 mg BID as compared to placebo (prespecified subgroup analysis Cohort A n=7; placebo n=10) and with administration of 1,100 mg BID as compared to pooled placebo (exploratory subgroup analysis Cohort B, n=14; placebo n=7).

Additional exploratory data reported from the Phase 2 MOONSONG trial showed rapid and potent antiviral effect of bemnifosbuvir as measured by an infectious virus assay which detected the amount of "live" virus capable of replication. The exploratory analysis included approximately 71% of all patients in MOONSONG (Cohort A and B) who had positive baseline cultures.

The results from the Phase 2 MOONSONG study include the following observations:

- rapid and potent reduction in viral load of -0.5 log<sub>10</sub> in the evaluable patient population (low and high risk, majority seropositive) of Cohort B with 1,100 mg BID bemnifosbuvir (n=18) versus placebo (n=6) at Day 3 of the study period (post-hoc exploratory analysis);
- rapid and potent reduction in viral load of -0.9 log<sub>10</sub> in the high-risk patient subgroup (post-hoc exploratory subgroup analysis) of Cohort B with 1,100 mg BID mg (n=11) versus placebo (n=4) at Day 3; and
- reduction in viral load of -0.3 log<sub>10</sub> in the high-risk patient subgroup (pre-specified exploratory subgroup analysis) of Cohort A with 550 mg BID (n=8) versus placebo (n=6) at Day 3, suggesting a dose response for bemnifosbuvir.



Bemnifosbuvir was generally well tolerated in this study. The proportion of patients experiencing any adverse event (AE) was 20% in the placebo group, 20% in the bemnifosbuvir 550 mg BID group and 27% in the bemnifosbuvir 1100 mg BID group. There were three non-drug related serious adverse events (SAEs) in each of the treatment groups and all other AEs were grade 1 or 2. Gastrointestinal (GI)-related AEs were the most commonly reported AEs: 8% in the placebo group; 7% in the bemnifosbuvir 550 mg BID group; 17% in the bemnifosbuvir 1100 mg BID group, with mild to moderate nausea/vomiting resulting in premature study drug discontinuation of 3% in the placebo group, 0% in the bemnifosbuvir 550 mg BID group and 17% in the bemnifosbuvir 1100 mg BID group. No clinically significant differences in laboratory abnormalities were observed in the treatment arms as compared to placebo.

**Global Phase 3 MORNINGSKY and MEADOWSPRING trials:** The MORNINGSKY study evaluating the effects of bemnifosbuvir in non-hospitalized adult and adolescent participants with mild or moderate

COVID-19 was closed out in December 2021. In February 2022, MEADOWSPRING, originally designed as a six-month Phase 3 follow-up study of participants previously enrolled in MORNINGSKY, was closed out with enrolled patients reaching three rather than six months of follow-up.

#### **Phase 1 and clinical pharmacology studies**

In addition to the Phase 2 clinical trials, supporting Phase 1 and clinical pharmacology studies, including a bronchoalveolar lavage study, multiple drug-drug interaction studies and a mass balance study, have been conducted and completed since we initiated our COVID-19 program. In these studies, the safety and PK of bemnifosbuvir has been evaluated at doses up to 1100 mg BID for 5 days in healthy subjects.

Results from the bronchoalveolar lavage study in healthy subjects demonstrated that bemnifosbuvir was efficiently delivered to the lungs (epithelial lining fluid, ELF), the primary site of SARS-CoV-2 infection. Five clinical drug-drug interaction studies were completed with topline results demonstrating an overall low drug-drug interaction potential associated with bemnifosbuvir.

Bemnifosbuvir has been generally well tolerated in healthy subjects. Consistent with the results from the Phase 2 outpatient clinical trial (MOONSONG), an increased incidence of mild to moderate GI-related adverse events, specifically nausea and vomiting, were observed at 1,100 mg BID in healthy subjects.

Currently we are conducting a Phase 1 clinical study in healthy subjects to evaluate the tolerability of AT-527 after dosing with or without food to assess whether the mild GI-related events observed at the 1,100 mg BID dose can be mitigated.

#### **Bemnifosbuvir and Ruzasvir for the Treatment of Hepatitis C**

##### **Hepatitis C virus (HCV)**

##### **Background**

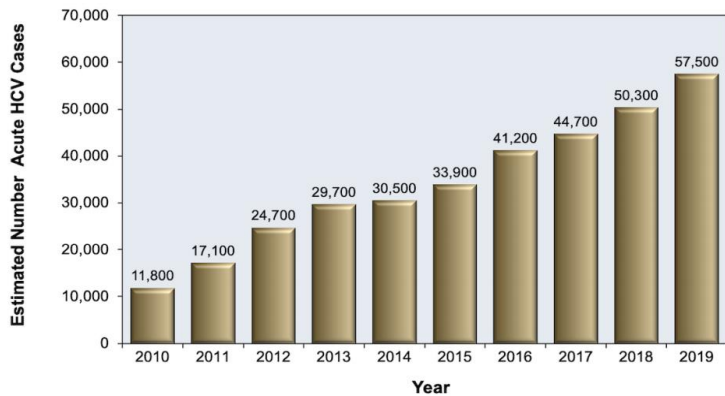
HCV is a blood-borne, positive sense, ssRNA virus, primarily infecting cells of the liver. HCV is a leading cause of chronic liver disease and liver transplants and spreads via blood transfusion, hemodialysis and needle sticks. In the United States, injection drug use accounts for approximately 60% of all new cases of HCV. Diagnosis of HCV is made through blood tests, including molecular tests that allow for the detection, quantification and analysis of viral genomes and the classification of an infection into specific viral genotypes. Hepatitis C becomes chronic Hepatitis C in 75% to 85% of cases, with an incubation period lasting from two to 26 weeks.

HCV is classified into seven genotypes and 67 subtypes, with genotype 1 being responsible for more than 70% of HCV cases in the United States. Patients with HCV are also classified by liver function status: compensated cirrhosis (liver scarring) denotes those patients that do not yet have impaired liver function, while decompensated cirrhosis describes patients with moderate to severe liver function impairment.

According to the WHO, an estimated 58 million people globally have chronic HCV infection, with about 1.5 million new infections occurring per year. Approximately 290,000 people die every year from HCV related liver diseases, with the majority of death resulting from cirrhosis and hepatocellular carcinoma (HCC - primary liver cancer).

Despite significant advances in treatment beginning in 2013, there remains a large, underserved, HCV patient population which continues to grow dramatically in the United States. While a portion of this increase results from increased diagnosis of HCV that began following the 2013 CDC issuance of guidelines for screening of all Americans born between the years 1945 and 1965, a large portion of this increase in incidence is attributable to the opioid crisis, IV drug use and HCV reinfection. The US HCV prevalence is expected to continue to remain steady over the coming years as rising HCV incidence offsets the number of new patients treated.

## Increasing incidence of HCV in the United States



Source: Centers for Disease Control and Prevention (CDC). 2019 Viral Hepatitis Surveillance Report—Hepatitis C. Published May 2021.

It is estimated that a substantial global market for HCV therapeutics will exist to 2050 and beyond. Estimated at approximately \$4 billion in global sales in 2021, with approximately 50% attributable to the United States, the HCV market remains large. We believe the U.S. HCV prevalence will remain steady over the coming years as rising HCV incidence offsets the number of new patients treated.

### Current treatment landscape

No vaccine exists for the prevention of HCV, but beginning in 2013 several sequentially introduced and improved oral antiviral therapeutics have boosted sustained virologic response rates to over 95% in a majority of patients, with treatment durations of eight to 12 weeks depending upon the regimen and patient population. The leading HCV products are comprised of a combination of agents with differing mechanisms of action and therapeutic targets: NS3/4A protease inhibitors, NS5A inhibitors, and NS5B nucleos(t)ide polymerase inhibitors. A patient's genotype, cirrhotic status, and prior treatment failures determine the appropriate antiviral therapeutic used in treatment. In the United States, currently the two leading therapeutics for treatment of chronic HCV are:

**Epclusa® (sofosbuvir/velpatasvir):** Epclusa, a combination regimen consisting of an NS5B inhibitor and an NS5A inhibitor, was first approved by the FDA in 2016 for the treatment of adults with chronic HCV infection with any of genotypes one through six infection, either without cirrhosis or with compensated cirrhosis. For patients with decompensated cirrhosis, Epclusa is approved for use in combination with ribavirin. Patients on Epclusa require 12 weeks of treatment.

**Mavyret® (glecaprevir/pibrentasvir):** Mavyret, a combination regimen consisting of a NS3/4A protease inhibitor and an NS5A inhibitor was first approved by the FDA in 2017 for the treatment of adults with chronic HCV with any of genotypes one through six infection, without cirrhosis or with compensated cirrhosis. Mavyret is also approved for HCV patients with genotype 1 infection who have been previously treated with a regimen either containing an NS5A inhibitor or an NS3/4A protease inhibitor (but not both). Mavyret was the first eight-week treatment approved for HCV genotypes one through six in adult patients without cirrhosis who have not been previously treated. In 2019, the FDA approved shortening the treatment duration from 12 weeks to eight weeks in treatment-naïve, compensated cirrhotic HCV patients



across genotypes one through six. Mavvyret is not approved for use in patients with decompensated cirrhosis.

With the exception of our HCV combination product candidate and CC-31244, an NS5B inhibitor product candidate from Cocystal Pharma, Inc., which is currently in Phase 2 clinical development, we are not aware of any other product candidates for the treatment of HCV in late stage clinical development in the United States.

#### **Our approach**

We are developing bempifosbuvir in combination with ruzasvir. Ruzasvir is an investigational oral, pan genotypic NS5A inhibitor for the treatment of chronic HCV infection that we licensed from Merck in December 2021. Based on our preclinical and clinical data to date relating to bempifosbuvir, together with data that Merck generated relating to ruzasvir, we believe that this combination, if approved, could offer the following potential benefits:

- Short treatment duration of eight weeks in HCV-infected patients with and without cirrhosis (compensated cirrhosis).
- Equivalent antiviral potency across all genotypes, regardless of cirrhosis status, including the difficult to treat genotype-3 population.
- Obviate the need for extensive pretreatment assessments, including genotyping, procedures to assess cirrhosis, and liver function assessment.
- Eliminate the need for ribavirin in patients with decompensated cirrhosis. Ribavirin, an antiviral first approved in 1986, carries several FDA boxed warnings, including the risk of hemolytic anemia and teratogenicity.
- Well tolerated regimen, with low potential for drug-drug interactions.

#### **Clinical development**

To date, we have completed two clinical trials of bempifosbuvir to support the treatment of chronic HCV infection.

##### **Phase 1 clinical trial of bempifosbuvir**

We conducted a Phase 1 trial to evaluate single and multiple doses of bempifosbuvir as a single agent in healthy and HCV-infected subjects for up to seven days. All HCV-infected subjects were treatment-naïve with HCV RNA  $3.5 \log_{10}$  IU/mL. The objectives of the trial were to assess safety, tolerability, PK and antiviral activity.

The trial evaluated single oral doses of bempifosbuvir up to 400 mg salt form (369 mg free base) in healthy subjects (Part A), single doses up to 600 mg salt form (553 mg free base) in non-cirrhotic HCV-infected subjects (Part B), and multiple doses up to 600 mg salt form (553 mg free base) once daily for seven days in non-cirrhotic genotype 1b ("GT1"), HCV-infected subjects (Part C). Additional cohorts evaluated 600 mg salt form (553 mg free base) once daily for seven days in non-cirrhotic genotype 3 ("GT3"), (Part D) and Child-Pugh A cirrhotic (GT 1,2,3), HCV-infected subjects (Part E). The tables below show the dosage and mean maximum HCV RNA reductions for each treatment cohort.

A total of 88 subjects were dosed across all parts of the trial, with 72 subjects who received active drug and 16 subjects who received placebo. In this trial, bempifosbuvir showed equivalent pan-genotypic antiviral activity in both cirrhotic and non-cirrhotic HCV infected patients. The mean maximum HCV reduction after a single dose (Part B) was  $2.3 \log_{10}$  IU/mL, and the mean maximum HCV RNA reduction after seven days of dosing with bempifosbuvir at 553 mg free base was  $4.6 \log_{10}$  IU/mL. Data also showed a mean maximum HCV RNA reduction of  $4.4 \log_{10}$  IU/mL after seven days of dosing of bempifosbuvir at 553 mg free base in non-cirrhotic genotype 1b ("GT1b"), HCV-infected subjects, and a mean reduction of  $4.5 \log_{10}$  IU/mL after seven days of dosing in non-cirrhotic GT3 HCV-infected subjects. The PK data in cirrhotic subjects was similar to non-cirrhotic subjects. Emax modeling predicted that a dose of 553 mg free base of bempifosbuvir once daily would result in maximum viral load reduction.

**Maximum HCV RNA change in Part B (single dose in non-cirrhotic, GT1 HCV-infected subjects)**

Maximum Reduction (log <sub>10</sub> IU/mL) beprenavir dosage (free base equivalent)	100 mg (92 mg) N=3	300 mg (277 mg) N=3	400 mg (369 mg) N=3	600 mg (553 mg) N=3
Mean ±SD*	0.8 ±0.153	1.7 ±0.564	2.2 ±0.391	2.3 ±0.255
Individual	0.6, 0.8, 0.9	1.1, 1.8, 2.2	1.8, 2.2, 2.5	2.1, 2.3, 2.6

**Maximum HCV RNA change in Part C (multiple dose in non-cirrhotic, GT1 HCV-infected subjects)**

Maximum Reduction (log <sub>10</sub> IU/mL)	Placebo QD** x 7 days (N=6)	150 mg (138 mg) QD x 7 days (N=6)	300 mg (277 mg) QD x 7 days (N=6)	600 mg (553 mg) QD x 7 days (N=6)
Mean ±SD	0.4±0.109	2.6±1.073	4.0±0.415	4.4±0.712
Individual	0.3, 0.3, 0.4, 0.4, 0.5, 0.6	1.7, 1.8, 1.8, 2.7, 3.0, 4.5	3.4, 3.7, 3.9, 4.2, 4.2, 4.5	3.5, 4.0, 4.1, 4.3, 5.2, 5.3

**Maximum HCV RNA change in Part D (multiple dose in non-cirrhotic, GT3 HCV-infected subjects) and Part E (multiple dose in cirrhotic HCV-infected subjects)**

Maximum Reduction (log <sub>10</sub> IU/mL)	Part D – GT3	Part E – Cirrhotic
	600 mg (553 mg) QD x 7 days (N=6)	600 mg (553 mg) QD x 7 days (N=6)
Mean ±SD	4.5±0.262	4.6±0.485
Individual	4.2, 4.4, 4.4, 4.5, 4.5, 5.0	GT1b: 4.0, 4.0, 4.5 GT2: 5.0 GT3: 4.8, 5.2

\* SD = standard deviation

\*\* QD = once daily

**Phase 2 clinical trial of beprinosbuvir in combination with daclatasvir**

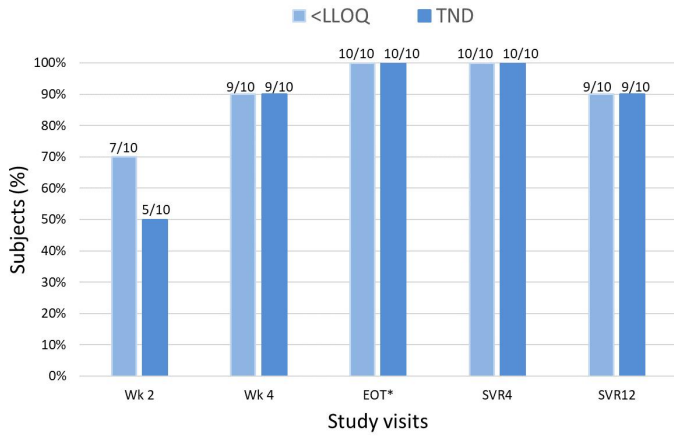
We conducted a Phase 2, open-label clinical trial to evaluate beprinosbuvir in combination with daclatasvir, an approved commercially available HCV NS5A inhibitor, in HCV-infected subjects. Ten treatment-naïve, non-cirrhotic GT1 HCV-infected subjects received 553 mg free base beprinosbuvir and 60 mg daclatasvir once daily for a period of eight or 12 weeks. The primary efficacy endpoint of the study was SVR12 (a sustained viral response, defined as HCV RNA < lower limit of quantitation (LLOQ) at 12 weeks after end of treatment (EOT)). Secondary efficacy endpoints included HCV RNA < Lower Limit Of Quantitation ("LLOQ"), and Target Not Detected ("TND") (an assessment of virologic response that is more rigorous than LLOQ), by study visit, virologic failure, and appearance of resistance-associated variants (RAVs) to either of the study drugs.

Despite the use of a less potent first-generation HCV NS5A inhibitor, daclatasvir, all subjects achieved HCV RNA < LLOQ and TND at the end of treatment (EOT); nine of the 10 subjects achieved SVR12. One subject who was TND by week 2 received 8 weeks of treatment, achieved SVR4, and then experienced likely virologic relapse at post-treatment week 12. The single subject who relapsed with GT 1b virus had the following multiple RAVs/variants both at baseline and at the SVR12 timepoint: NS5A: R30Q; NS5B: L159F/A218S/C316N. Phenotypic analysis demonstrated that beprinosbuvir retained the same potency against clinical isolates obtained from this relapsed subject at baseline and SVR12 (only a 1.1 and 0.8-

fold shift, respectively, in EC<sub>50</sub> compared to reference). Compared to sofosbuvir, the EC<sub>50</sub> and EC<sub>90</sub> values for bemnifosbuvir were ~10-fold lower. Thus, the significance of the RAVs in this case is unclear. No other subjects had pre-existing NS5A RAVs at baseline.

As shown in the graph below, viral load decreased rapidly after initiation of study drugs, with 70% of subjects achieving plasma HCV RNA < LLOQ by week 2 (and 50% achieving TND by week 2). We believe that the rapid early clearance of HCV RNA observed in this trial supports continued evaluation of bemnifosbuvir in shortened treatment regimens, ideally with a more potent, next-generation HCV NS5A inhibitor.

**Proportion (%) of subjects achieving HCV RNA <LLOQ and TND by study visit with bemnifosbuvir in combination with daclatasvir**



#### **Bemnifosbuvir HCV safety**

There were no serious adverse events, dose-limiting toxicities or adverse events leading to trial discontinuation observed in our HCV Phase 1 or Phase 2 clinical trials of bemnifosbuvir. The most common side effects observed were headache and small increases in blood lipid levels, with no consistent patterns in other reported effects. Most side effects were not severe and were not thought to be related to bemnifosbuvir.

#### **Ruzasvir**

Ruzasvir is an investigational oral, highly potent pan-genotypic NS5A inhibitor that we licensed from Merck in December 2021. In studies conducted by Merck, ruzasvir demonstrated *in vitro* potent antiviral activity with an EC<sub>50</sub> in the sub- to low picomolar range against all HCV genotypes (<10 pM against GTs 1-7). The antiviral activity of ruzasvir was evaluated in a proof-of-concept study in HCV-infected patients, where viral load reductions >3 log<sub>10</sub> were observed in GT1, GT2 and GT3-infected patients after treatment with monotherapy. This potent clinical antiviral activity is on par with what was achieved, as single agents, with velpatasvir and pibrentasvir, the NS5A inhibitor components of Mavyret and Epclusa, respectively. These proof-of-concept data supported evaluation of ruzasvir in larger phase 2 multiple drug combination studies (including 2 and 3 drug regimens) previously conducted by Merck. These studies

included treatment-naïve and interferon-experienced patients with or without compensated cirrhosis. In general, high SVR12 rates (>90%) were observed in 2-drug combination studies (ruzasvir plus uprifosbuvir, a pyrimidine nucleotide prodrug, for 12 weeks) conducted by Merck in GT1, GT2, GT4 and GT6-infected patients (C-Breeze 1 and 2). A lower SVR12 rate was observed in GT-3 subjects with compensated cirrhosis (40% SVR12; C-Breeze 1). Atea believes this lower rate is attributed to the reduced antiviral activity associated with the nucleotide uprifosbuvir in GT-3 cirrhotic subjects as an increase in ruzasvir dose to 180 mg substantially increased the SVR12 rate in this population (68% SVR12; C-Breeze 2), highlighting the preserved dose-related clinical antiviral activity of ruzasvir in GT-3 subjects with cirrhosis.

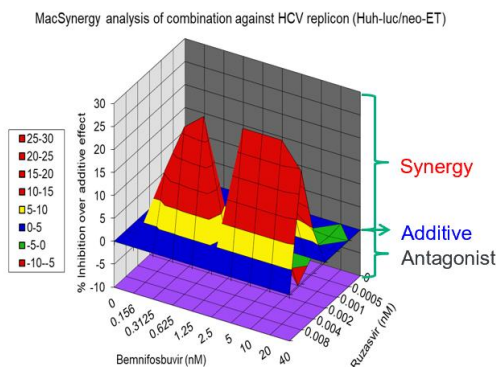
Over 1200 HCV-infected participants have received ruzasvir at daily doses up to 180 mg for durations up to 24 weeks as part of 2-drug and 3-drug regimens with or without ribavirin. The overall safety data indicates that ruzasvir has been generally well-tolerated with no consistent treatment-related changes in labs, vital signs, or ECG safety parameter values. Serious adverse events and discontinuations due to adverse events were rare in all studies conducted by Merck.

#### Rationale supporting the combination of bempifosbuvir and ruzasvir for HCV

With the antiviral potency observed with bempifosbuvir, especially in more difficult to treat genotype-3 infected patients, we believe that the combination of ruzasvir and bempifosbuvir has the potential to improve on the SVR12 rates observed in the prior studies conducted by Merck.

To further support our development of the combination of bempifosbuvir and ruzasvir in patients, we have conducted *in vitro* synergy experiments in HCV GT1b replicon assays (Huh-luc/neo-ET), where HCV replicon cells were treated with multiple concentrations of AT-511, the free base of bempifosbuvir, and ruzasvir either alone or in combination. As shown in the figure below, these experiments demonstrated that the combination resulted in substantially greater inhibition of HCV replication than either agent alone, suggesting a synergistic antiviral effect between the two inhibitors.

#### *In vitro* Synergy: Assay performed in HCV GT1b replicon (Huh-luc/neo-ET)



Collectively, these data support the clinical development of bempifosbuvir and ruzasvir used in combination for the treatment of chronic HCV infection.

#### Planned clinical development

In 2022, we plan to initiate a Phase 2 trial of bempifosbuvir in combination with ruzasvir in treatment-naïve, HCV-infected patients either without cirrhosis or with compensated cirrhosis. This study will

evaluate the safety and efficacy of the pan-genotypic combination consisting of 550 mg QD of bemnifosbuvir and 180 mg QD of ruzasvir after eight or 12 weeks of treatment.

Results from this study are intended to support future larger studies of bemnifosbuvir in combination with ruzasvir in broad patient populations for treatment durations of eight weeks or potentially less (six weeks) as well as in patients with decompensated cirrhosis for treatment durations of 12 weeks without ribavirin

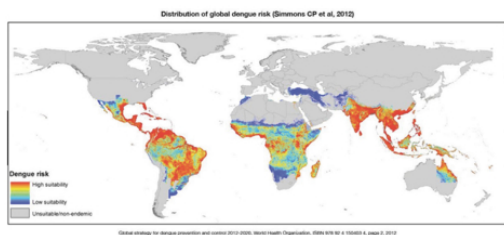
Prior to our licensing of ruzasvir from Merck, we had been developing AT-777, an NS5A inhibitor, that we had intended to develop as part of a fixed dose combination with bemnifosbuvir (fixed dose combination was referred to as AT-787). This program was paused at the outset of the COVID-19 pandemic given industry-wide challenges in conducting clinical studies at that time. With the license from Merck, we have prioritized development of ruzasvir over AT-777/AT-787, and have no immediate plans to conduct clinical studies utilizing AT-777 or the combination AT-787.

#### AT-752 for the treatment of dengue

##### Background

Dengue, which is caused by a positive sense ssRNA virus belonging to the Flaviviridae family, is a mosquito-borne viral infection. Dengue causes flu-like symptoms in both children and adults and is spread through the bite of an infected mosquito. There are five dengue viral serotypes, and infection with one serotype does not produce immunity to another serotype. Thus, a person could be infected with dengue multiple times and reinfection typically results in a more severe disease. Symptoms include fever, eye pain, headache, swollen glands, rash, muscle pain, bone pain, nausea, vomiting, and joint pain, and last two to seven days post-infection.

Globally four billion people live in high-risk dengue areas, with up to 400 million infected each year, resulting in 500,000 hospitalizations. The WHO has called dengue the most important mosquito-borne viral disease in the world. Although dengue rarely occurs in the continental United States, it is endemic in Puerto Rico, Southeast Asia, Latin America and the Pacific Islands, as shown in the map below. Seventy percent of the global disease burden for dengue is in Asia.



According to the Center for Disease Control ("CDC"), 5% of infected patients develop a life-threatening form of dengue called severe dengue. Those who develop severe dengue may have some or all of the following complications: severe abdominal pain, fatigue, severe bleeding, organ impairment, and plasma leakage. The mortality rate of severe dengue ranges between 12% and 44%, if left untreated. The global economic cost burden of dengue was estimated at \$8.9 billion in 2013, with nearly 50% of the costs associated with hospitalizations.

##### Current treatment landscape

There are no FDA or EU approved therapies indicated for the treatment of dengue. Current treatment protocols involve supportive care, including analgesics, judicious fluid replacement, and bed rest. In 2019, a vaccine, Dengvaxia developed by Sanofi Pasteur Inc. ("Sanofi"), was approved by the FDA for the prevention of disease caused by dengue virus serotypes 1, 2, 3 and 4 in children ages nine to 16 with laboratory-confirmed previous dengue infection and living in endemic areas.

Takeda Pharmaceuticals Co Ltd, ("Takeda"), is also advancing a dengue vaccine, TAK-003, which is in Phase 3 development. Primary endpoint analysis of its ongoing Phase 3 trial in children ages four to 16 years showed protection against virologically-confirmed dengue.

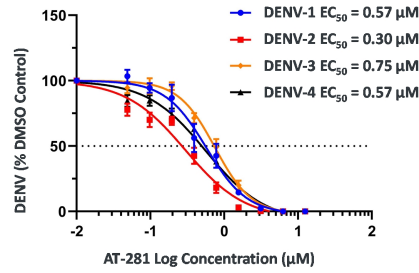
Therapeutic candidates in addition to AT-752 currently in clinical development for the treatment of dengue fever include a dengue NS4B inhibitor being developed by Janssen Pharmaceutical Companies which is in Phase 2a development in adult patients with confirmed dengue fever and a dengue NS4B inhibitor being developed by Novartis Pharmaceuticals Corporation which is in Phase 1 clinical development.

#### Our approach

We are developing AT-752, an oral, purine nucleotide prodrug product candidate for the treatment of dengue. AT-752 has shown potent activity against all dengue serotypes and other flaviviruses tested in preclinical studies. AT-752 is designed to target the inhibition of the viral polymerase. We also intend to explore the potential development of AT-752 as a prophylactic treatment for dengue, which we believe, if approved, could be directed at the travelers' market.

#### Preclinical development

The antiviral activity of AT-281, the free base of AT-752, was evaluated against all four dengue serotypes in vitro. These studies showed potent, concentration dependent inhibition of all dengue strains tested with EC<sub>50</sub>s ranging from 0.30 to 0.75 μM.

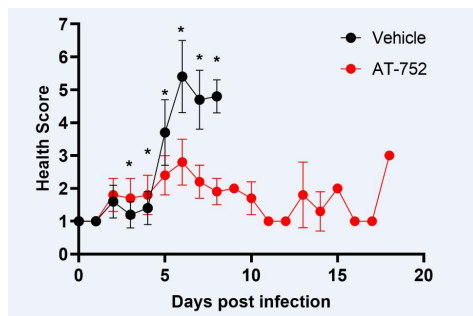


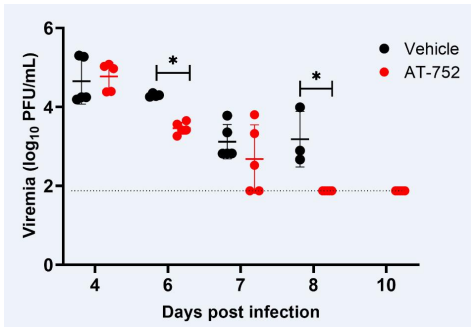
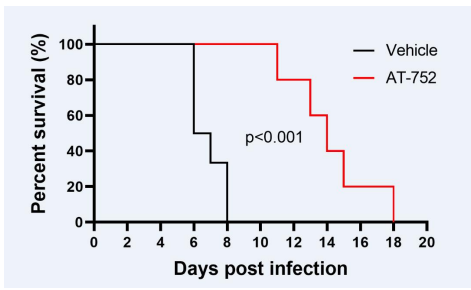
AT-281 was also evaluated under contract with the National Institutes of Health and Infectious Disease against a variety of flaviviruses. Huh-7 cells were infected with individual viral strains and exposed to serial dilutions of AT-281. A virally induced cytopathic effect ("CPE") assay, using either a neutral red dye uptake endpoint or a virus yield reduction measurement using a standard endpoint dilution CCID<sub>50</sub> assay, was used to measure the antiviral EC<sub>50</sub> or EC<sub>90</sub> value, respectively. Uninfected cell controls concurrently exposed to drug were used to determine cytotoxicity (CC<sub>50</sub>) using the CPE assay. AT-281 demonstrated sub-micromolar potencies against all flaviviruses tested (summarized in the table below). No toxicity was detected for AT-281 up to the highest concentration tested (172 μM).

Virus	Strain	EC <sub>90</sub> (μM)	CC <sub>50</sub> (μM)	SI <sup>a</sup>
Dengue-2	New Guinea C	0.64	>170	>270
Dengue-3	H87	0.77 <sup>b</sup>	>170	>220
Japanese Encephalitis	SA-14	0.21 <sup>b</sup>	>170	>820
West Nile	Kern 515, WNo2	0.43	>170	>400
Yellow Fever	YFV 17D	0.26	>170	>660
Zika	MR766	0.64 <sup>b</sup>	>170	>270
Powassan	Spooner	0.74	>170	>400
Usutu	TC-508	0.72	>170	>400

<sup>a</sup>SI = selectivity index (CC<sub>50</sub>/EC<sub>90</sub> or CC<sub>50</sub>/EC<sub>50</sub>); <sup>b</sup>EC<sub>50</sub>

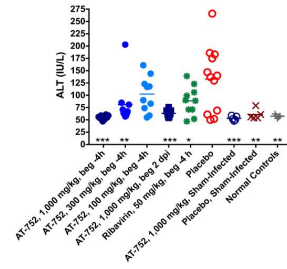
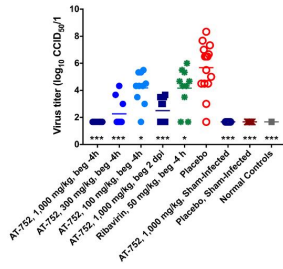
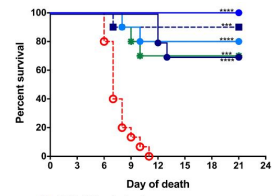
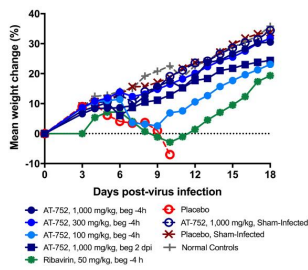
We have evaluated the activity of AT-752 in a preclinical animal model of dengue disease in which AG129 mice were treated orally with AT-752 (1000 mg/kg, p.o.) four hours before subcutaneous inoculation with D2Y98P dengue strain followed by subsequent dosing of AT-752 twice daily (500 mg/kg, p.o.) for seven days, starting one hour post inoculation. All vehicle-treated mice succumbed to fatal central nervous system sequelae within 8 days of infection, as typically observed for this model; however, mice treated with AT-752 showed notable differences in overall health, survival, and viremia. As shown in the graphs below, viral RNA in serum was statistically significantly lower than control by day 6 and below the limit of detection ("LOD") (LOD: 50 copies per mL) on day eight, after seven days of drug treatment.





Additionally, the potent antiviral activity of AT-752 was evaluated in a preclinical animal model of yellow fever virus disease in which hamsters were treated orally with AT-752 for seven days starting either four hours prior to inoculation (100, 300 or 1000 mg/kg) or two days post-inoculation (1000 mg/kg) with virus (Jimenez hamster-adapted strain V#2653). As shown in the graphs below, compared to animals treated with vehicle or the positive control ribavirin (50 mg/kg), weight loss prevention and survival were substantially improved when AT-752 treatment was started either before or after inoculation. Furthermore, significant reductions in serum viral titers on day four and ALT levels (a measure of virally-impaired liver function) on day six were observed in all AT-752-treated animals.





\*\*\*p<0.001, \*\*p<0.01, \*p<0.05 as compared to placebo treatment

## Clinical development

### Phase 1 clinical trial

We have recently completed a first-in-human, randomized, double-blind, placebo-controlled study of AT-752. This study was conducted in 65 healthy adults to investigate the safety, tolerability, and PK (with embedded food effect) of AT-752. The study consisted of two sequential parts: Part A comprised of a single ascending dose including a food effect cohort and Part B comprised of multiple ascending doses. In this study, AT-752 was generally well tolerated after either single or multiple doses in healthy subjects. There were no serious adverse events reported and no drug related drug discontinuations. Most adverse events were Grade 1 (mild) in intensity and no adverse events with severity of Grade 3 or above were reported. The most common adverse events across both parts of the study were headache, nausea, and vomiting. Gastrointestinal-related events (e.g. nausea, vomiting, abdominal pain, diarrhea, and constipation) were observed more commonly with AT-752 as compared to placebo, although cases were mild/moderate in intensity and were self-limiting or managed with ondansetron (vomiting). Most changes in laboratory parameters were mild (Grade 1) with no apparent relationship between the incidence of any laboratory abnormality and AT-752 dose level.

In 2022, we anticipate initiating two clinical trials of AT-752. One will be a human challenge study in the United States to evaluate viral load and viral kinetics in healthy subjects who are challenged with a Dengue Virus-1 Live Virus Human Challenge viral strain after receiving either AT-752 or placebo. We currently anticipate that this study will begin in the first half of 2022.

Additionally, we are initiating a global Phase 2 randomized, double-blind, placebo-controlled, dose-ranging trial to evaluate PK, pharmacodynamics, and safety of AT-752 in patients with dengue infection.

This study which will be conducted in geographic regions where dengue fever is endemic and is expected to enroll approximately 60 subjects. The primary objective of this study is to investigate the antiviral activity of AT-752 versus placebo (reduction of dengue virus RNA from baseline) in adult subjects with confirmed dengue infection.

We intend to pursue FDA expedited development and review programs for AT-752. Dengue is also defined as a tropical disease under the Federal Food, Drug and Cosmetic Act (the "FDCA"), and therefore FDA approval of AT-752 for the treatment of Dengue may result in a tropical disease priority review voucher that may be used for a subsequent NDA or biologics license application.

### **Candidates for the Treatment of Respiratory Syncytial Virus (RSV)**

#### **Respiratory Syncytial Virus (RSV)**

##### **Background**

RSV, a negative ssRNA virus belonging to the Pneumoviridae subfamily of the Paramyxoviridae family, is a seasonal respiratory virus that can be serious for infants, older adults, and the immuno-compromised population. Although the virus is seasonal, the duration, peaks and severity of the virus vary each season. In the United States, RSV infections generally occur during fall, winter and spring, but the timing and severity can vary from year to year and from region to region. Two different strains of the virus co-circulate each season, and RSV epidemics last from four to six months.

Globally, RSV affects 64 million people, according to the National Institutes of Health (the "NIH"), with annual mortality estimated at 160,000 deaths.

The primary symptoms of RSV infections include coughing, wheezing, fever, decreased appetite, and runny nose. RSV is the most common cause of bronchiolitis (inflammation of the small airways in the lung) and pneumonia (infection of the lungs) in children in the United States. Almost all children contract the RSV infection by their third year of life with 75,000 to 125,000 children being hospitalized each year in the United States. Globally, it is estimated that RSV results in 3.2 million hospital admissions in children younger than five years of age.

Among the elderly, the CDC estimates that RSV is responsible for 177,000 hospitalizations in the United States. An estimated 14,000 annual deaths are caused by RSV in the United States in adults older than age 65. Additionally, in immunocompromised persons, RSV can lead to significant morbidity and mortality.

##### **Current treatment landscape**

Treatment for RSV typically focuses on supportive care, which can include nasal suction, fever management, hydration, and oxygen. The FDA approved aerosolized ribavirin in 1986 for the treatment of serious RSV infections in hospitalized children. However, ribavirin, a nucleoside analog, carries several safety concerns, including potential toxicity for exposed persons. Aerosolized ribavirin has not been approved for use in the elderly or immunocompromised populations.

In addition, the FDA approved Synagis (palivizumab) in 1998 for the prevention of lower respiratory tract disease caused by RSV in children at high risk of RSV disease. Synagis is administered as an injection every month during RSV season. Synagis has not been approved for treatment of RSV, nor is it indicated for use in populations other than children under 24 months of age.

There are multiple RSV therapeutic and prophylaxis products in clinical development for the pediatric and adult market segments, including late-stage vaccine candidates from GSK and Pfizer targeting the elderly and maternal populations, late-stage immuno-prophylaxis candidates from AZ and Merck targeting the pediatric population and therapeutic candidates from Enanta, Janssen and Ark Biopharm targeting the pediatric population.

##### **Our approach**

Our development efforts in RSV are focused on inhibitors (both nucleosides and nucleotide prodrugs) of the RSV RdRp. We believe our RSV lead candidates have the potential to inhibit both the initiation of viral replication, as well as viral transcription. We plan to develop the selected product candidate in both oral and parenteral dosage formulations for both adult and pediatric patients.

## Development history

We have terminated development of our previous lead candidate AT-889 and are focused on optimizing the inhibitory potency and selectivity of other leads in our library of nucleos(t)ide analogs

## Development strategy

Currently, we are evaluating the antiviral activity and selectivity of our lead compounds in *in vitro* studies to inform our selection of the most promising lead candidate. Once chosen, we will assess the *in vivo* antiviral activity of such lead candidate in a small animal model, and conduct IND-enabling toxicology and other required studies. Thereafter we intend to nominate a product candidate for clinical development. We anticipate nominating our lead candidate and initiating the IND-enabling studies in the second half of 2022.

## Roche License Agreement

In October 2020, we entered into the Roche License Agreement, with F. Hoffmann-La Roche Ltd and Genentech, Inc. in connection with AT-511, bemnifosbuvir, their backup compounds (including AT-752) (the "Compounds"), products containing any Compound (the "Products"), and related companion diagnostics (the "Companion Diagnostics").

Subject to the terms and conditions of the Roche License Agreement, we granted Roche (i) an exclusive, sublicensable, worldwide (excluding the United States) license to make, sell, import and export the Compounds, the Products and the Companion Diagnostics in all fields of use, except for certain hepatitis C virus use (the "Field"), (ii) a non-exclusive, sublicensable license to make, import and export the Compounds, the Products and the Companion Diagnostics in the Field in the United States and (iii) a non-exclusive, sublicensable license to research and develop the Compounds, the Products and the Companion Diagnostics in the United States. We also agreed that Roche would manufacture the commercial supply of bemnifosbuvir. On February 22, 2021, we announced that Chugai Pharmaceutical Co., Ltd. in-licensed from Roche the exclusive right to develop and market bemnifosbuvir for the treatment of COVID-19 in Japan.

Subject to the terms and conditions of the Roche License Agreement, Roche granted us (i) an exclusive, sublicensable license to distribute, register and sell the Compounds and the Products in the United States, (ii) a non-exclusive, sublicensable license to research, develop, use, import, export and market the Compounds and the Products in the United States and (iii) a non-exclusive, sublicensable, worldwide (excluding the United States) license to research and develop the Compounds and the Products in the Field.

Subject to the terms and conditions of the Roche License Agreement, Roche and we jointly developed bemnifosbuvir for COVID-19 on a worldwide-basis and equally shared the costs associated with such development activities.

As partial consideration of the rights we granted to Roche under the Roche License Agreement, Roche paid us an upfront payment of \$350 million in November 2020. Additionally, upon realization of a development milestone in June 2021, we received an additional \$50 million from Roche.

On November 12, 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. On December 7, 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 the Compounds, the Products and the Companion Diagnostics in all fields of use.

#### **License Agreement with Merck**

In December 2021, we entered into a license agreement with Merck (the "Merck License Agreement") for the development, manufacture and commercialization of ruzasvir. Ruzasvir is the NS5A inhibitor we are developing in combination with benvifosbuvir for the treatment of HCV.

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

In consideration for the rights we acquired under the Merck License Agreement, we paid Merck an upfront payment in the amount of \$25 million and we will be required to pay Merck milestone payments up to \$135 million in the aggregate upon our achievement of certain development and regulatory milestones and up to \$300 million in the aggregate upon our achievement of certain sales based milestones. Additionally, we have agreed to pay Merck tiered royalties based on annual net sales of Products ranging from high single digit to mid teens percentages, subject to certain adjustments. Our royalty payment obligations will continue on a country-by-country and Product-by-Product basis until the later of (i) the expiration of the last to expire valid claim of a licensed Merck patent claiming such Product (or a Compound contained in such Product) and (ii) a period of years after the first commercial sale of such Product in such country.

Under the terms of the Merck License Agreement, we are obligated to use commercially reasonable efforts to develop and commercialize at least one Product in the Field in certain countries.

The term of the Merck License Agreement will continue, on a Product-by-Product and country-by-country basis, until expiration of all royalty payment obligations arising under the Merck License Agreement. We may terminate the Merck License Agreement for convenience upon 90 days prior written notice. Each party has the right to terminate the Merck License Agreement in the event of the other party's material breach of the terms of the Merck License Agreement subject to a 60 day cure period and in the event of the other party's bankruptcy or insolvency. Merck has the right to terminate the Merck License Agreement immediately if we commence any interference or opposition proceeding or other challenge to the validity or enforceability of any Merck patent licensed to us under the Merck License Agreement or if we otherwise oppose any extension of, or the grant of any supplementary protection certificate with respect to, any such Merck patent.

Upon any termination of the Merck License Agreement, the license granted to us by Merck will terminate. Upon termination of the Merck License Agreement by us for convenience other than as a result of a safety issue, or upon any termination by Merck, Merck will have an exclusive, fully paid, perpetual, sublicensable license to certain of our patents and know-how that are reasonably necessary to develop, manufacture or commercialize a Product that contains ruzasvir as the sole active agent, as such Product exists at termination. Additionally, if requested by Merck, during a period of time after delivery of the notice of termination of the Merck License Agreement by Merck or by us for convenience other than as a result of a safety issue, we will have the obligation to negotiate with Merck for the grant to Merck of a non-exclusive, royalty bearing license to certain of our patents and know-how that are reasonably necessary to develop, manufacture or commercialize a Product that is comprised of the combination of ruzasvir and benvifosbuvir, as such Product exists at termination, with certain license terms pre-specified in the Merck License Agreement.

#### **Manufacturing**

We do not currently own or operate manufacturing facilities for the production of preclinical or clinical product candidates, nor do we have plans to develop or operate our own manufacturing operations in the future. We currently rely upon third-party contract manufacturing organizations ("CMOs"), to produce our product candidates for both preclinical and clinical use. Although we rely on CMOs, we also have personnel with extensive manufacturing experience that can oversee the relationship with our manufacturing partners. We believe that any materials required for the manufacture of our product candidates could be obtained from more than one source.

## Competition

As a clinical-stage biopharmaceutical company, we face competition from a wide array of companies in the pharmaceutical and biotechnology industries. These include both small companies and large companies with much greater financial and technical resources and far longer operating histories than our own. We may also compete with the intellectual property, technology, and product development efforts of academic, governmental, and private research institutions.

Our competitors may have significantly greater financial resources, established presence in the market, expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and reimbursement, and marketing approved products than we do. These competitors also compete with us in recruiting and retaining qualified scientific, sales, marketing, and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

The key competitive factors affecting the success of any product candidates that we develop, if approved, are likely to be their efficacy, safety, convenience, price, and the availability of reimbursement from government and other third-party payors. Our commercial opportunity for any of our product candidates could be reduced or eliminated if our competitors develop and commercialize products that are more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, and may commercialize products more quickly than we are able to.

We are aware of the following competitors in the areas that we are initially targeting:

### SARS-CoV-2

Many therapies and vaccines are approved, authorized for use or being investigated for the treatment of COVID-19 in the United States, including:

- Molnupiravir (Ridgeback Biotherapeutics LP/Merck & Co., Inc.), a nucleoside analog authorized for emergency use by the FDA for the treatment of mild-to-moderate COVID-19 in adults at high-risk for progression to severe COVID, including hospitalization or death and for whom alternative COVID-19 treatment options authorized by FDA are not accessible or clinically appropriate.
- Paxlovid™ (nirmatrelvir tablets and ritonavir tablets) (Pfizer Inc.), a protease inhibitor authorized for emergency use by the FDA for the treatment of mild to moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) at high risk for progression to severe COVID-19, including hospitalization or death.
- Veklury® (remdesivir) (Gilead Sciences, Inc.), a RdRp inhibitor is approved by the FDA for the treatment of COVID-19 in adults and pediatric patients (12 years of age and older and weigh at least 40 kg) who are (i) hospitalized, or (ii) not hospitalized and have mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization and death. Additionally, the FDA has granted an emergency use authorization for the treatment of pediatric patients weighing 3.5 kg to less than 40 kg or pediatric patients less than 12 years of age weighing at least 3.5 kg who are (i) hospitalized, or (ii) not hospitalized and have mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization of death.
- REGEN-COV® (casirivimab and imdevimab) (Regeneron Pharmaceuticals, Inc.), an antibody cocktail authorized for emergency use by the FDA for the treatment of mild to moderate COVID-19) in certain adult and pediatric patients (12 years of age and older weighing at least 40 kg) at high risk for progression to severe COVID-19, including hospitalization or death. REGEN-COV is not authorized to treat certain patients, including those in geographic regions where infection is likely to have been caused by a non-susceptible SARS-Co-V-2 variant.
- Bamlanivimab and etesevimab (Eli Lilly and Company), a neutralizing antibody program authorized for emergency use by the FDA to treat mild to moderate COVID-19 in certain adults and pediatric

patients, including neonates, at high risk for progression to severe COVID-19, including hospitalization or death. Bamlanivimab and etesevimab are not authorized to treat certain patients, including those in geographic regions where infection is likely to have been caused by a non-susceptible SARS-CoV-2 variant.

- Sotrovimab (Vir Biotechnology Inc./GlaxoSmithKline), an antibody authorized for emergency use by the FDA to treat mild-to-moderate COVID-19 in certain adults and pediatric patients (12 years of age and older) at high risk for progression to severe COVID-19, including hospitalization or death. VIR-7832 is another antibody in clinical development by Vir Biotechnology Inc./GlaxoSmithKline.
- Evusheld™ (AstraZeneca), a long-acting antibody combination authorized for emergency use by the FDA for pre-exposure prophylaxis of COVID-19 in adults and adolescents with moderate to severe immune compromise and who may not mount an adequate immune response to COVID-19 vaccination, as well as those individuals for whom COVID-19 vaccination is not recommended.
- Bebtelovimab (LY-CoV1404; LY3853113) (Lilly), an investigational neutralizing IgG1 monoclonal antibody (mAb) directed against the spike protein of SARS-CoV-2, submitted for EUA approval.
- Ensovibep (MP04020) (Molecular Partners AG and Novartis AG), a multi targeted direct acting antiviral candidate in phase 3 clinical development. MP0423 is another candidate in development by Molecular Partners AG and Novartis AG).
- Mupadolimab (CPI-006) (Corvus Pharmaceuticals), an immunomodulatory antibody in clinical development.
- Spikevax™ (Moderna Inc.) approved by the FDA for the prevention of COVID-19 in individuals 18 years of age and older.
- Comirnaty® (Pfizer-BioNTech) approved by the FDA for the prevention of COVID-19 in individuals 16 years of age and older. The Pfizer-BioNTech COVID-19 vaccine is also authorized for emergency use for individuals 5 years of age and older and Pfizer-BioNTech have submitted a request for emergency use authorization for use in children 6 months through 4 years of age.
- Janssen Pharmaceutical Companies' COVID-19 vaccine (Janssen Biotech Inc.) authorized by the FDA for emergency use for the prevention of COVID-19 in individuals 18 years of age and older.

Additional companies working on investigational vaccines or treatments include Novavax, Inc., Inovio Pharmaceuticals, Inc., Biogen Inc., CanSino Biologics Inc., AbbVie Inc., Sanofi, AstraZeneca, GSK, Aligos Therapeutics, Inc., Enanta Pharmaceuticals, Inc., Arbutus Biopharma Corporation and Translate Bio Inc.

The potential treatments and vaccines for COVID-19 continues to evolve. The list above addresses the products or product candidates approved or authorized for emergency use or under clinical development in the United States as of the date of this Annual Report on Form 10-K that we believe could be the most competitive with a bemnifosbuvir combination therapy, but is not a comprehensive list of every treatment or vaccine that is in development for COVID-19.

#### **Dengue Virus**

In 2019, a vaccine, Dengvaxia® developed by Sanofi Pasteur Inc. ("Sanofi"), was approved by the FDA for the prevention of disease caused by dengue virus serotypes 1, 2, 3 and 4 in children ages nine to 16 with laboratory-confirmed previous dengue infection and living in endemic areas.

Takeda Pharmaceuticals Co Ltd, ("Takeda"), is also advancing a dengue vaccine, TAK-003, which is in Phase 3 development. Primary endpoint analysis of its ongoing Phase 3 trial in children ages four to 16 years showed protection against virologically-confirmed dengue.

Therapeutics in addition to AT-752 currently in clinical development for the treatment of dengue fever include a dengue NS4B inhibitor being developed by Janssen Pharmaceutical Companies which is in Phase 2a clinical development in adult patients with confirmed dengue fever and a dengue NS4B inhibitor being developed by Novartis Pharmaceuticals Corporation which is in Phase 1 clinical development.

## HCV

FDA-approved treatments for patients with chronic HCV include Epclusa® and Vosevi® marketed by Gilead Sciences, Inc. and Mavyret®, marketed by AbbVie Inc. We are also aware of an investigational agent for HCV, currently in Phase 2 testing, being developed by Cocrystal Pharma Inc.

## RSV

Supportive care is the most common course of treatment for RSV and includes oxygen, fluid management, bronchodilators, and corticosteroids. Ribavirin, approved in 1986, is used to treat severe cases of RSV infection, but carries significant side effects and risks associated with its use, especially in infants. Synagis® (palivizumab), marketed by Swedish Orphan Biovitrum AB in the United States and AstraZeneca plc outside of the United States, is an FDA-approved, seasonal monoclonal antibody injection given monthly to help protect high-risk infants from severe RSV. Synagis is not approved as a treatment for RSV.

There are multiple RSV therapeutic and prophylaxis products in clinical development for the pediatric and adult market segments, with late-stage vaccine candidates from GSK and Pfizer targeting the elderly and maternal populations, late-stage immuno-prophylaxis candidates from AZ and Merck targeting the pediatric population and therapeutic candidates from Janssen and Ark Biopharm targeting the pediatric population.

At this time, we are aware of investigational agents for the treatment of RSV being developed by Janssen Pharmaceuticals, Inc., Enanta Pharmaceuticals Inc., ReViral Ltd, and Ark Biosciences Inc.

## Commercialization

Given the stage of development of our lead asset, we have not yet invested in a commercial infrastructure or distribution capabilities. We believe that the commercialization of bempifosbuvir in the United States could be achieved by a small Atea team across sales, marketing, reimbursement and other commercial activities. While we currently plan to establish our own commercial organization in the United States and potentially in other selected markets, we continue to consider and evaluate in each market the potential advantages and enhancements of our commercial capabilities that may be realized as a result of a collaboration between us and a pharmaceutical or other company.

## Intellectual Property

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for our nucleotide therapeutic products for viral diseases, including our purine nucleotide compounds for SARS-CoV-2, dengue fever and HCV. We seek to protect our proprietary compounds and methods of treatment for viral diseases using our nucleotide compounds, alone and in combination with other therapeutic agents, in addition to dosage forms, dosing regimens and formulations for their administration. We also seek protection on the manufacturing process for the production of our nucleotide compounds. Our success also depends on our ability to operate without infringing, misappropriating or otherwise violating on the proprietary rights of others and to prevent others from infringing, misappropriating or otherwise violating our proprietary rights.

Our policy is to seek to protect our proprietary position by filing U.S. and foreign patent applications covering our proprietary technologies, inventions, and improvements that are important to the development and implementation of our business. In addition, we currently plan to seek patent term adjustments, restorations, and/or patent term extensions where applicable in the United States, Europe and other jurisdictions. We also rely on trade secrets, know-how, continuing technological innovation and potential in-licensing opportunities to develop and maintain our proprietary position. Additionally, we expect to benefit, where appropriate, from statutory frameworks in the United States, Europe and other countries that provide a period of regulatory data exclusivity to compensate for the time required for regulatory approval of our drug products.

As of December 31, 2021, we are the sole owner of nine patent families covering our product candidates and proprietary nucleotide compounds, which include composition of matter, pharmaceutical compositions, methods of use, and processes of manufacture as described in more detail below. Our owned patent estate as of December 31, 2021, on a worldwide basis, includes more than 180 pending,

granted, or allowed patent applications with fourteen issued U.S. patents, ten pending U.S. non-provisional applications, three pending U.S. provisional applications, four pending international patent applications filed under the Patent Cooperation Treaty ("PCT"), and more than 90 pending or granted patent applications that have entered the national phase of prosecution in countries outside the United States.

As of December 31, 2021, we are the exclusive licensee of three patent families from MSD International GmbH (Merck, Sharp & Dohme Corp.) covering composition of matter, process of preparation, and formulations of the NS5A inhibitor ruzasvir (MK-8408), which collectively include two issued U.S. patents, granted patents in France, Great Britain, and Germany and one pending U.S. patent application and one pending patent application in the EPO.

The exclusivity terms of our patents depend upon the laws of the countries in which they are obtained. In the countries in which we currently file, the patent term is 20 years from the earliest date of filing of a non-provisional patent application. The term of a U.S. patent may be extended to compensate for the time required to obtain regulatory approval to sell a drug (a patent term extension) or by delays encountered during patent prosecution that are caused by the U.S. Patent and Trademark Office (referred to as patent term adjustment). For example, the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Act, permits a patent term extension for FDA-approved new chemical entity drugs of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review and diligence during the review process. Patent term extensions in the United States cannot extend the term of a patent beyond a total of 14 years from the date of product approval, only one patent covering an approved drug or its method of use may be extended, and only those claims covering the approved drug, or an approved method for using it may be extended. A similar kind of patent extension, referred to as a Supplementary Protection Certificate, is available in Europe. Legal frameworks are also available in certain other jurisdictions to extend the term of a patent. We currently intend to seek patent term extensions on any of our issued patents in any jurisdiction where we have a qualifying patent and the extension is available; however, there is no guarantee that the applicable regulatory authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions. Further, even if our patent is extended, the patent, including the extended portion of the patent, may be held invalid or unenforceable by a court of final jurisdiction in the United States or a foreign country.

Current issued patents and patent applications covering the composition of matter for our present clinical candidates AT-511, bempifosbuvir, AT-281 (the free base of AT-752), and AT-752 will expire on dates ranging from 2036 to 2038, if the applications are issued and held valid by a court of final jurisdiction if challenged. Current patent applications covering the use of AT-511 and bempifosbuvir for the treatment of SARS-CoV-2 will expire on dates ranging from 2037 to 2041, if the applications are issued and held valid by a court of final jurisdiction if challenged. Current issued patents and patent applications covering the use of AT-511 and bempifosbuvir for the treatment of HCV will expire on dates ranging from 2036 to 2039, if the applications are issued and held valid by a court of final jurisdiction if challenged. Current patent applications covering the use of AT-281 and AT-752 for the treatment of dengue fever will expire on a date in 2037, if the applications are issued and held valid by a court of final jurisdiction if challenged.

Current patent applications covering the composition of matter for our present HCV combination drug clinical candidate AT-787 will expire on a date in 2039, if the applications are issued and held valid by a court of final jurisdiction if challenged. Current patent applications covering the use of AT-787 for the treatment of HCV will expire on dates ranging from 2036 to 2039, if the applications are issued and held valid by a court of final jurisdiction if challenged.

However, any of our patents, including patents that we may rely on to protect our market for approved products, may be held invalid or unenforceable by a court of final jurisdiction. Alternatively, we may decide that it is in our interest to settle a litigation in a manner that affects the term or enforceability of our patent. Changes in either the patent laws or in interpretations of patent laws in the United States and other jurisdictions may diminish our ability to protect our inventions and enforce our intellectual property rights. Accordingly, we cannot predict the breadth or enforceability of claims that have been or may be granted on our patents or on third-party patents. The pharmaceutical and biotechnology industries are



characterized by extensive litigation regarding patents and other intellectual property rights. Our ability to obtain and maintain our proprietary position for our nucleotide compounds and the use of these compounds will depend on our success in enforcing patent claims that have been granted or may grant. We do not know whether any of the pending patent applications that we have filed or may file or license from third parties will result in the issuance of any additional patents. The issued patents that we own or may receive in the future may be challenged, invalidated, or circumvented, and the rights granted under any issued patents may not provide us with sufficient protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may be able to independently develop and commercialize drugs with similar mechanisms of action and/or duplicate our methods of treatments or strategies without infringing our patents. Because of the extensive time required for clinical development and regulatory review of a drug we may develop, it is possible that, before any of our drugs can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of any such patent. For more information regarding risks relating to intellectual property, see Part I, Item 1A. "Risk Factors—Risks Related to Intellectual Property."

Our patent families, as of December 31, 2021, are further described below.

**AT-511 and bennifosbuvir**

We own a first patent family that describes AT-511 or a pharmaceutically acceptable salt thereof (for example, bennifosbuvir), pharmaceutical compositions of AT-511 or the pharmaceutical salts thereof, and methods to treat HCV using AT-511 or a salt thereof. This family consists of eight issued U.S. patents (U.S. Pat. Nos. 9,828,410; 10,000,523; 10,005,811; 10,239,911; 10,815,266; 10,870,672; 10,870,673; and 10,875,885) and two pending U.S. applications covering AT-511 or a pharmaceutically acceptable salt thereof and its pharmaceutical compositions. This patent family is now also in the national stage of prosecution or granted in the African Regional Intellectual Property Organization ("ARIPO"), Australia, Brazil, Canada, China, Colombia, the Eurasian Patent Office ("EAPO"), Egypt, the European Patent Office ("EPO"), Georgia, Hong Kong, Indonesia, Israel, India, Japan, Korea, Mexico, Macao, Malaysia, Nigeria, New Zealand, the Philippines, Russia, Saudi Arabia, Singapore, Thailand, Vietnam, Ukraine, South Africa, and the United Arab Emirates. We have more than 20 foreign patents granted or allowed, and more than 20 pending patent applications. The expected year of expiration for this patent family, where issued, valid and enforceable, is 2036, without regard to any extensions, adjustments, or restorations of term that may be available under national law.

We also own a second patent family that specifically covers bennifosbuvir, pharmaceutical compositions, and methods to treat HCV using bennifosbuvir. This family includes three issued U.S. patent (U.S. Pat. No. 10,519,186, U.S. Patent No. 10,906,938, and U.S. Patent No. 10,894,804), and two pending U.S. applications bennifosbuvir. This family is currently in the national phase of prosecution in Argentina, ARIPO, Australia, Brazil, Canada, China, Colombia, the EAPO, the EPO, Georgia, Hong Kong, Indonesia, Israel, India, Japan, Korea, Mexico, Malaysia, Nigeria, New Zealand, the Philippines, Russia, Singapore, Taiwan, Thailand, Vietnam, Ukraine, Uzbekistan, and South Africa. We have three granted foreign patents and over 30 pending applications. The expected year of expiration for this patent family, if issued, valid and enforceable, is 2038, without regard to any extensions, adjustments, or restorations of term that may be available under U.S. or other national laws.

We own two patent families that disclose methods for the treatment of SARS-CoV-2 using AT-511 or bennifosbuvir. These families include one granted U.S. patent (U.S. Patent No. 10,874,687), three pending U.S. applications and applications pending in Argentina, China, the EPO, Japan, and Taiwan. The expected year of expiration for patents issued from these families, if valid and enforceable, is 2040 or 2041, without regard to any extensions, adjustments, or restorations of term that may be available under U.S. or other national laws.

We own a fifth patent family that discloses the use of AT-511 or a pharmaceutically acceptable salt thereof for the treatment or prevention of a positive-stranded RNA virus infection, including a *Coronaviridae* or *Flaviviridae* viral infection. This family consists of one allowed application US 2020-0222442 and one issued patent (U.S. Patent No. 10,946,033) and is currently pending or granted in Australia, Brazil, Canada, China, the EAPO, the EPO, Hong Kong, Indonesia, Japan, Korea, Malaysia, Nigeria, Russia, Singapore, Thailand, Vietnam, and South Africa. We have over 30 foreign patents

granted and over 20 pending patent applications. The expected year of expiration for this patent family, if issued, valid and enforceable, is 2037, without regard to any extensions, adjustments, or restorations of term that may be available under U.S. or other national laws.

We own a sixth patent family that discloses the use of AT-511 and bennifosbuvir for the treatment of HCV in patients with cirrhosis of the liver. This family includes one pending U.S. application. This family is currently in the national phase of prosecution in China, the EPO, Hong Kong, Japan, Korea, Russia, and Taiwan. The expected year of expiration for this patent family, if issued, valid and enforceable, is 2039, without regard to any extensions, adjustments, or restorations of term that may be available under U.S. or other national laws.

We own a seventh patent family that describes methods to treat SARS-CoV-2 virus. This family consists of one international application filed under the PCT, as well as one application in Argentina and one application in Taiwan. The expected year of expiration for patents issued from non-provisional patent applications filed on the basis of this patent application, if valid and enforceable, is 2041, without regard to adjustments of term that may be available under U.S. or other national laws.

We also own an eighth patent family that discloses methods for manufacturing AT-511 and bennifosbuvir. This family consists of one international application filed under the PCT. The expected year of expiration for patents issued from non-provisional patent applications filed on the basis of these provisional patent applications, if valid and enforceable, is 2041, without regard to adjustments of term that may be available under U.S. or other national laws.

We also own a ninth patent family that discloses new commercial scale processes for the manufacture of AT-511 and bennifosbuvir. This family consists of four U.S. provisional applications. The expected year of expiration for patents issued from these non-provisional patent applications, if valid and enforceable, is 2041, without regard to any adjustments of term that may be available under U.S. or other national law.

#### **AT-787**

We own a tenth patent family that discloses the combination of AT-511 or bennifosbuvir and AT-777 (i.e., AT-787) for the treatment of HCV. This family includes two pending U.S. applications, and have entered the national phase in Argentina, China, the EPO, Japan, Korea, Russia, and Taiwan. The expected year of expiration for this patent family, if issued, valid and enforceable, is 2039, without regard to any extensions, adjustments, or restorations of term that may be available under U.S. or other national laws.

#### **AT-281 and AT-752**

The first patent family described above also describes AT-281, a pharmaceutically acceptable salt thereof (for example, AT-752) and pharmaceutical compositions of AT-281 or a pharmaceutical salt thereof and their use to treat HCV infection.

The second patent family described above also describes AT-752 and pharmaceutical compositions of AT-752. One of these pending U.S. applications in this patent family covers AT-752 and pharmaceutical compositions of AT-752.

The fifth patent family described above also includes a disclosure of the use of AT-281 or a pharmaceutically acceptable salt thereof for the treatment or prevention of an RNA viral infection, including dengue fever, yellow fever, and Zika virus in addition to the treatment and prevention of a Coronaviridae viral infection. Therefore, we have three patent families that describe AT-281 or AT-752 and methods of treatment for viral infections using AT-281 or AT-752.

#### **Ruzasvir**

We have exclusively licensed three patent families from MSD International GmbH (Merck, Sharp & Dohme Corp.) covering composition of matter, process of preparation, and formulations of ruzasvir (MK-8408), a pan-genotype NS5A inhibitor to treat HCV. The family covering the composition of matter includes one granted U.S. patent (U.S. Patent No. 9,555,038), and granted patents in France, Great Britain, and Germany. The expected expiration date is in 2034. The family describing a process of preparation includes one granted U.S. patent (U.S. Patent No. 10,457,690), with an expected expiration date in 2036. The family describing formulations includes one pending U.S. patent application and one pending patent application in the EPO, which if granted, is expected to expire in 2039.

We also solely own two provisional applications covering the combination of bempifosbuvir and ruzasvir, which if granted, will have an expiration date in 2042.

#### **Government Regulation and Product Approval**

Government authorities in the United States, at the federal, state and local level, and other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing and export and import of products such as those we are developing. A new drug must be approved by the FDA through the new drug application ("NDA"), process before it may be legally marketed in the United States.

#### **U.S. Drug Development Process**

In the United States, the FDA regulates drugs under the FDCA and its implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies in accordance with FDA's good laboratory practice requirements and other applicable regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an independent institutional review board ("IRB"), or ethics committee at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practice requirements ("GCPs") to establish the safety and efficacy of the proposed drug for its intended use;
- submission to the FDA of an NDA after completion of all pivotal trials;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current good manufacturing practice ("cGMP"), requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity, and of selected clinical investigation sites to assess compliance with GCPs; and
- FDA review and approval of the NDA to permit commercial marketing of the product for particular indications for use in the United States.

Prior to beginning the first clinical trial with a product candidate in the United States, a sponsor must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an IND product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. The IND also includes results of animal and *in vitro* studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. Once submitted, the IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all

research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. While the IND is active, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report, among other information, must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or *in vitro* testing suggesting a significant risk to humans, and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

Furthermore, an independent IRB or ethics committee for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site and must monitor the study until completed. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

**Phase 1:** The product candidate is initially introduced into healthy human subjects, and in some cases, patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.

**Phase 2:** The product candidate is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

**Phase 3:** The product candidate is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

Post-approval trials, sometimes referred to as Phase 4 studies, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

During the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase 2, and before an NDA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach agreement on the next phase of development. Sponsors typically use the meeting at the end of the Phase 2 trial to discuss Phase 2 clinical results and present plans for the pivotal Phase 3 clinical trials that they believe will support approval of the new drug.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements.

The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug. In addition, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

#### **U.S. Review and Approval Process**

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, preclinical and other non-clinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. The submission of an NDA is subject to the payment of substantial user fees; a waiver of such fees may be obtained under certain limited circumstances. Additionally, no user fees are assessed on NDAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once filed, the FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve the product's identity, strength, quality and purity. Under the Prescription Drug User Fee Act ("PDUFA"), guidelines that are currently in effect, the FDA has a goal of ten months from the date of "filing" of a standard NDA for a new molecular entity to review and act on the submission. This review typically takes twelve months from the date the NDA is submitted to FDA because the FDA has approximately two months to make a "filing" decision after it the application is submitted.

The FDA may refer an application for a novel drug to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP and adequate to assure consistent production of the product within required specifications. Additionally, before approving a NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCPs.

After the FDA evaluates an NDA, it will issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A Complete Response Letter usually describes the specific deficiencies in the NDA identified by the FDA and may require additional clinical data, such as an additional clinical trials or other significant and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing. If a Complete Response Letter is issued, the sponsor must resubmit the NDA or, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the NDA does not satisfy the criteria for approval.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations or restrictions on the indicated uses for which such product may be marketed. For example, the FDA may approve the NDA with a Risk Evaluation and Mitigation Strategy ("REMS"), to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a medicine and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication

plans, or elements to assure safe use, such as restricted distribution methods, patient registries, and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may also require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization and may limit further marketing of the product based on the results of these post-marketing studies. In addition, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could impact the timeline for regulatory approval or otherwise impact ongoing development programs.

In addition, the Pediatric Research Equity Act ("PREA"), requires a sponsor to conduct pediatric clinical trials for most drugs, for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, original NDAs and supplements must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must evaluate the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The sponsor or FDA may request a deferral of pediatric clinical trials for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug is ready for approval for use in adults before pediatric clinical trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric clinical trials begin. The FDA must send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current or fails to submit a request for approval of a pediatric formulation.

#### **Emergency Use Authorization**

The Commissioner of the FDA, under delegated authority from the Secretary of Health and Human Services ("HHS") may, under certain circumstances in connection with a declared public health emergency, allow for the marketing of a product that does not otherwise comply with FDA regulations by issuing an EUA for such product. Before an EUA may be issued by HHS, the Secretary must declare an emergency based a determination that public health emergency exists that effects or has the significant potential to affect, national security, and that involves a specified biological, chemical, radiological, or nuclear agent or agents ("CBRN"), or a specified disease or condition that may be attributable to such CBRN. On February 4, 2020, the HHS Secretary determined that there is such a public health emergency that involves the virus now known as SARS-CoV-2, the virus that causes the COVID-19 infection. Once the determination of the threat or emergency has been made, the Secretary of HHS must then declare 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 – on the basis of his determination of a public health emergency that has the potential to affect national security or the health and security of U.S. citizens living abroad that involves SARS-CoV-2 – that circumstances exist justifying authorization of drugs and biologics during the COVID-19 pandemic, subject to the terms of any EUA that is issued.

Once an EUA declaration has been issued, 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 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. Products subject to an EUA must still comply with the conditions of the EUA, including labeling and marketing requirements. Moreover, 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.

#### **Expedited Development and Review Programs**

The FDA offers a number of expedited development and review programs for qualifying product candidates. For example, the FDA Fast Track program is intended to expedite or facilitate the process for reviewing product candidates that meet certain criteria. Specifically, new drugs are eligible for Fast Track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate

the potential to address unmet medical needs for the disease or condition. With regard to a Fast Track product candidate, the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

A product candidate intended to treat a serious or life-threatening disease or condition may also be eligible for Breakthrough Therapy designation to expedite its development and review. A product candidate can receive Breakthrough Therapy designation if preliminary clinical evidence indicates that the product candidate, alone or in combination with one or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the Fast Track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product candidate, including involvement of senior managers.

Any marketing application for a drug submitted to the FDA for approval, including a product with a Fast Track designation or Breakthrough Therapy designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. An NDA is eligible for priority review if the product candidate is designed to treat a serious condition, and if approved, would provide a significant improvement in safety or effectiveness compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an NDA designated for priority review in an effort to facilitate the review. The FDA endeavors to review applications with priority review designations within six months of the filing date as compared to ten months for review of new molecular entity NDAs under its current PDUFA review goals.

In addition, a product candidate may be eligible for accelerated approval. Product candidates intended to treat serious or life-threatening diseases or conditions may be eligible for accelerated approval upon a determination that the product candidate has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials to verify the predicted clinical benefit. Products receiving accelerated approval may be subject to expedited withdrawal procedures if the sponsor fails to conduct the required clinical trials, or if such trials fail to verify the predicted clinical benefit. In addition, the FDA currently requires pre-approval of promotional materials as a condition for accelerated approval, which could adversely impact the timing of the commercial launch of the product.

Fast Track designation, Breakthrough Therapy designation, priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process. Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

#### **Tropical Disease Priority Review Voucher Program**

In 2007, Congress authorized the FDA to award priority review vouchers ("PRVs"), to sponsors of certain tropical disease product applications. The FDA's Tropical Disease Priority Review Voucher Program is designed to encourage development of new drug and biological products for the prevention and treatment of certain tropical diseases affecting millions of people throughout the world. Under this program, a sponsor who receives an approval for a drug or biologic for the prevention or treatment of a tropical disease that meets certain criteria may qualify for a PRV that can be redeemed to receive priority review of a subsequent NDA or Biologics License Application ("BLA"), for a different product. The sponsor of a tropical disease drug product receiving a priority review voucher may transfer (including by sale) the voucher to another sponsor of an NDA or BLA. The FDCA does not limit the number of times a priority review voucher may be transferred before the voucher is used.

For a product to qualify for a PRV, (i) the sponsor must request approval of the product for the prevention or treatment of a "tropical disease" listed in Section 524 of the FDCA, (ii) the product must otherwise qualify for priority review, and (iii) the product must contain no active ingredient (including any salt or ester of an active ingredient) that has been approved by the FDA in any other NDA or BLA. The Food and Drug Administration Reauthorization Act of 2017 made further changes to the eligibility criteria for receipt of a tropical disease PRV under this program. Specifically, applications submitted after September 30, 2017 must also contain reports of one or more new clinical investigations (other than bioavailability studies) that were essential to the approval of the application and conducted or sponsored by the sponsor.

#### Post-approval Requirements

Any products manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual program fees for any marketed products.

Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, which impose certain procedural and documentation requirements upon drug manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, imposition of post-market studies or clinical studies to assess new safety risks, or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters, or untitled letters;
- clinical holds on clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of drug products. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies



actively enforce the laws and regulations prohibiting the promotion of off label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe, in their independent professional medical judgment, legally available products for uses that are not described in the product's labeling and that differ from those tested and approved by the FDA. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict marketers' communications on the subject of off-label use of their products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined companies from engaging in off-label promotion. The FDA and other regulatory agencies have also required that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA-approved labelling.

#### **Marketing Exclusivity**

Marketing exclusivity provisions authorized under the FDCA can delay the submission or the approval of certain marketing applications. The FDCA provides a five-year period of non-patent data exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not approve or even accept for review an abbreviated new drug application ("ANDA"), or an NDA submitted under Section 505(b)(2) ("505(b)(2) NDA"), submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovative drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder.

The FDCA alternatively provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for drugs containing the active agent for the original indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to any preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Pediatric exclusivity is another type of marketing exclusivity available in the United States. Pediatric exclusivity provides for an additional six months of marketing exclusivity attached to another period of exclusivity if a sponsor conducts clinical trials in children in response to a written request from the FDA. The issuance of a written request does not require the sponsor to undertake the described clinical trials.

#### **Other Healthcare Laws**

Pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Such laws include, without limitation, U.S. federal and state anti-kickback, fraud and abuse, false claims, pricing reporting, and physician payment transparency laws and regulations regarding drug pricing and payments or other transfers of value made to physicians and other licensed healthcare professionals as well as similar foreign laws in the jurisdictions outside the United States. Violation of any of such laws or any other governmental regulations that apply may result in significant penalties, including, without limitation, administrative civil and criminal penalties, damages, disgorgement fines, additional reporting requirements and oversight obligations, contractual damages, the curtailment or restructuring of operations, exclusion from participation in governmental healthcare programs and/ or imprisonment.

## Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidate for which we may seek regulatory approval. Sales in the United States and in foreign jurisdictions will depend, in part, on the availability of sufficient coverage and adequate reimbursement from third-party payors, which include government health programs such as Medicare, Medicaid, TRICARE and the Veterans Administration, as well as managed care organizations and private health insurers. Prices at which we or our customers seek reimbursement for our product candidates can be subject to challenge, reduction or denial by third-party payors.

The process for determining whether a third-party payor will provide coverage for a product is typically separate from the process for setting the reimbursement rate that the payor will pay for the product. In the United States, there is no uniform policy among payors for coverage or reimbursement. Decisions regarding whether to cover any of a product, the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies, but also have their own methods and approval processes. 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 can require manufacturers to provide scientific and clinical support for the use of a product to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product that receives approval. Third-party payors may not consider our product candidates to be medically necessary or cost-effective compared to other available therapies, or the rebate percentages required to secure favorable coverage may not yield an adequate margin over cost or may not enable us to maintain price levels sufficient to realize an appropriate return on our investment in drug development. Additionally, decreases in third-party reimbursement for any product or a decision by a third-party payor not to cover a product could reduce physician usage and patient demand for the product.

## Healthcare Reform

In the United States and in foreign jurisdictions, there has been, and continues to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect the profitable sale of product candidates.

Among policy makers and payors in the United States, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the "ACA") was passed, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly affected the pharmaceutical industry. The ACA increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1%; required collection of rebates for drugs paid by Medicaid managed care organizations; required manufacturers to participate in a coverage gap discount program, in which manufacturers must 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; imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell certain "branded prescription drugs" to specified federal government programs, implemented a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected; expanded eligibility criteria for Medicaid programs; created 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 established a Center for Medicare Innovation at the Centers for

Medicare & Medicaid Services ("CMS") to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

There remain judicial and political 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 without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to health care, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes included aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, including the Bipartisan Budget Act of 2018, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, unless additional Congressional action is taken. In addition, on January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for pharmaceutical products. The likelihood of success of these and other measures initiated by the former Trump administration is uncertain.

Individual states in the United States have also become increasingly active in implementing regulations designed to control pharmaceutical 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. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine which drugs and suppliers will be included in their healthcare programs. Furthermore, there has been increased interest by third party payors and governmental authorities in reference pricing systems and publication of discounts and list prices.

#### **Data Privacy & Security**

Numerous state and federal laws, regulations and standards govern the collection, use, access to, confidentiality and security of health-related and other personal information, and could apply now or in the future to our operations or the operations of our partners. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws and consumer protection laws and regulations govern the collection, use, disclosure, and protection of health-related and other personal information. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

Further, certain foreign laws govern the privacy and security of personal data, including health-related data. For example, the GDPR imposes strict requirements for processing the personal data of individuals within the European Economic Area. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. Further, from January 1, 2021, companies have had to comply with 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 UK GDPR mirrors the fines under the GDPR, i.e., fines up to the greater of €20 million (£17.5 million) or 4% of global turnover.

#### **Government Regulation Outside of the United States**

In addition to regulations in the United States, we are subject to a variety of regulations in other jurisdictions, such as the European Union, governing, among other things, clinical trials, marketing authorization and any commercial sales and distribution of our products once approved. Whether or not we obtain FDA approval for a product candidate, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. The requirements and process governing the conduct of clinical trials, approval process, product licensing, pricing and reimbursement vary from country to country. Failure to comply with applicable foreign regulatory requirements, may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

#### **Non-clinical studies and clinical trials**

Similarly to the United States, the various phases of non-clinical and clinical research in the EU are subject to significant regulatory controls.

Non-clinical studies are performed to demonstrate the health or environmental safety of new chemical or biological substances. Non-clinical studies must be conducted in compliance with the principles of good laboratory practice ("GLP") as set forth in EU Directive 2004/10/EC. In particular, non-clinical studies, both in vitro and in vivo, must be planned, performed, monitored, recorded, reported and archived in accordance with the GLP principles, which define a set of rules and criteria for a quality system for the organizational process and the conditions for non-clinical studies. These GLP standards reflect the Organization for Economic Co-operation and Development requirements.

Clinical trials of medicinal products in the EU must be conducted in accordance with EU and national regulations and the International Conference on Harmonization ("ICH") guidelines on Good Clinical Practices ("GCP") as well as the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. If the sponsor of the clinical trial is not established within the EU, it must appoint an EU entity to act as its legal representative. The sponsor must take out a clinical trial insurance policy, and in most EU member states, the sponsor is liable to provide 'no fault' compensation to any study subject injured in the clinical trial.

The regulatory landscape related to clinical trials in the EU has been subject to recent changes. 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. Unlike directives, the CTR is directly applicable in all EU member states without the need for member states to further implement it into national law. The CTR notably harmonizes the assessment and supervision processes for clinical trials throughout the EU via a Clinical Trials Information System, which contains a centralized EU portal and database.

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, much like the FDA and IRB respectively, 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 CTA must include, among other things, a copy of the trial protocol and an investigational medicinal product dossier containing information about the manufacture and quality of the medicinal product under investigation. 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.

Medicines used in clinical trials must be manufactured in accordance with Good Manufacturing Practice ("GMP"). Other national and EU-wide regulatory requirements may also apply.

#### **Marketing Authorization**

In order to market our future product candidates in the EU and many other foreign jurisdictions, we must obtain separate regulatory approvals. More concretely, in the EU, medicinal product candidates can only be commercialized after obtaining a marketing authorization ("MA"). To obtain regulatory approval of a product candidate under EU regulatory systems, we must submit a MA application ("MAA"). The process for doing this depends, among other things, on the nature of the medicinal product. There are two types of MAs:

- "Centralized MA" are issued by the European Commission through the centralized procedure, based on the opinion of the Committee for Medicinal Product for Human Use ("CHMP") of the European Medicines Agency ("EMA") and are valid throughout the EU. The centralized procedure is mandatory for certain types of product candidates, such as: (i) medicinal products derived from biotechnology processes, such as genetic engineering, (ii) designated orphan medicines, (iii) medicinal products containing a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, neurodegenerative diseases, diabetes, auto-immune and other immune dysfunctions and viral diseases and (iv) advanced therapy medicinal products ("ATMPs") such as gene therapy, somatic cell therapy or tissue-engineered medicines. The centralized procedure is optional for product candidates containing a new active substance not yet authorized in the EU, or for product candidates that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU.
- "National MAs" are issued by the competent authorities of the EU member states, only cover their respective territory, and are available for product candidates not falling within the mandatory scope of the centralized procedure. Where a product has already been authorized for marketing in an EU member state, this national MA can be recognized in another member state through the mutual recognition procedure. If the product has not received a national MA in any member state at the time of application, it can be approved simultaneously in various member states through the decentralized procedure. Under the decentralized procedure an identical dossier is submitted to the competent authorities of each of the member states in which the MA is sought, one of which is selected by the applicant as the reference member state.

Under the centralized procedure the maximum timeframe for the evaluation of a MAA by the EMA is 210 days.

MAs have an initial duration of five years. After these five years, the authorization may be renewed for an unlimited period on the basis of a reevaluation of the risk-benefit balance.

#### **Data and Marketing Exclusivity**

The EU also provides opportunities for market exclusivity. Upon receiving MA, reference products generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, the data exclusivity period prevents generic or biosimilar applicants from relying on the pre-clinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar MA in the EU during a period of eight years from the date on which the reference product was first authorized in the EU. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until 10 years have elapsed from the initial MA of the reference product in the EU. The overall 10-year market exclusivity period can be extended to a maximum of eleven years if, during the first eight years of those 10 years, the MA holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. However, there is no guarantee that a product will be considered by the EU's regulatory authorities to be a new chemical entity, and products may not qualify for data exclusivity.

The aforementioned EU rules are generally applicable in the European Economic Area ("EEA") which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland.

Failure to comply with EU and member state laws that apply to the conduct of clinical trials, manufacturing approval, MA of medicinal products and marketing of such products, both before and after grant of the MA, manufacturing of pharmaceutical products, statutory health insurance, bribery and anti-corruption or with other applicable regulatory requirements may result in administrative, civil or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials, or to grant MA, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the MA, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties.

#### **Brexit and the Regulatory Framework in the United Kingdom**

The United Kingdom ("UK") left the EU on January 31, 2020, following which existing EU medicinal product legislation continued to apply in the UK during the 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 the 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. The TCA includes specific provisions concerning pharmaceuticals, which include the mutual recognition of GMP inspections of manufacturing facilities for medicinal products and GMP documents issued, but does not foresee wholesale mutual recognition of UK and EU pharmaceutical regulations.

EU laws which have been transposed into UK law through secondary legislation continue to be applicable as "retained EU law". However, new legislation such as the EU CTR 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 medicinal products and medical devices. This allows new rules to be introduced in the future by way of secondary legislation, which aims to allow flexibility in addressing regulatory gaps and future changes in the fields of human medicines, clinical trials and medical devices.

As of January 1, 2021, the Medicines and Healthcare products Regulatory Agency ("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 ("GB"); broadly, Northern Ireland will continue to follow the EU regulatory regime, but its national competent authority will remain the MHRA. The MHRA has published a guidance on how various aspects of the UK regulatory regime for medicines will operate in GB and in Northern Ireland following the expiry of the Brexit transition period on December 31, 2020. The guidance includes clinical trials, importing, exporting, and pharmacovigilance and is relevant to any business involved in the research, development, or commercialization of medicines in the UK. The new guidance was given effect via the Human Medicines Regulations (Amendment etc.) (EU Exit) Regulations 2019 (the "Exit Regulations").

The MHRA has introduced changes to national licensing procedures, including procedures to prioritize access to new medicines that will benefit patients, including a 150-day assessment and a rolling review procedure. All existing EU MAs for centrally authorized products were automatically converted or grandfathered into UK MAs, effective in GB (only), free of charge on January 1, 2021, unless the MA holder chooses to opt-out. In order to use the centralized procedure to obtain a MA that will be valid throughout the EEA, companies must be established in the EEA. Therefore after Brexit, companies established in the UK can no longer use the EU centralized procedure and instead an EEA entity must hold any centralized MAs. In order to obtain a UK MA to commercialize products in the UK, an applicant must be established in the UK and must follow one of the UK national authorization procedures or one of the remaining post-Brexit international cooperation procedures to obtain an MA to commercialize products in the UK.

There will be no pre-MA orphan designation. Instead, the MHRA will review applications for orphan designation in parallel to the corresponding MA application. The criteria are essentially the same, but have been tailored for the market, i.e., the prevalence of the condition in GB, rather than the EU, must not

be more than five in 10,000. Should an orphan designation be granted, the period of market exclusivity will be set from the date of first approval of the product in GB.

#### Human Capital Resources

As of February 15, 2022, we had 59 full-time employees, including 17 employees with M.D. or Ph.D. degrees. Of these full-time employees, 41 employees are engaged in research and development activities. None of our employees is represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

Our human capital resource priorities include attracting, recruiting, retaining, incentivizing and integrating our existing and new employees. The principal purpose of our competitive equity and cash compensation and benefits programs is to promote and support these priorities. We consider our human capital resources strategy to be comprehensive and built to foster our core way of working which is grounded on the principles of scientific rigor in a collaborative, entrepreneurial, and results-oriented manner. We plan to continue to evaluate our suite of human capital resources as we grow.

#### Organization

Atea Pharmaceuticals, Inc. was incorporated in July 2012 and began principal operations in March 2014. The Company is located in Boston, Massachusetts. Atea Pharmaceuticals Securities Corporation, a Massachusetts corporation incorporated in 2016, is a wholly owned subsidiary of Atea Pharmaceuticals, Inc.

#### Available Information

We file or furnish electronically with the Securities and Exchange Commission (the "SEC") our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements and other information, as well as amendments to those reports. These and other SEC filings are available to the public over the Internet at the SEC's website at <http://www.sec.gov>. We make available on our website at <https://ateapharma.com>, under "Investors," free of charge, copies of these reports as soon as reasonably practicable after filing or furnishing these reports with the SEC.

#### Information about our Executive Officers and Directors

The following table sets forth the name, age and position of each of our executive officers and directors as of the date of this Annual Report on Form 10-K.

Name	Age	Position
<b>Executive Officers</b>		
Jean-Pierre Sommadossi, Ph.D.	65	President and Chief Executive Officer and Chairman of the Board of Directors
Andrea Corcoran	59	Chief Financial Officer, Executive Vice President, Legal and Secretary
Janet Hammond, M.D., Ph.D.	61	Chief Development Officer
Maria Arantxa Horga, M.D.	53	Chief Medical Officer
John Vavricka	58	Chief Commercial Officer
Wayne Foster	53	Executive Vice President and Chief Accounting Officer
<b>Directors</b>		
Franklin Berger (1)(2)	72	Director (Lead Director)
Jerome Adams, M.D. (3)(4)	47	Director
Barbara Duncan (1)(3)	57	Director
Bruno Lucidi (1)(2)	62	Director
Polly A. Murphy, D.V.M., Ph.D. (3)(4)	57	Director
Bruce Polsky, M.D. (2)(4)	67	Director

(1) Member of the Audit Committee.

(2) Member of the Compensation Committee.

(3) Member of the Nominating and Corporate Governance Committee.

(4) Member of the Strategy and Public Policy Committee.

## Executive Officers

*Jean-Pierre Sommadossi, Ph.D.*, is the founder of our company and has served as our President and Chief Executive Officer and as Chairman of our Board since July 2012. Prior to that, he co-founded and held several roles at Idenix Pharmaceuticals, Inc., a biopharmaceutical company, from 1998 to 2010, including Principal Founder and Chief Executive Officer and Chairman. Dr. Sommadossi also co-founded Pharmasset, Inc., a biopharmaceutical company, in 1998. Dr. Sommadossi also serves on the board of directors of ABG Acquisition Corporation since February 2021 and as the Chairman of the board of directors of Kezar Life Sciences, Inc., a biopharmaceutical company, since June 2015, Chairman of the board of directors of Panchrest, Inc., a marketing authorized representative in healthcare, since 2013, Chairman of the board of directors of Biothea Pharma, Inc., a biotechnology company since 2021. Dr. Sommadossi also serves as a member of the board of directors of The BioExec Institute since 2004. Previously, Dr. Sommadossi served as Vice Chair of the board of directors of Rafael Pharmaceuticals, Inc., a biopharmaceutical company, from October 2016 to November 2020 and as Chair of the board of directors of PegaOne, Inc., a biopharmaceutical company from September 2020 to January 2021. Dr. Sommadossi also served as a member of the Harvard Medical School Discovery Council from 2010 to 2021. Dr. Sommadossi received his Ph.D. and Pharm.D. degrees from the University of Marseilles in France. We believe that Dr. Sommadossi's extensive scientific, operational, strategic and management experience in the biotech industry qualifies him to serve on our Board.

*Andrea Corcoran* has served as our Chief Financial Officer since October 2020, our Secretary since September 2014 and our Executive Vice President, Legal since December 2013. Ms. Corcoran also served as Executive Vice President, Administration from September 2014 to October 2020. Prior to joining us, Ms. Corcoran served as Senior Vice President, Strategy and Finance at iBio, Inc., a biotechnology company, from 2011 to 2012, as General Counsel and Secretary at Tolerx, Inc., a biopharmaceutical company, from 2007 to 2011, and as Executive Vice President of Idenix Pharmaceuticals, Inc. from 1998 to 2007. Ms. Corcoran received her J.D. from Boston College Law School and her B.S. from Providence College.

*Janet Hammond, M.D., Ph.D.*, has served as our Chief Development Officer since August 2020. Prior to joining us, Dr. Hammond served at AbbVie, Inc., a biopharmaceutical company, from November 2016 to August 2020 as Vice President and Therapeutic Area Head for General Medicine and Infectious Disease Development and at F. Hoffmann-La Roche from March 2011 to November 2016 as Senior Vice President, Global Head of Infectious Diseases and Head of Pharmaceutical Research and Early Development China. Dr. Hammond received her M.D. and Ph.D. from the University of Cape Town, South Africa, and her Sc.M. in Clinical Investigation from Johns Hopkins University School of Hygiene and Public Health.

*Maria Arantxa Horga, M.D.*, has served as our Chief Medical Officer since January 2021 and previously served as our Acting Chief Medical Officer since October 2020 and as Executive Vice President, Clinical Sciences since August 2020. Prior to joining us, Dr. Horga served as Vice President, Pharmacovigilance and Medical Affairs at Biohaven Pharmaceuticals from October 2019 to August 2020. Prior to that, Dr. Horga served as Vice President, Global Head of Clinical Program Execution, Site Head of the Roche NY Innovation Center from July 2017 to August 2019, and as Global Head of Translational Medicine, Infectious Diseases at F. Hoffmann-La Roche from 2012 to 2016. Dr. Horga received her M.D. from the Santander School of Medicine and completed her residency in Pediatrics and a fellowship in Pediatric Infectious Diseases at the Mount Sinai School of Medicine.

*John Vavricka* has served as our Chief Commercial Officer since October 2018. Prior to joining us, Mr. Vavricka cofounded and served as the Chief Executive Officer of Biothea Pharma, Inc., a biotechnology company, from March 2018 to June 2021. Prior to that Mr. Vavricka founded and served as the Chief Executive Officer and President of Iroko Pharmaceuticals, Inc., a global pharmaceuticals company, from 2007 to 2015. Mr. Vavricka received his B.S. from Northwestern University.

*Wayne Foster* has served as our Executive Vice President, Finance and Chief Accounting Officer since January 2022. Prior to that he was our Senior Vice President, Finance and Administration from December 2019 to January 2022. Before joining us, Mr. Foster served as Vice President of Finance at Mersana Therapeutics, Inc., a biopharmaceutical company, from January 2012 to September 2019. Mr. Foster received his B.B.A. from the University of Massachusetts Amherst.



## Directors

*Franklin Berger* has served as a member and the Lead Director of our Board since September 2019. Mr. Berger has served as Founder and Managing Director at FMB Research LLC, a consulting firm, since June 2005. Mr. Berger also serves on the boards of directors of BELLUS Health, Inc. since May 2010, ESSA Pharma Inc. since March 2015, Kezar Life Sciences, Inc. since January 2016, Atreca Inc. since October 2014 and Rain Therapeutics Inc. since May 2020. Mr. Berger previously served on the boards of directors of Tocagen, Inc. from October 2014 to December 2020, of Proteostasis Therapeutics, Inc. from February 2016 to December 2020, and of Five Prime Therapeutics, Inc. from October 2014 to April 2021. Mr. Berger received his B.A. and M.A. from Johns Hopkins University and his M.B.A. from Harvard Business School. We believe that Mr. Berger's financial background and experience as an equity analyst in the biotechnology industry combined with his experience serving on the boards of directors of multiple public companies qualifies him to serve on our Board.

*Jerome Adams, M.D.*, has served as a member of our Board since May 2021. Dr. Adams also serves as Director of Health Equity Initiatives at Purdue University since October 2021. Dr. Adams served as the 20th Surgeon General of the United States from September 2017 to January 2021, where he focused on the opioid epidemic and was a member of the COVID-19 Task Force. Prior to that, Dr. Adams served as the State Health Commissioner for the State of Indiana from November 2014 to September 2017, where he presided over Indiana's efforts to deal with state-wide, unprecedented HIV outbreak. Dr. Adams was a practicing anesthesiologist and Associate Professor in the Department of Anesthesiology at Indiana University from January 2008 to until September 2017. Earlier in his career, Dr. Adams was a Clinical Research Assistant at Eli Lilly and Company. He has served in leadership positions at a number of professional organizations, including the American Medical Association, the Indiana State Medical Association, and the Indiana Society of Anesthesiologists. Dr. Adams received his B.S. in Biochemistry and B.A. in Psychology from the University of Maryland, Baltimore County, his M.D. from the Indiana University School of Medicine and his M.P.H. from the University of California, Berkeley. We believe that Dr. Adams' extensive public sector experience, including his work on the COVID-19 Task Force, qualifies him to serve on our board.

*Barbara Duncan* has served as a member of our Board since October 2020. Ms. Duncan served at Intercept Pharmaceuticals, Inc. as Chief Financial Officer and Treasurer from May 2009 to June 2016. Ms. Duncan also serves as Chair of the board of directors of Fusion Pharmaceuticals Inc. since November 2020, on the board of directors of Jounce Therapeutics, Inc. since June 2016, Adaptimmune Therapeutics plc since June 2016, and Ovid Therapeutics, Inc. since June 2017. Previously, Ms. Duncan served on the boards of directors of Immunomedics, Inc. from March 2019 to October 2020, Innoviva, Inc., from November 2016 through April 2018, Aevi Genomic Medicine, Inc., from June 2015 through January 2020, and ObsEva S.A. from November 2016 to May 2021. Ms. Duncan received her B.A. from Louisiana State University and her M.B.A. from the Wharton School, University of Pennsylvania. We believe Ms. Duncan is qualified to serve on our Board due to her experience in the biotechnology industry and with public companies.

*Bruno Lucidi* has served as a member of our Board since September 2014. Mr. Lucidi has served as an independent consultant to biotechnology companies since July 2013. Mr. Lucidi served as a Life Sciences Expert at Wallonia Trade and Foreign Investment Agency, an economic development agency, from January 2017 to June 2020. From October 2017 to September 2019, Mr. Lucidi was Chief Executive Officer at AgenTus Therapeutics, a pre-clinical stage biopharmaceutical company. Mr. Lucidi was trained in Oncology at the Gustave Roussy Institute, Villejuif, France, in Marketing and Strategic Management of Companies at the Ecole Supérieure de Commerce, Paris, France, and in Finance, Merger and Acquisitions at the Investment Banking Institute in New York. We believe Mr. Lucidi is qualified to serve on our Board due to his extensive experience in the life sciences industry.

*Polly A. Murphy, D.V.M., Ph.D.* has served as a member of our Board since August 2020. Dr. Murphy has served as Chief Business Officer at UroGen Pharma, Inc. since August 2020. Prior to that, Dr. Murphy served in various leadership roles at Pfizer, Inc. from September 2012 to August 2020, including as Vice President and Head of Commercial Development Pfizer Oncology Business Unit from January 2019 to August 2020, Vice President and Head of Global Marketing and Commercial Development Pfizer Oncology Business Unit from June 2017 to December 2018, and as Vice President and Head of Strategy

and Business Development for Pfizer China from November 2013 to May 2018. Dr. Murphy received her D.V.M. and Ph.D. from Iowa State University. We believe Dr. Murphy is qualified to serve on our Board due to her experience in the pharmaceutical industry in business development and commercialization.

*Bruce Polsky, M.D.*, has served as a member of our Board since November 2014. Dr. Polsky is the chair of the Department of Medicine at NYU Langone Hospital – Long Island in Mineola, New York, where he has practiced since May 2015. He also serves as professor and Chair of the Department of Medicine at NYU Long Island School of Medicine and as an Associate Dean at NYU Long Island School of Medicine since February 2019. Dr. Polsky is a leading clinical virologist who played an active role in clinical investigations of HIV/AIDS, HBV, HCV and other viral infections. From December 1998 to May 2015, Dr. Polsky was at Mount Sinai St. Luke's and Mount Sinai Roosevelt Hospitals, where he served as Chair of the Department of Medicine and as Chief of the Division of Infectious Diseases, among other positions. Dr. Polsky received his M.D. from Wayne State University. We believe Dr. Polsky is qualified to serve on our Board due to his extensive clinical experience in the life sciences industry.

**Item 1A. Risk Factors.**

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

**Risks Related to COVID-19**

***There is significant uncertainty around our development of bempifosbuvir (AT-527) as a potential treatment for COVID-19 as we transition from developing bempifosbuvir as a monotherapy to development in combination with other drugs or drug candidates.***

Our development of bempifosbuvir for the treatment of COVID-19 is in its early stages, and we may not be successful in our development of bempifosbuvir 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 bempifosbuvir, outside of the United States (other than for certain HCV uses). Together with Roche, in April 2021, we initiated a Phase 3 clinical trial to study bempifosbuvir in adult 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 bempifosbuvir 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 bempifosbuvir in patients with COVID-19 were ongoing. One of these Phase 2 clinical trials enrolled hospitalized patients and the other Phase 2 clinical trial (MOONSOONG) 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 meaningful statistical analyses. In January 2022 we determined to close out the Phase 2 clinical trial in hospitalized patients. As a result, we do not expect to receive or report any additional results from this Phase 2 clinical trial in hospitalized patients

beyond our prior interim analyses and subsequent analysis of samples derived from patients who were included in the interim analysis.

Currently we are focusing our COVID-19 development efforts on the advancement of a potential combination therapy. The initial regimen we are seeking to advance is a combination of bemnifosbuvir and a protease inhibitor. We do not know whether this combination of bemnifosbuvir with a protease inhibitor will produce a synergistic benefit or otherwise lead to positive outcomes for the patients we are seeking to treat. In addition, clinical trials evaluating combination regimens will be 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 not yet developed a protease inhibitor to evaluate in combination with bemnifosbuvir. Although we have begun efforts to discover a protease inhibitor utilizing our internal discovery capabilities, 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 would be allowed to enter clinical trials. 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 product candidates 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.

We have committed significant financial and personnel resources to the development of bemnifosbuvir and we plan to continue to commit significant financial and personnel resources towards the development of a combination of bemnifosbuvir with an agent with a different mechanism of action (together, a "bemnifosbuvir COVID-19 combination") as a potential treatment for COVID-19. If we are unable to successfully develop a bemnifosbuvir COVID-19 combination for the treatment of COVID-19, we will have taken resources away from other development programs and will not be able to recuperate the resources dedicated to developing a bemnifosbuvir COVID-19 combination as a potential treatment for COVID-19, which could have a material adverse impact on our business. If we are able to initiate preclinical or clinical development of the bemnifosbuvir COVID-19 combination and the data from our preclinical studies or clinical trials are not supportive of further development of such bemnifosbuvir COVID-19 combination as a treatment for COVID-19, 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 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 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 COVID-19 combination, if successfully developed and approved, our business could be adversely impacted.

***A bemnifosbuvir COVID-19 combination, even if successfully developed and approved, may 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, 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 molnupiravir 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

are currently seeking 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 for the treatment of COVID-19 for certain patients requiring hospitalization and sotrovimab, a monoclonal antibody for the treatment of high risk adults and adolescents with mild to moderate COVID-19 for which VIR Biotechnology, Inc. and GlaxoSmithKline have received emergency use authorization from the FDA for certain COVID-19 therapeutics. In addition to therapeutics, vaccines indicated for active immunization to prevent COVID-19 have been authorized by the FDA. In August 2021, the FDA approved vaccines from Pfizer and BioNTech and Moderna, Inc. ("Moderna"), each of which were found to be more than 90% effective in preventing COVID-19 during clinical trials. In addition, in February 2021, the FDA granted emergency use authorization to a vaccine developed by Janssen Pharmaceutical Company ("Janssen") Each of Pfizer and BioNTech, Moderna and Janssen 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. 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, we may not be able to successfully commercialize a bempifosbuvir COVID-19 combination for the treatment of COVID-19, even if approved, 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.***

In December 2019, SARS-CoV-2 surfaced in China. Since then, COVID-19 has spread globally. The recent global emergence of variants of SARS-CoV-2, including the Delta and Omicron variants, 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, have 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 continuation or renewal of previously relaxed measures 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. 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 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 production of our product candidates, and our ability to raise capital.

**The COVID-19 pandemic may materially and adversely affect our clinical trials.**

As a result of the COVID-19 pandemic, 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, 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 outbreak 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.

SARS-CoV-2 is a novel pathogen that has evolved rapidly since its identification in December 2019 with more than six million variants being identified as of February 20, 2022 of which seven have been designated by the World Health Organization as either variants of concern or interest. 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 bempifosbuvir or are consistent with the underlying disease. Any increase in the severity or incidence of adverse events deemed to be related to bempifosbuvir 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 commercial-scale product, 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, we are transitioning our strategy for developing bemnifosbuvir to treat patients with COVID-19 from a monotherapy approach to a combination therapy approach. As a result, we discontinued our Phase 3 monotherapy trial. We expect that the development of any proposed combination therapy will require us 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 do not anticipate receiving 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 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 years ended December 31, 2021 and December 31, 2020, our operating expenses were \$213.0 million and \$59.7 million, respectively. Prior to the quarter ended March 31, 2021, we had incurred significant operating losses. 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. We do not expect to maintain operating income in 2022 and 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 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 new product candidates, acquire or in-license a drug or drug candidate for our bemnifosbuvir COVID-19 combination, 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 achieve profitability. Our expenses will also increase substantially if or as we:

- initiate clinical trials of our most advanced product candidate, bemnifosbuvir in combination with another agent 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 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 Merck License Agreement 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 and as a result of becoming, as of December 31, 2021, a large accelerated filer.

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 may incur operating losses in 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 continue to incur substantial expenses to continue the clinical development of bennifosbuvir COVID-19 combination for the treatment of COVID-19, the combination of bennifosbuvir and ruzasvir for the treatment of HCV and AT-752 for the treatment of dengue for future clinical trials for other product candidates and to continue to identify new product candidates.

We will continue to need additional capital to fund future clinical trials and preclinical development, which we may raise through equity offerings, debt financings, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or other sources. Additional sources of financing might not be available on favorable terms, if at all. If we do not succeed in raising additional funds on acceptable terms, we might be unable to initiate or complete planned clinical trials or seek regulatory approvals of any of our product candidates from the FDA, or any foreign regulatory authorities, and could be forced to discontinue product development. In addition, attempting to secure additional financing 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 December 31, 2021 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 bennifosbuvir and develop for the treatment of patients with COVID-19
- the scope, progress, results and costs of our preclinical studies and clinical trials;



- 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 and timing of changes in pharmaceutical pricing and reimbursement infrastructure;
- 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. 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 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 may 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 clinical trials of bemnifosbuvir, AT-752 and ruzasvir, 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 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 expect to utilize federal and state research and development credit carryforwards of \$0.7 million and \$0.3 million, respectively during the year ended December 31, 2021. As of December 31, 2021, we had federal NOLs of \$0.4 million which may be available to offset future taxable income, if any.

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.

We performed an analysis through December 31, 2020 pursuant to Section 382 of the Code to determine whether any limitations might exist on the utilization of NOLs and other tax attributes. Based on this analysis, we have determined that ownership changes occurred in 2014. In addition, based on publicly available statements of acquisition of beneficial ownership, we identified an ownership change on December 31, 2021 which did not have an impact on our consolidated financial statements. We are in the

process of completing a Section 382 study for the fiscal year 2021, the results of which could indicate that the ownership shift occurred prior to December 31, 2021. 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 identify and develop a bempifosbuvir COVID19 combination product candidate for the treatment of COVID-19. If we are not successful in identifying and developing a bempifosbuvir COVID19 combination product candidate, our business will be harmed. Our business is also highly dependent on the success of our most advanced product candidates, including the combination of bempifosbuvir and rusazvir 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 identify and develop a bempifosbuvir COVID19 combination product candidate for the treatment of COVID-19 and to develop, obtain regulatory approval for and successfully commercialize the combination of bempifosbuvir and rusazvir for the treatment of HCV. We currently have no products that are approved for commercial sale and have not completed the development of any of our product candidates, and we may never be able to develop marketable products. We expect that a substantial portion of our efforts and expenditures will be devoted to identifying and developing a potential bempifosbuvir COVID19 combination product candidate for the treatment of COVID-19, which will require preclinical and clinical development and expenses related to discovering, acquiring or in-licensing a drug or drug candidate to combine with bempifosbuvir. 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 bempifosbuvir and rusazvir for the treatment of HCV and AT-752 for the treatment 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, a Phase 2 clinical trial evaluating bempifosbuvir for the treatment of mild-to-moderate 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. For example, we first advanced the development of bempifosbuvir as a potential monotherapy treatment for COVID-19 to Phase 3 clinical trial development before refocusing our efforts on the development of bempifosbuvir combination regimens for the treatment of patients with COVID-19, which has required us to re-start our clinical development of bempifosbuvir in this indication.

If our competitors develop products to treat diseases 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. If we are not successful in the clinical development of our most advanced product candidates or in identifying and developing a bempifosbuvir COVID-19 combination 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 or our collaborators' 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 is lengthy and uncertain. 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, and the outcome of preclinical studies and early-stage clinical trials may not be predictive of the success of later clinical trials. This is particularly true in the development of therapeutics for the treatment of COVID-19, 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, are often susceptible to varying interpretations, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their drugs. To date, we have not completed any late-stage or pivotal clinical trials for any of our product candidates. We cannot guarantee that any of our planned or ongoing clinical trials will be initiated or conducted as planned or completed on schedule, if at all. We also cannot be sure that submission of any future IND or similar application will result in the FDA or other regulatory authority, as applicable, allowing future clinical trials to begin in a timely manner, if at all. Moreover, even if these trials begin, issues may arise that could cause regulatory authorities to suspend or terminate such clinical trials. A failure of one or more clinical trials can occur at any stage of testing, and our future clinical trials may not be successful. Events that may prevent successful or timely initiation or completion of clinical trials include but are not limited to:

- inability to generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation or continuation of clinical trials;
- delays in reaching a consensus with regulatory authorities on study design or implementation of the clinical trials;
- delays or failure in obtaining regulatory authorization to commence a 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, 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, and availability of an increasing number of therapeutic options, may impact the initiation or successful completion of clinical trials.

Any inability to successfully initiate or complete 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 expect to continue doing for our 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 development 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 closes 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.***

We intend to develop a becnifosbuvir COVID-19 combination, which we expect will combine becnifosbuvir with a protease inhibitor for the treatment of COVID-19. Even if any product candidate we develop was to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to bear the risks that the FDA or similar foreign regulatory authorities could revoke approval of the therapy used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. Combination therapies are commonly used for the treatment of viral infections, and we would be subject to similar risks if we develop any of our product candidates for use in combination with other drugs or biologics or for indications other than COVID-19. Developing combination therapies using approved therapeutics, as we may decide to do for our product candidates, also 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.

In addition, we also intend to evaluate becnifosbuvir 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.

***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 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 bempifosbuvir COVID-19 combination, bempifosbuvir in combination with ruzsazvir and AT-752, 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 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 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 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.***

We may seek an EUA from the FDA or comparable emergency use authorizations from other foreign regulatory authorities with respect to our COVID-19 product candidate. The FDA has the authority to issue an EUA 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.

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 one or more of our product candidates, we may be required to conduct additional clinical trials before we are able to submit NDAs or comparable marketing applications for such product candidates.

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 we obtain an EUA or other emergency authorizations for one or more of our product candidates, it is possible that such EUA or other authorizations may be revoked and we may be required to cease any commercialization activities, which 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 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 oral antivirals have been recently 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, such as the EMA following its relocation to Amsterdam and resulting staff changes, 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 announced its intention to postpone most inspections of foreign manufacturing facilities, and on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic 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 May 2021, the FDA outlined a detailed plan to move toward a more consistent state of inspectional operations, and in July 2021, the FDA resumed standard inspectional operations of domestic facilities and was continuing to maintain this level of operation as of September 2021. 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.

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 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 will 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 system failures, deficiencies or intrusions which could materially affect our results.***

Our computer systems, as well as those of our CROs and other contractors and consultants, are vulnerable to failure or 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 and infrastructure 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. 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.

If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product candidate development programs. For example, the loss of preclinical studies or clinical trial data from completed, ongoing or planned studies or 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. Although, to our knowledge, we have not experienced any such material security breach to date, any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen.

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 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 regulate 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 for a given product and its uses. 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 obtain marketing approval of and 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, in which manufacturers must 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;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- extension of a manufacturer's Medicaid rebate liability to covered 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. Prior to the Supreme Court's decision, President Biden issued an executive order to initiate a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began on February 15, 2021 and remained open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how other healthcare reform measures of the Biden administration will impact our business.

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 included aggregate reductions of Medicare payments to providers of 2% per fiscal year, effective April 1, 2013 which, due to subsequent legislative amendments, will stay in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, unless additional congressional action is taken. In addition, in January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Additionally, the orphan drug tax credit was reduced as part of a broader tax reform. These new laws or any other similar laws introduced in the future may result in additional reductions in Medicare and other healthcare funding, which could negatively affect our customers and accordingly, our financial operations.

Moreover, payment methodologies may be subject to 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.

In addition, 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, including, in the United States, HIPAA, and, in the EU, Regulation 2016/679, known as the General Data Protection Regulation (the "GDPR"). 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. In the event that we are subject to or affected by HIPAA, GDPR, the CCPA, the CPRA or other domestic or foreign 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 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 from 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 launched a public consultation on its draft revised data transfers mechanisms in August 2021. 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, and remains under review by the European Commission during this period. 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.

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

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

Most healthcare providers in the US, including research institutions from which we obtain patient health information, are subject to privacy and security regulations promulgated under HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act. We do not believe that we are currently acting as a covered entity or business associate under HIPAA and thus are not directly subject to its requirements or penalties. However, any person may be prosecuted under HIPAA's criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information. Even when HIPAA does not apply, according to the Federal Trade Commission (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 may maintain sensitive personally identifiable information, including health 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.

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 local 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 compounds 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 is an increasing number of therapeutics becoming available for the treatment of COVID-19 including two oral antiviral therapies. There are also several drugs 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. 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, for at least as long as the public health emergency declared by the Secretary of HHS in March 2020 at the outset of the COVID-19 pandemic continues, we currently expect the U.S. federal government will be the primary and perhaps exclusive purchaser of therapeutics for the treatment of COVID-19. Even if we succeed in developing a bennifosbuvir COVID-19 combination, we may not be able to compete effectively if bennifosbuvir COVID-19 combination or our other product candidates do not satisfy government procurement requirements and our future results of operations may be adversely impacted if government procurement needs for such product candidates decline due to over-saturated supply or reduced patient demand.

***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 our product candidates 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.

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 many 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 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, we have only recently begun to manufacture ruzasvir, the product candidate we licensed from Merck in December 2021. 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 bempifosbuvir and ruzasvir.

We rely and expect to continue 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;
- 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;
- 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.

In particular, we have relied on third parties located in China to manufacture and supply certain materials for our current product candidates, and 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 and commercialize our product candidates successfully.

***We do not have multiple sources of supply for some 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 each of the components used in the manufacturing of bemnifosbuvir, AT-752 or ruzasvir or any of our other product candidates. For each of our product candidates, we have sole suppliers located in China for our active pharmaceutical ingredients. 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 preclinical studies and 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 bennifosbuvir 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 bennifosbuvir, including global manufacture of clinical trial material and certain operations necessary for the conduct of clinical trials, ceased. To the extent that such activities are necessary for the continued development of a bennifosbuvir COV19 combination, we will be responsible for the conduct and costs 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 Merck License Agreement 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 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 manufacturers' 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 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 AT-752), AT-752, AT-777, AT-787, 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 bennifosbuvir. The Observation generally challenges the patentability of the hemisulfate salt bennifosbuvir over the free

base AT-511. On August 1, 2019, we filed a response to the Observation describing that the bennifosbuvir hemisulfate salt of AT-511 is not obvious in view of the AT-511 free base because bennifosbuvir 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 bennifosbuvir 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 bennifosbuvir. The anonymous party asserted that it would have been obvious that the hemisulfate salt of AT-511 (bennifosbuvir) 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 bennifosbuvir 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 bennifosbuvir. 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.

***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 bempifosbuvir, our ability to successfully commercialize bempifosbuvir 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 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 organization, 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;
- managing our internal development efforts effectively, including the clinical and FDA review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; 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 February 15, 2022, we had 59 full-time employees. Our focus on the 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 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. If the equity and credit markets deteriorate, including as a result of a resurgence of COVID-19, political unrest or war, it 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 U.K. 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 U.K. 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 Trade and Cooperation Agreement 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 February 28, 2022. Therefore, these stockholders will 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 could become a party to foreign opposition proceedings, such as at the EPO, or patent litigation and other proceedings in a foreign court. 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. 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. In 2021, extreme fluctuations occurred in our stock price with closing prices 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 \$5.80 on February 23, 2022.

The stock market in general, The Nasdaq Global Select Market and biopharmaceutical companies in particular have experienced extreme volatility in trading volume that 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; 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 will 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, and particularly now that we are no longer an emerging growth company, we will incur 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"), in this second annual report filed with the SEC after becoming a public company, we are required to furnish a report by our management on our internal control over financial reporting. 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 is required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 in this Annual Report

on Form 10-K for the year ending December 31, 2021. 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 1B. Unresolved Staff Comments.**

Not applicable.

**Item 2. Properties.**

Our principal office is located at 125 Summer Street, Boston, Massachusetts, where we lease 5,634 square feet of office space. We lease this space under a lease agreement, as amended, that terminates on July 31, 2022. On July 19, 2021, we entered into a sublease pursuant to which we have leased additional office space in Boston, Massachusetts. The term of the Sublease commenced on January 1, 2022 and will end on December 31, 2026. We believe that our facilities are sufficient to meet our current needs and that suitable additional space will be available as and when needed.

**Item 3. Legal Proceedings.**

We are not subject to any material legal proceedings.

**Item 4. Mine Safety Disclosures.**

Not applicable.

**Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.****Certain Information Regarding the Trading of Our Common Stock**

Our common stock has been listed on The NASDAQ Global Select Market under the symbol "AVIR" since October 30, 2020.

**Holders of Our Common Stock**

As of February 25, 2022 there were 23 stockholders of record of our common stock, which does not reflect stockholders whose shares were held in nominee or street name by brokers.

**Dividends**

We have never declared or paid any cash dividends on our common stock. We currently intend to retain all available funds and any future earnings to fund the development and expansion of our business, and therefore do not anticipate paying cash dividends in the foreseeable future. Any future determination to pay dividends will be at the discretion of our board of directors and will depend on our financial condition, results of operations, capital requirements, business prospects, contractual arrangements, any limitations on payment of dividends present in any future debt agreements and other factors that our board of directors may deem relevant, and will be subject to the restrictions contained in any future financing instruments.

**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 net proceeds from our IPO have been invested primarily in money market accounts. 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.

**Stock Performance Graph**

The performance graph compares the performance of our common stock to the S&P 500 Index and to the Nasdaq Biotechnology Index from October 30, 2020 (the first date that shares of our common stock were publicly traded) through December 31, 2021. The comparison assumes \$100 was invested in our common stock and in each of the foregoing indices after the market closed on October 30, 2020, and it assumes reinvestment of dividends, if any. The stock price performance included in this graph is not necessarily indicative of, nor is it intended to forecast, future stock price performance



The following performance graph and related information is furnished and shall not be deemed to be "soliciting material" or to be "filed" with the SEC for purposes of Section 18 of the Exchange Act, nor shall such information be deemed incorporated by reference into any filings under the Exchange Act or the Securities Act, except to the extent that we specifically incorporate it by reference into such filing.

The following table shows the high and low closing prices for our common stock as reported by The NASDAQ Global Select Market for the quarterly periods in the years ended December 31, 2020 (since October 30, 2020) and December 31, 2021:

	<b>2020</b>	
	<b>High</b>	<b>Low</b>
Fourth Quarter 2020 (beginning October 30, 2020)	\$ 41.78	\$ 26.36
	<b>2021</b>	
	<b>High</b>	<b>Low</b>
First Quarter 2021	\$ 88.44	\$ 41.42
Second Quarter 2021	\$ 59.08	\$ 19.22
Third Quarter 2021	\$ 35.06	\$ 21.33
Fourth Quarter 2021	\$ 44.59	\$ 7.67

**Item 6. Reserved**



## Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

*The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and the related notes to those statements included elsewhere in this Annual Report on Form 10-K. In addition to historical financial information, the following discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results and timing of selected events may differ materially from those anticipated in these forward-looking statements as a result of many factors, including those discussed in Part I, Item 1A, "Risk Factors" and elsewhere in this Annual Report on Form 10-K. See "Special Note Regarding Forward-Looking Statements."*

### Overview

We are a clinical-stage biopharmaceutical company focused on discovering, developing and commercializing antiviral therapeutics to improve the lives of patients suffering from difficult to treat, life-threatening viral infections. Our current focus is on the development of product candidates to treat COVID-19, hepatitis C virus ("HCV"), dengue and respiratory syncytial virus ("RSV").

#### COVID 19 – Bepnifosbuvir Combination Regimen

Our most advanced product candidate for the treatment of COVID-19 is bepnifosbuvir, an investigational, novel, orally administered guanosine nucleotide analog polymerase inhibitor which we believe could be a preferred backbone for an oral combination regimen. Bepnifosbuvir 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. As we anticipate continued rapid emergence and evolution of viral variants together with the potential for viral drug resistance to single agent therapies which could render previously effective monotherapy obsolete, we have prioritized the development of bepnifosbuvir as combination therapy for the treatment of COVID-19.

We do not know whether this combination of bepnifosbuvir with a protease inhibitor will produce a synergistic benefit or otherwise lead to positive outcomes for the patients we are seeking to treat. We have not yet developed a protease inhibitor to evaluate in combination with bepnifosbuvir. Although we have begun efforts to discover a protease inhibitor utilizing our internal discovery capabilities, 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 would be allowed to enter clinical trials. Alternatively, we may in-license or acquire the rights to develop and commercialize a protease inhibitor drug candidate from a third party.

#### HCV – Bepnifosbuvir in combination with ruzasvir

For the treatment of chronic HCV infection, we are advancing a novel combination of bepnifosbuvir and ruzasvir, an investigational nonstructural protein 5A ("NS5A") inhibitor that we exclusively in-licensed from Merck in December 2021. As single agents, both bepnifosbuvir and ruzasvir have demonstrated potent pan-genotypic antiviral activity against HCV. As ruzasvir is a Phase 2-ready NS5A inhibitor that has already been evaluated by Merck in over 1,200 HCV-infected patients, we have prioritized clinical development of the ruzasvir/bepnifosbuvir combination program over the AT-777/AT-787 programs (AT-777 being our prior lead NS5A inhibitor program which was paused at the outset of the COVID-19 pandemic given industry-wide challenges in conducting clinical studies at that time).

#### 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 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.

#### **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 AT-527 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 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.

#### **IPO**

On November 3, 2020, we completed the initial public offering of our common stock (the "IPO"). In connection with the IPO, we issued 14,375,000 shares of common stock at \$24.00 per share for net proceeds of \$317.6 million after deducting underwriting discounts and commissions and offering expenses. Upon closing of the IPO, all then-outstanding shares of our former convertible preferred stock converted into 57,932,090 shares of common stock.

#### **COVID 19 Update**

While we believe there is currently an urgent need for 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 and the endemic does not result, whether due to a significant decrease in 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 combination, if successfully developed and approved, our business could be adversely impacted.

#### **Financial Operations Overview**

As of December 31, 2021, we had cash and cash equivalents of \$764.4 million. Net cash used in operating activities was \$87.0 million for the year ended December 31, 2021. 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 expect to incur additional costs as we continue to operate as a public company, particularly now that we have become a large accelerated filer as of December 31, 2021. 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.

We expect to continue 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 bennifosbuvir for the treatment of COVID-19;
- continue clinical development of AT-752 for the treatment of dengue;
- initiate clinical development of bennifosbuvir and ruzasvir for the treatment of HCV;
- continue IND-enabling activities and commence clinical development activities for product candidates for the treatment of RSV;
- maintain, expand, protect and enforce our intellectual property portfolio;
- hire additional research, development and general and administrative personnel;
- establish commercialization capabilities; and
- incur additional costs as we continue to operate as a public company, particularly now that we are a large accelerated filer as of December 31, 2021.

#### **Components of Results of Operations**

##### **Revenue**

We do not have any products approved for sale and to date, we have not generated any revenue from product sales.

Our revenue has been collaboration revenue solely derived from the Roche License Agreement, which became effective in October 2020 and terminated on February 10, 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 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, facility costs, including depreciation. 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 consolidated financial statements included elsewhere in this annual report on Form 10-K, during the term of the Roche License Agreement from October 2020 through its termination, effective 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 are recorded in research and development expenses. These costs represent a material portion of our total expenses. Subsequent to the termination, we will be liable to Roche for the cost of activities associated with Roche's transfer of certain information to us.

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

	Years Ended December 31,		
	2021	2020	2019
	(in thousands)		
COVID-19 external costs	\$ 93,508	\$ 23,043	\$ —
Dengue external costs	9,396	2,167	768
HCV external costs	27,514	1,831	5,837
RSV external costs	1,887	1,127	1,379
Internal research and development costs	34,900	9,855	2,186
Total research and development expenses	<u>\$ 167,205</u>	<u>\$ 38,023</u>	<u>\$ 10,170</u>

We are focusing substantially all of our resources on the development of our product candidates, particularly benvifosbuvir. 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 and higher consulting, legal and accounting services costs associated with complying with Nasdaq and SEC requirements, investor relations costs and director and officer insurance premiums associated with being a public company.

#### Interest Income and Other, Net

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

#### Income Taxes

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

## Results of Operations

### Comparison of the Years Ended December 31, 2021 and 2020

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

	Years Ended December 31,		Change
	2021	2020	
	(in thousands)		
Collaboration revenue	\$ 351,367	\$ 48,633	\$ 302,734
Operating expenses:			
Research and development	167,205	38,023	129,182
General and administrative	45,785	21,640	24,145
Total operating expenses	212,990	59,663	153,327
Income (loss) from operations	138,377	(11,030)	149,407
Interest income and other, net	213	83	130
Income (loss) before income taxes	138,590	(10,947)	149,537
Income taxes	17,400	—	17,400
Net income (loss) and comprehensive income (loss)	\$ 121,190	\$ (10,947)	\$ 132,137

#### Revenue

Collaboration revenue for the years ended December 31, 2021 and 2020 was derived from the Roche License Agreement that was executed in October 2020. See Note 3 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for a description of the accounting treatment of the Roche License Agreement, including recognition of all remaining deferred revenue following receipt of the termination notice from Roche.

#### Research and Development Expenses

Research and development expenses increased by \$129.2 million from \$38.0 million for the year ended December 31, 2020 to \$167.2 million for the year ended December 31, 2021. The increase in research and development expenses was primarily due to a \$104.1 million increase in external expenses incurred related to CRO and CMO services in connection with the advancement of product candidates for the treatment of COVID-19, HCV and dengue, including \$76.6 million related to our share of costs incurred by Roche and a \$25.0 million charge related to the upfront payment for the license agreement with Merck. In addition, there was an increase of \$25.0 million in internal spend primarily due to an increase in personnel-related expenses, including salaries and bonuses, benefits and stock-based compensation expense of \$14.6 million for our research and product development employees and consulting fees, and \$2.4 million in other research and development expenses. Research and development expenses include a reduction of \$7.3 million representing a reimbursement of Roche's share of certain expenses incurred that are subject to ASC 808 as discussed in Note 3 to our audited consolidated financial statements included elsewhere in this annual report on Form 10-K.

#### General and Administrative Expenses

General and administrative expenses increased by \$24.1 million from \$21.6 million for the year ended December 31, 2020 to \$45.8 million for the year ended December 31, 2021. The increase in general and administrative expenses was primarily due to the expansion of our organization and reflected an increase of \$20.6 million in payroll and personnel-related expenses, including salaries, benefits and stock-based compensation expense of \$17.6 million; an increase in professional fees of \$2.6 million; and an increase in other general and administrative expenses of \$0.9 million.

#### Interest Income and Other, Net

Interest income and other, net, increased by \$0.1 million for the year ended December 31, 2021 compared to the year ended December 31, 2020, primarily due to higher balances of cash equivalents.

### Income Taxes

Income taxes were \$17.4 million and \$0 million for the years ended December 31, 2021 and 2020, respectively. The effective tax rate for the years ended December 31, 2021 and 2020 was 12.5% and 0%, respectively. The increase in income tax expense was primarily due to revenue recognized in 2021 from our former collaboration with Roche.

### Comparison of the Years Ended December 31, 2020 and 2019

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

	Years Ended December 31,		Change
	2020	2019	
	(in thousands)		
Collaboration revenue	\$ 48,633	\$ —	\$ 48,633
Operating expenses:			
Research and development	38,023	10,170	27,853
General and administrative	21,640	4,438	17,202
Total operating expenses	59,663	14,608	45,055
Loss from operations	(11,030)	(14,608)	3,578
Interest income and other, net	83	574	(491)
Net loss	\$ (10,947)	\$ (14,034)	\$ 3,087

### Revenue

Collaboration revenue for the year ended December 31, 2020 was derived from the Roche License Agreement that was executed in October 2020. See Note 3 to our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K for a description of the accounting treatment of the Roche License Agreement.

### Research and Development Expenses

Research and development expenses increased by \$27.8 million from \$10.2 million for the year ended December 31, 2019 to \$38.0 million for the year ended December 31, 2020. The increase in research and development expenses was primarily due to a \$20.2 million increase in external expenses incurred related to CRO and CMO services in connection with the advancement of product candidates for the treatment of COVID-19 and dengue, partially offset by a decrease in external spend related to our HCV and RSV programs and an increase of \$6.5 million in internal spend primarily due to an increase in personnel-related expenses, including salaries and bonuses, benefits and stock-based compensation expense of \$3.3 million for our research and product development employees and consulting fees, and \$1.1 million in other research and development expenses. Research and development expenses include a reduction of \$7.9 million representing Roche's share of certain expenses incurred that are subject to ASC 808 as discussed in Note 3 to our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K. We also recorded research and development expense of \$2.1 million relating to our share of costs incurred by Roche.

### General and Administrative Expenses

General and administrative expenses increased by \$17.2 million from \$4.4 million for the year ended December 31, 2019 to \$21.6 million for the year ended December 31, 2020. The increase in general and administrative expenses was primarily due to the expansion of our organization and reflected an increase of \$5.8 million in payroll and personnel-related expenses, including salaries, benefits and stock-based compensation expense of \$3.5 million; professional fees of \$10.0 million including \$7.0 million paid in connection with Roche License Agreement, and an increase in other general and administrative expenses of \$1.4 million.

### Interest Income and Other, Net

Interest income and other, net, decreased by \$0.5 million for the year ended December 31, 2020 compared to the year ended December 31, 2019, primarily due to lower interest rates.

## Liquidity and Capital Resources

### Sources of Liquidity

As of December 31, 2021, we had cash and cash equivalents of \$764.4 million. We believe that our available cash and cash equivalents will be sufficient to fund our planned operations through at least 2025.

### 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 for and commercialize any of our product candidates and we do not know when, or if, this will occur. 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. We are subject to all of the risks typically related to the development of new product candidates, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. Moreover, we expect to incur additional general and administrative costs as we continue to operate as a public company, particularly now that we are a large accelerated filer as of December 31, 2021.

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.

In November 2021, we entered into a sales agreement (the "Sales Agreement") with Jefferies LLC ("Jefferies"), pursuant to which we may from time to time offer and sell shares of our common stock for an aggregate offering price of up to \$200.0 million, through or to Jefferies, acting as sales agent or principal. As of December 31, 2021, no shares have been issued under the Sales Agreement.

See Part I, 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:

	Years Ended December 31,		
	2021	2020	2019
	(in thousands)		
Net cash provided by (used in) operating activities	\$ (87,005)	\$ 296,734	\$ (12,829)
Net cash used in investing activities	(4)	(26)	(2)
Net cash provided by financing activities	1,465	531,748	—
Net increase (decrease) in cash, cash equivalents and restricted cash	<u>\$ (85,544)</u>	<u>\$ 828,456</u>	<u>\$ (12,831)</u>

#### Cash Flows from Operating Activities

Net cash used in operating activities for the year ended December 31, 2021 was \$87.0 million. Cash used in operating activities was primarily due to net income of \$121.2 million increased by stock-based compensation of \$39.6 million, an increase in accounts payable and accrued expenses of \$54.2 million, an increase in prepaid expenses and other assets of \$0.6 million all offset by a decrease in deferred revenue of \$301.4 million.

Net cash provided by operating activities was \$296.7 million for the year ended December 31, 2020. Cash provided by operating activities was primarily due to an increase in deferred revenue of \$301.4 million related to the Roche License Agreement, an increase in accounts payable and accrued expenses of \$11.9 million and stock based compensation of \$7.5 million, partly offset by the use of funds in our operations to develop our product candidates, resulting in a net loss of \$10.9 million. Additional uses of cash during the period included an increase in prepaid expenses and other current assets \$7.3 million and unbilled accounts receivable of \$5.8 million. The net increase in deferred revenue of \$301.4 was the result of the \$350.0 million upfront payment offset by revenue recognized of \$48.6 million.

Net cash used in operating activities was \$12.8 million for the year ended December 31, 2019. Cash used in operating activities was primarily due to the use of funds in our operations to develop our product candidates resulting in a net loss of \$14.0 million, offset by stock based compensation of \$0.6 million and increases in accounts payable and accrued expenses of \$0.6 million.

#### Cash Flows from Investing Activities



Net cash used in investing activities was less than \$0.1 million and consisted of purchases of property and equipment for each of the years ended December 31, 2021, 2020 and 2019.

*Cash Flows from Financing Activities*

Net cash provided by financing activities was \$1.4 million for the year ended December 31, 2021 and consisted of proceeds from issuance of common stock as a result of the exercise of stock options.

Net cash provided by financing activities was \$531.8 million for the year ended December 31, 2020, which consisted primarily of \$106.6 million of net proceeds from the sale of Series D convertible preferred stock, \$107.5 million of net proceeds from the sale of Series D-1 convertible preferred stock and \$317.6 million of net proceeds from the initial public offering.

Net cash used in financing activities during the year ended December 31, 2019 was less than \$0.1 million and consisted of payments of deferred financing costs.

**Contractual Obligations and Commitments**

We lease our office space under a non-cancelable operating lease in Boston, Massachusetts, that expires in July 2022. On July 19, 2021, we entered into a sublease agreement pursuant to which we will lease additional office space in Boston, Massachusetts. The term of the sublease commenced on January 1, 2022 and will expire on December 31, 2026.

The following table summarizes our contractual obligations as of December 31, 2021:

	Payments Due by Period				
	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years	Total
	(in thousands)				
Operating lease obligations	\$ 989	\$ 1,626	\$ 1,693	\$ —	\$ 4,308

We enter into contracts in the normal course of business with third-party contract organizations for preclinical and clinical studies and testing, manufacture and supply of our preclinical materials and other services and products used for operating purposes. These contracts do not contain any minimum purchase commitments and generally provide for termination following a certain period after notice, and therefore we believe that our non-cancelable obligations under these agreements are not material. Payments due upon cancellation consist only of payments for services provided and expenses incurred up to the date of cancellation.

In December 2021, we entered into a license agreement with Merck (the "Merck License Agreement") for the development, manufacture and commercialization of ruzasvir. Ruzasvir is the NS5A inhibitor we are developing in combination with benvinfosbuvir for the treatment of HCV.

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

In consideration for the rights we acquired under the Merck License Agreement, we paid Merck a non-refundable upfront payment in the amount of \$25,000 in February 2022 and will be required to pay Merck milestone payments up to \$135,000 in the aggregate upon its achievement of certain development and regulatory milestones and up to \$300,000 in the aggregate upon its achievement of certain sales-based milestones. Additionally, we will pay Merck tiered royalties based on annual net sales of Products ranging from high single digits to mid-teens percentages. Our royalty payment obligations will continue until the later of (i) the expiration of the last to expire valid claim of a licensed Merck patent claiming such Product (or a Compound contained in such Product) and (ii) a period of years after the first commercial sale of such Product in such country. We may terminate the Merck License Agreement for convenience upon prior written notice. The first potential milestone would be payable upon the commencement of a Phase 3 clinical trial.

The table above also does not include potential milestone and success fees that we may be required to pay under agreements we have entered into with certain consultants. We have 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.

#### **Critical Accounting Policies and Estimates**

Our financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. The effects of material revisions in estimates, if any, will be reflected in the consolidated financial statements prospectively from the date of change in estimates.

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

#### **Revenue Recognition**

As of December 31, 2021, all of our revenue to date had been collaboration revenue generated under the Roche License Agreement.

We analyze our collaboration arrangements to assess whether they are within the scope of Accounting Standards Codification ASC Topic 808, *Collaborative Arrangements* ("ASC 808"), to determine whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards that are dependent on the commercial success of such activities. If we conclude that some or all aspects of the arrangement are within the scope of ASC 808 and do not represent a transaction with a customer, we recognize our allocation of the shared costs incurred with respect to the jointly conducted activities as a component of the related expense in the period incurred. If we conclude that some or all aspects of the arrangement represent a transaction with a customer, we account for those aspects of the arrangement within the scope of ASC 606, *Revenue from Contracts with Customers* ("ASC 606").

To determine the appropriate amount of revenue to be recognized for arrangements that we determine are within the scope of ASC 606, we perform the following steps: (i) identify the contract(s) with the customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) each performance obligation is satisfied. ASC 606 requires significant judgment and estimates and results in changes to, but not limited to: (i) the determination of the transaction price, including estimates of variable consideration, (ii) the allocation of the transaction price, including the determination of estimated selling price, and (iii) the pattern of recognition, including the application of proportional performance as a measure of progress on service-related promises and application of point-in-time recognition for supply-related promises.

The transaction price is generally comprised of an upfront payment due at contract inception and variable consideration in the form of payments for our services and materials and milestone payments due upon the achievement of specified events. Other payments we could be entitled to include tiered royalties earned when customers recognize net sales of licensed products. We consider the existence of any significant financing component within our arrangements and have determined that a significant financing component does not exist in our arrangements as substantive business purposes exist to support the payment structure other than to provide a significant benefit of financing. We measure the transaction price based on the amount of consideration to which we expect to be entitled in exchange for transferring the promised goods and/or services to the customer. We utilize either the expected value method or the

most likely amount method to estimate the amount of variable consideration, depending on which method is expected to better predict the amount of consideration to which we will be entitled. Amounts of variable consideration are included in the transaction price to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. With respect to arrangements that include payments for a development or regulatory milestone payment, we evaluate whether the associated event is considered probable of achievement and estimate the amount to be included in the transaction price using the most likely amount method. Milestone payments that are not within our control or the licensee, such as those dependent upon receipt of regulatory approval, are not considered to be probable of achievement until the triggering event occurs. At the end of each reporting period, we re-evaluate the probability of achievement of each milestone and any related constraint, and if necessary, adjust our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenue and net loss in the period of adjustment. For arrangements that include sales-based royalties, including milestone payments based upon the achievement of a certain level of product sales, wherein the license is deemed to be the sole or predominant item to which the payments relate, we recognize revenue upon the later of: (i) when the related sales occur or (ii) when the performance obligation to which some or all of the payment has been allocated has been satisfied (or partially satisfied). Consideration that would be received for optional goods and/or services is excluded from the transaction price at contract inception.

We generally allocate the transaction price to each performance obligation based on a relative standalone selling price basis. We develop assumptions that require judgment to determine the standalone selling price for each performance obligation in consideration of applicable market conditions and relevant entity-specific factors, including factors that were contemplated in negotiating the agreement with the customer and estimated research and development costs. However, in certain instances, we allocate variable consideration entirely to one or more performance obligation if the terms of the variable consideration relate to the satisfaction of the respective performance obligation and the amount allocated is consistent with the amount we would expect to receive for the satisfaction of the respective performance obligation.

We recognize revenue based on the amount of the transaction price that is allocated to each respective performance obligation when or as the performance obligation is satisfied by transferring a promised good or service to the customer. For performance obligations that are satisfied at a point in time, we recognize revenue when control of the goods and/or services is transferred to the customer. For performance obligations that are satisfied over time, we recognize revenue by measuring the progress toward complete satisfaction of the performance obligation using a single method of measuring progress which depicts the performance in transferring control of the associated goods and/or services to the customer. We generally use input methods to measure the progress toward the complete satisfaction of performance obligations satisfied over time. With respect to arrangements containing a license to our intellectual property that is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenue from amounts allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. Significant management judgment is required in determining the level of effort and costs required under an arrangement and the period over which we are expected to complete our performance obligations under an arrangement. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenue and net loss in the period of adjustment.

Until receipt in November 2021 of the notice from Roche that Roche was terminating the Roche License Agreement effective February 2022, we recognized collaboration revenue over the expected performance period based on its measure of progress towards the completion of certain activities referred to as its Combined Performance Obligation. We concluded that the notice of termination represents a contract modification for accounting purposes. We further concluded that upon receipt of the notice of termination, the Combined Performance Obligation has been completely satisfied. As a result, we recognized all remaining deferred revenue as collaboration revenue within the consolidated statements of operations and

comprehensive income for the year ended December 31, 2021 (see Note 3, Collaboration Revenue, for a detailed discussion).

#### *Contract costs*

We recognize as an asset the incremental costs of obtaining a contract with a customer if the costs are expected to be recovered. We have elected a practical expedient wherein we recognize the incremental costs of obtaining a contract as an expense when incurred if, at inception, the expected amortization period of the asset that we otherwise would have recognized is one year or less. In connection with the Roche License Agreement, we incurred an incremental cost of \$7.0 million, which was included in general and administrative costs in the statement of operations and comprehensive loss for the year ended December 31, 2021 included elsewhere in this Annual Report on Form 10-K.

#### *Accrued Research and Development*

We have entered into various agreements with CMOs and CROs. Our research and development accruals are estimated based on the level of services performed, progress of the studies, including the phase or completion of events, and contracted costs. The estimated costs of research and development provided, but not yet invoiced, are included in accrued liabilities on the balance sheet. If the actual timing of the performance of services or the level of effort varies from the original estimates, we will adjust the accrual accordingly. Payments made to CMOs and CROs under these arrangements in advance of the performance of the related services are recorded as prepaid expenses and other current assets until the services are rendered. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, there have not been any material adjustments to our prior estimates of accrued research and development expenses.

#### *Stock-Based Compensation*

We use a fair value-based method to account for all stock-based compensation arrangements with employees and non-employees, including stock options and stock awards. The fair value of the option granted is recognized on a straight-line basis over the period during which an optionee is required to provide services in exchange for the option award, known as the requisite service period, which usually is the vesting period. In determining fair value of the stock options granted, we use the Black-Scholes model, which requires the input of subjective assumptions. These assumptions include: estimating the fair market value of the common stock, estimating the length of time employees will retain their vested stock options before exercising them (expected term), the estimated volatility of our common stock price over the expected term (expected volatility), risk-free interest rate and expected dividends. See Note 10 to our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K for information concerning certain of the specific assumptions we used in applying the Black-Scholes option pricing model to determine the estimated fair value of our stock options granted during the years ended December 31, 2021, 2020 and 2019, respectively. Estimating the fair value of our common stock prior to the completion of our initial public offering involved significant judgement and the use of estimates.

#### *Estimating the Fair Value of Common Stock*

Prior to our IPO, we were required to estimate the fair value of the common stock underlying our share-based awards when performing the fair value calculations using the Black-Scholes option pricing model. Prior to our IPO, the fair value of the common stock underlying our stock options has been determined on each grant date by our board of directors, with input from management, considering the most recently available third-party valuation of our common shares. All options to purchase shares of our common stock are intended to be granted with an exercise price per share no less than the estimated fair value per share of our common stock underlying those options on the date of grant, based on the information known to us on the date of grant.

In the absence of a public trading market for our common stock prior to our IPO, on each grant date, we developed an estimate of the fair value of our common stock based on valuations from an independent third-party valuation firm using information known to us on the date of grant, a review of any recent events and their potential impact on the estimated fair value per share of the common stock.

The third-party valuations of our common stock were determined in accordance with the guidelines outlined in the American Institute of Certified Public Accountants Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation (the "Practice Aid").

The assumptions used to determine the estimated fair value of our common stock are based on numerous objective and subjective factors, combined with management judgment, including:

- external market conditions affecting the pharmaceutical and biotechnology industry and trends within the industry;
- our stage of development and business strategy;
- the rights, preferences and privileges of our redeemable convertible preferred stock relative to those of our common stock;
- the prices at which we sold shares of our redeemable convertible preferred stock;
- our financial condition and operating results, including our levels of available capital resources;
- the progress of our research and development efforts;
- equity market conditions affecting comparable public companies; and
- general U.S. market conditions and the lack of marketability of our common stock.

The Practice Aid identifies various available methods for allocating enterprise value across classes and series of capital stock to determine the estimated fair value of common stock at each valuation date. In accordance with the Practice Aid, we considered the following methods:

- *Option Pricing Method.* Under the option pricing method, or OPM, shares are valued by creating a series of call options with exercise prices based on the liquidation preferences and conversion terms of each equity class. The estimated fair values of the preferred and common stock are inferred by analyzing these options.
- *Probability-Weighted Expected Return Method.* The probability-weighted expected return method, or PWERM, is a scenario-based analysis that estimates value per share based on the probability-weighted present value of expected future investment returns, considering each of the possible outcomes available to us, as well as the economic and control rights of each share class.

Based on our early stage of development and other relevant factors, we determined that OPM method as well as a hybrid approach of the OPM and the PWERM methods were the most appropriate methods for allocating our enterprise value to determine the estimated fair value of our common stock. In determining the estimated fair value of our common stock, our board of directors also considered the fact that our stockholders could not freely trade our common stock in the public markets. Accordingly, we applied discounts to reflect the lack of marketability of our common stock based on the weighted-average expected time to liquidity. The estimated fair value of our common stock at each grant date reflected a non-marketability discount partially based on the anticipated likelihood and timing of a future liquidity event.

Upon the completion of our initial public offering, the fair value of our common stock is based on the daily closing quoted market price of our common stock.

We also account for any modifications to share based payments in accordance with ASC Topic 718, *Compensation – Stock Compensation* (ASC 718).

#### **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.

#### **SEC Filing Status**

Based on our public float as of June 30, 2021, we became a large accelerated filer, and lost emerging growth company status as of December 31, 2021. As of December 31, 2021, we are required to adopt new or revised accounting standards when they are applicable to public companies that are not emerging growth companies and are required to comply with the auditor attestation requirements Section 404(b) of the Sarbanes-Oxley Act.

#### **Recently Issued Accounting Pronouncements**

See the section titled "Summary of Significant Accounting Policies—Recently Issued Accounting Pronouncements" in Note 2 to our consolidated financial statements included elsewhere in this Annual Report for additional information.

#### **Item 7A. 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 December 31, 2021, we had cash and cash equivalents of \$764.4 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 significant impact on our results of operations for any periods presented herein.

#### **Item 8. Financial Statements and Supplementary Data.**

The financial statements required to be filed pursuant to this Item 8 are appended to this Annual Report on Form 10-K. An index of those financial statements is found in Item 15 of this Annual Report on Form 10-K.

#### **Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.**

None.

#### **Item 9A. Controls and Procedures.**

##### **Management's Evaluation of our Disclosure 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 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.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer (our principal executive officer and principal financial officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2021. Based upon such evaluation, our Chief

Executive Officer and Chief Financial Officer have concluded that, as of December 31, 2021, our disclosure controls and procedures were effective at the reasonable assurance level.

#### **Changes in Internal Control Over Financial Reporting**

There were no changes to 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 December 31, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### **Management's Annual Report on Internal Control Over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act.

Under the supervision of and with the participation of our principal executive officer and principal financial officer, our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2021 based on the criteria set forth in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, management concluded that our internal control over financial reporting was effective as of December 31, 2021.

The effectiveness of our internal control over financial reporting as of December 31, 2021 has been audited by KPMG LLP, an independent registered public accounting firm, as stated in their report appearing below.

#### **Report of Independent Registered Public Accounting Firm**

To the Stockholders and Board of Directors  
Atea Pharmaceuticals, Inc.:

##### *Opinion on Internal Control Over Financial Reporting*

We have audited Atea Pharmaceuticals, Inc. and subsidiary's (the Company) internal control over financial reporting as of December 31, 2021, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2021, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2021 and 2020, the related consolidated statements of operations and comprehensive income (loss), convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the years in the three-year period ended December 31, 2021, and the related notes (collectively, the consolidated financial statements), and our report dated February 28, 2022 expressed an unqualified opinion on those consolidated financial statements.

##### *Basis for Opinion*

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent

with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

*Definition and Limitations of Internal Control Over Financial Reporting*

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ KPMG LLP

Boston, Massachusetts  
February 28, 2022

**Item 9B. Other Information.**

None.

**Item 9C. Disclosure Regarding Foreign Jurisdictions That Prevent Inspections**

[Not applicable.]



**Item 10. Directors, Executive Officers and Corporate Governance.****Code of Ethics**

Our board of directors has adopted a written Code of Business Conduct and Ethics applicable to all officers, directors and employees, including our principal executive officer, principal financial officer, principal accounting officer and controller, or persons performing similar functions. We have posted a current copy of our Code of Business Conduct and Ethics on our website at [www.ateapharma.com](http://www.ateapharma.com) in the "Investors" section under "Corporate Governance." We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding amendment to, or waiver from, a provision of our Code of Business Conduct and Ethics, as well as Nasdaq's requirement to disclose waivers with respect to directors and executive officers, by posting such information on our website at the address and location specified above. The information contained on our website is not incorporated by reference into this Annual Report on Form 10-K.

**Executive Officers and Directors**

The information concerning our executive officers and directors required by this Item 10 is contained under the caption "Executive Officers and Directors" at the end of Part I, Item I, Business, of this Annual Report on Form 10-K. The remainder of the information required to be disclosed by this Item 10 will be included in our definitive Proxy Statement for the 2022 Annual Meeting of Stockholders under the headings "Corporate Governance," "Delinquent Section 16(a) Reports" (if applicable) and "Committees of the Board" and is incorporated herein by reference.

**Item 11. Executive Compensation.**

The information required by this Item 11 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2022 Annual Meeting of Stockholders and is incorporated herein by reference.

**Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.**

The information required by this Item 12 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2022 Annual Meeting of Stockholders and is incorporated herein by reference.

**Item 13. Certain Relationships and Related Transactions, and Director Independence.**

The information required by this Item 13 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2022 Annual Meeting of Stockholders and is incorporated herein by reference.

**Item 14. Principal Accountant Fees and Services.**

The information required by this Item 14 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2022 Annual Meeting of Stockholders and is incorporated herein by reference.

Our independent registered public accounting firm is KPMG LLP, Boston, MA, Auditor Firm ID: 185.

**Item 15. Exhibits, Financial Statement Schedules.**

## (1) Financial Statements

The following documents are included on pages F-1 through F-26 attached hereto and are filed as part of this Annual Report on Form 10-K.

[Report of Independent Registered Accounting Firm](#)

F-2

[Consolidated Balance Sheets](#)

F-4

[Consolidated Statements of Operations and Comprehensive Income \(Loss\)](#)

F-5

[Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity \(Deficit\)](#)

F-6

[Consolidated Statements of Cash Flows](#)

F-7

[Notes to Consolidated Financial Statements](#)

F-8

## (2) Financial Statement Schedules

Schedules have been omitted since they are either not required or not applicable or the information is otherwise included herein.

## (3) Exhibits

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed/ Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
3.1	<a href="#">Restated Certificate of Incorporation</a>	8-K	001-39661	3.1	11/5/2020	
3.2	<a href="#">Amended and Restated Bylaws</a>	8-K	001-39661	3.2	11/5/2020	
4.1	<a href="#">Specimen Stock Certificate evidencing the shares of common stock</a>	S-1	333-249404	4.2	10/9/2020	
4.2	<a href="#">Description of Capital Stock</a>	10-K	001-39661	4.2	3/30/2021	
4.3	<a href="#">Fourth Amended and Restated Stockholders Agreement, as amended</a>	S-1/A	333-249404	4.1	10/23/2020	
10.1#	<a href="#">2020 Incentive Award Plan and form of agreements thereunder</a>	S-1/A	333-249404	10.2	10/26/2020	
10.1.1#	<a href="#">Form of Performance-Based Restricted Stock Unit Award Agreement (CEO) under the 2020 Incentive Award Plan</a>					*
10.1.2#	<a href="#">Form of Performance-Based Restricted Stock Unit Award Agreement (Non-CEO Executive) under the 2020 Incentive Award Plan</a>					*
10.2#	<a href="#">2020 Employee Stock Purchase Plan</a>	S-1/A	333-249404	10.3	10/26/2020	
10.3#	<a href="#">Non-Employee Director Compensation Program</a>					*
10.4#	<a href="#">Form of Indemnification Agreement for Directors and Officers</a>	S-1/A	333-249404	10.5	10/26/2020	
10.5^	<a href="#">License Agreement, dated as of December 23, 2021, by and between the Registrant and MSD International GMBH</a>					*
10.6#	<a href="#">Employment Agreement between the Company and Jean-Pierre Sommadossi, Ph.D., dated October 25, 2020</a>	S-1/A	333-249404	10.9	10/26/2020	
10.7#	<a href="#">Employment Agreement between the Company and Andrea Corcoran, dated October 25, 2020</a>	S-1/A	333-249404	10.10	10/26/2020	

Exhibit Number	Exhibit Description	Incorporated by Reference			Filing Date	Filed/ Furnished Herewith
		Form	File No.	Exhibit		
10.8#	<a href="#">Employment Agreement between the Company and Janet Hammond, MD, PhD, dated November 3, 2020</a>	10-K	001-39661	10.8	3/30/2021	
10.9#	<a href="#">Employment Agreement between the Company and Arantxa Horga, MD, dated November 3, 2020</a>	10-K	001-39661	10.9	3/30/2021	
10.10#	<a href="#">Employment Agreement between the Company and John Vavricka, dated November 3, 2020</a>	10-K	001-39661	10.10	3/30/2021	
10.11#	<a href="#">Employment Agreement between the Company and Wayne Foster, dated November 3, 2020</a>	10-K	001-39661	10.11	3/30/2021	
10.12#	<a href="#">2013 Stock Incentive Plan, as amended, and form of agreements thereunder</a>	S-1	333-249404	10.1	10/9/2020	
10.13	<a href="#">Lease Agreement between the Registrant and OPG 125 SUMMER OWNER (DE) LLC</a>	S-1/A	333-249404	10.5	10/26/2020	
10.14	<a href="#">Sublease Agreement, dated as of July 19, 2021, by and between the Company and DataRobot, Inc.</a>	8-K	001-39661	10.1	7/23/2021	
10.15#	<a href="#">Consulting Agreement, dated May 18, 2021, by and between the Company and Upstream Wellness and Health LLC.</a>	8-K	001-39661	10.1	5/20/2021	
21.1	<a href="#">List of Subsidiaries of the Registrant</a>					*
23.1	<a href="#">Consent of Independent Registered Public Accounting Firm</a>					*
31.1	<a href="#">Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a).</a>					*
31.2	<a href="#">Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a).</a>					*
32.1	<a href="#">Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350.</a>					**
32.2	<a href="#">Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350.</a>					**
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.
- ^ Portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.
- # Indicates management contract or compensatory plan.

**Item 16. Form 10-K Summary**

None.



INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

<a href="#">Report of Independent Registered Public Accounting Firm</a>	F-2
<a href="#">Consolidated Balance Sheets</a>	F-4
<a href="#">Consolidated Statements of Operations and Comprehensive Income (Loss)</a>	F-5
<a href="#">Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)</a>	F-6
<a href="#">Consolidated Statements of Cash Flows</a>	F-7
<a href="#">Notes to Consolidated Financial Statements</a>	F-8

## Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors  
Atea Pharmaceuticals, Inc.:

### *Opinion on the Consolidated Financial Statements*

We have audited the accompanying consolidated balance sheets of Atea Pharmaceuticals, Inc. and subsidiary (the Company) as of December 31, 2021 and 2020, the related consolidated statements of operations and comprehensive income (loss), convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the years in the three-year period ended December 31, 2021, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021 and 2020, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2021, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2021, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission, and our report dated February 28, 2022 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

### *Basis for Opinion*

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

### *Critical Audit Matter*

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of a critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

*Assessment of the satisfaction of the Combined Performance Obligation pursuant to the Roche License Agreement*

As discussed in Note 3 to the consolidated financial statements, on November 12, 2021, F. Hoffmann-LaRoche Ltd. and Genentech, Inc. (collectively, Roche) provided the Company a notice of termination of a license agreement (the Roche License Agreement), which will be effective in February 2022. The Company concluded it had satisfied the provision of the license to Roche, the performance of the Atea Ongoing Studies and the Atea Manufacturing Obligations (collectively, the Combined Performance Obligation) as of December 31, 2021. The Company recognized revenue of \$351,367 thousand for the year ended December 31, 2021, including all remaining deferred revenue related to the Roche License Agreement.

We identified the assessment of the satisfaction of the Combined Performance Obligation pursuant to the Roche License Agreement as a critical audit matter. A high degree of subjective, complex auditor judgment was required in assessing the audit evidence obtained regarding satisfaction of the Combined Performance Obligation as of December 31, 2021.

The following are the primary procedures we performed to address this critical audit matter. We evaluated the design and tested the operating effectiveness of certain internal controls related to the revenue process, including a control related to the satisfaction of the Combined Performance Obligation. We evaluated the satisfaction of the Combined Performance Obligation by (1) examining the Roche License Agreement to evaluate the obligations to be delivered subsequent to the receipt of the notice of termination, and (2) inspecting written communications between the Company and Roche and inquiring of Company legal and research and development personnel to corroborate management's interpretation of the Company's remaining obligations under the Roche License Agreement.

/s/ KPMG LLP

We have served as the Company's auditor since 2014.

Boston, Massachusetts  
February 28, 2022



**ATEA PHARMACEUTICALS, INC.****Consolidated Balance Sheets**

(in thousands, except share and per share amounts)

	<b>December 31,</b>	
	<b>2021</b>	<b>2020</b>
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 764,375	\$ 850,117
Unbilled other receivable	—	5,815
Prepaid expenses and other current assets	8,028	7,545
Total current assets	772,403	863,477
Property and equipment, net	23	48
Other assets	466	107
Total assets	\$ 772,892	\$ 863,632
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities		
Accounts payable	\$ 4,534	\$ 60
Accrued expenses and other current liabilities	52,349	14,368
Deferred revenue	—	301,367
Total current liabilities	56,883	315,795
Other liabilities	5,932	36
Total liabilities	62,815	315,831
Commitments and contingencies (see Note 7)		
Stockholders' equity:		
Preferred stock, \$0.001 par value per share; 10,000,000 shares authorized; no shares issued and outstanding as of December 31, 2021 and 2020	—	—
Common stock, \$0.001 par value; 300,000,000 shares authorized; 83,102,730 and 82,436,937 shares issued and outstanding as of December 31, 2021 and 2020	83	82
Additional paid-in capital	653,964	612,879
Retained earnings (accumulated deficit)	56,030	(65,160)
Total stockholders' equity	710,077	547,801
Total liabilities and stockholders' equity	\$ 772,892	\$ 863,632

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

**ATEA PHARMACEUTICALS, INC.**  
**Consolidated Statements of Operations and Comprehensive Income (Loss)**

(in thousands, except share and per share amounts)

	Years Ended December 31,		
	2021	2020	2019
Collaboration revenue	\$ 351,367	\$ 48,633	\$ —
Operating expenses			
Research and development	167,205	38,023	10,170
General and administrative	45,785	21,640	4,438
Total operating expenses	212,990	59,663	14,608
Income (loss) from operations	138,377	(11,030)	(14,608)
Interest income and other, net	213	83	574
Income (loss) before income taxes	138,590	(10,947)	(14,034)
Income taxes	17,400	—	—
Net income (loss) and comprehensive income (loss)	\$ 121,190	\$ (10,947)	\$ (14,034)
Net income (loss) per share attributable to common stockholders			
Basic	\$ 1.46	\$ (0.51)	\$ (1.39)
Diluted	\$ 1.37	\$ (0.51)	\$ (1.39)
Weighted-average number of common shares used in computing net income (loss) per share attributable to common stockholders			
Basic	82,820,037	21,592,441	10,091,100
Diluted	88,249,243	21,592,441	10,091,100

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

**ATEA PHARMACEUTICALS, INC.**
**Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)**

(in thousands, except share amounts)

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Retained Earnings (Accumulated Deficit)	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount			
Balance – January 1, 2019	33,645,447	\$ 69,114	10,091,100	\$ 10	\$ 4,008	\$ (40,179)	\$ (36,161)
Stock-based compensation expense	—	—	—	—	624	—	624
Net loss	—	—	—	—	—	(14,034)	(14,034)
Balance – December 31, 2019	33,645,447	69,114	10,091,100	10	4,632	(54,213)	(49,571)
Issuance of Series D convertible preferred stock, net of issuance costs of \$869	15,313,382	106,631	—	—	—	—	—
Issuance of Series D-1 convertible preferred stock, net of issuance costs of \$15	8,973,261	107,485	—	—	—	—	—
Issuance of common stock for exercise of stock options	—	—	18,747	—	27	—	27
Stock-based compensation in connection with vesting of restricted stock	—	—	20,000	—	657	—	657
Initial public offering, net of issuance costs of \$3,245	—	—	14,375,000	14	317,591	—	317,605
Conversion of preferred stock into common stock	(57,932,090)	(283,230)	57,932,090	58	283,172	—	283,230
Stock-based compensation expense	—	—	—	—	6,800	—	6,800
Net loss	—	—	—	—	—	(10,947)	(10,947)
Balance – December 31, 2020	—	—	82,436,937	82	612,879	(65,160)	547,801
Issuance of common stock for exercise of stock options	—	—	665,793	1	1,464	—	1,465
Stock-based compensation expense	—	—	—	—	39,621	—	39,621
Net income	—	—	—	—	—	121,190	121,190
Balance – December 31, 2021	—	\$ —	83,102,730	\$ 83	\$ 653,964	\$ 56,030	\$ 710,077

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

**ATEA PHARMACEUTICALS, INC.**  
**Consolidated Statements of Cash Flows**

(in thousands)

	Year Ended December 31,		
	2021	2020	2019
<b>Cash flows from operating activities</b>			
Net income (loss)	\$ 121,190	\$ (10,947)	\$ (14,034)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities			
Stock-based compensation expense	39,621	7,457	624
Depreciation and amortization expense	29	19	17
Changes in operating assets and liabilities			
Unbilled accounts receivable	—	(5,815)	—
Prepaid expenses and other current assets	(483)	(7,296)	(43)
Other assets	(161)	—	0
Accounts payable	10,289	(488)	157
Accrued expenses and other liabilities	43,877	12,437	450
Deferred revenue	(301,367)	301,367	—
Net cash provided by (used in) operating activities	(87,005)	296,734	(12,829)
<b>Cash flows from investing activities</b>			
Additions to property and equipment	(4)	(26)	(2)
Net cash used in investing activities	(4)	(26)	(2)
<b>Cash flows from financing activities</b>			
Net proceeds from issuance of convertible preferred stock	—	214,116	—
Proceeds from issuance of common stock	1,465	27	—
Net proceeds from initial public offering of common stock	—	317,605	—
Net cash provided by financing activities	1,465	531,748	—
Net increase (decrease) in cash, cash equivalents and restricted cash	(85,544)	828,456	(12,831)
Cash, cash equivalents and restricted cash at the beginning of period	850,224	21,768	34,599
Cash, cash equivalents and restricted cash at the end of period	\$ 764,680	\$ 850,224	\$ 21,768
Cash, cash equivalents and restricted cash at the end of period			
Cash and cash equivalents	\$ 764,375	\$ 850,117	\$ 21,661
Restricted cash	305	107	107
Total cash, cash equivalents and restricted cash	\$ 764,680	\$ 850,224	\$ 21,768
<b>Supplemental disclosure of non-cash financing activities</b>			
Conversion of preferred stock to common stock upon closing of initial public offering	\$ —	\$ 283,230	\$ —

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

# ATEA PHARMACEUTICALS, INC.

## Notes to Consolidated Financial Statements

(in thousands, except share and per share amounts)

### 1. Nature of Business

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 life-threatening viral infections.

In October 2020, the Company entered into a license agreement, (the "Roche License Agreement") with F. Hoffmann-La Roche Ltd and Genentech, Inc. (collectively "Roche"), granting Roche an exclusive license to develop and commercialize certain of the Company's compounds including its lead product candidate bemnifosbuvir outside of the United States. As part of the consideration, Roche agreed to pay the Company an upfront payment of \$350,000 (the "Roche Upfront Payment"), which was received in November 2020. In 2021, the Company also received \$50,000 pursuant to a milestone under the Roche License Agreement.

On November 12, 2021, Roche provided the Company a notice of termination of the Roche License Agreement. Under the terms of the Roche License Agreement, the termination was 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, and the Company has full rights to continue the clinical development and future commercialization of bemnifosbuvir worldwide.

On November 3, 2020, the Company completed an initial public offering of its common stock (the "IPO"). In connection with the IPO, the Company issued 14,375,000 shares of its common stock at \$24.00 per share for net proceeds of \$317,605 after deducting underwriting discounts and commissions and offering expenses payable by the Company. Upon closing of the IPO, all outstanding shares of the Company's convertible preferred stock converted into 57,932,090 shares of common stock.

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, and additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval, prior to commercialization. Even if the Company is able to generate revenues from the sale of its product candidates, if approved, it may not become profitable. If the Company fails to become profitable or is unable to sustain profitability on a continuing basis, then it may be unable to continue its operations at planned levels and be forced to reduce its operations. The Company 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 expects to generate operating losses for the foreseeable future. The Company believes that its cash and cash equivalents of \$764,375 as of December 31, 2021 will be sufficient to fund its operations for at least the next twelve months.

The Company may seek additional capital through one or more or a combination of financing through the sale of additional equity or debt securities, or funding in connection with any 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 shareholders.

## **2. Summary of Significant Accounting Policies**

### ***Basis of Presentation and Use of Estimates***

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America, or GAAP.

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

### ***Principles of Consolidation***

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

### ***Revenue Recognition***

Through December 31, 2021, all of the Company's revenue was collaboration revenue generated from the Roche License Agreement.

Until receipt in November 2021 of the notice from Roche that Roche was terminating the Roche License Agreement effective February 2022, the Company recognized collaboration revenue over the expected performance period based on its measure of progress towards the completion of certain activities referred to as its Combined Performance Obligation. The Company concluded that the notice of termination represents a contract modification for accounting purposes. The Company further concluded that upon receipt of the notice of termination, the Combined Performance Obligation has 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 for the year ended December 31, 2021 (see Note 3, Collaboration Revenue, for a detailed discussion).

The Company analyzes its collaboration arrangements to assess whether they are within the scope of Accounting Standards Codification ASC Topic 808, *Collaborative Arrangements* ("ASC 808"), to determine whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards that are dependent on the commercial success of such activities. If the Company concludes that some or all aspects of the arrangement are within the scope of ASC 808 and do not represent a transaction with a customer, the Company recognizes its allocation of the shared costs incurred with respect to the jointly conducted activities pursuant to ASC 730, *Research and Development*. As such, the Company will expense costs as incurred, including any reimbursements made, and recognize reimbursements received as a reduction of research and development expense. If the Company concludes that some or all aspects of the arrangement represent a transaction with a customer, the Company accounts for those aspects of the arrangement within the scope of ASC 606, *Revenue from Contracts with Customers* ("ASC 606").

To determine the appropriate amount of revenue to be recognized for arrangements that the Company determines are within the scope of ASC 606, it performs the following steps: (i) identify the contract(s) with the customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) each performance obligation is satisfied. ASC 606 requires significant judgment and estimates and results in changes to, but not limited to: (i) the determination of the transaction price, including estimates of variable consideration, (ii) the allocation of the transaction price, including the

determination of estimated selling price, and (iii) the pattern of recognition, including the application of proportional performance as a measure of progress on service-related promises and application of point-in-time recognition for supply-related promises.

The transaction price is generally comprised of an upfront payment due at contract inception and variable consideration in the form of payments for the Company's services and materials and milestone payments due upon the achievement of specified events. Other payments the Company could be entitled to include tiered royalties earned when customers recognize net sales of licensed products. The Company considers the existence of any significant financing component within its arrangements and has determined that a significant financing component does not exist in its arrangements as substantive business purposes exist to support the payment structure other than to provide a significant benefit of financing. The Company measures the transaction price based on the amount of consideration to which it expects to be entitled in exchange for transferring the promised goods and/or services to the customer. The Company utilizes either the expected value method or the most likely amount method to estimate the amount of variable consideration, depending on which method is expected to better predict the amount of consideration to which the Company will be entitled. Amounts of variable consideration are included in the transaction price to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. With respect to arrangements that include payments for a development or regulatory milestone payment, the Company evaluates whether the associated event is considered probable of achievement and estimate the amount to be included in the transaction price using the most likely amount method. Milestone payments that are not within the Company's control or the customer's, such as those dependent upon receipt of regulatory approval, are not considered to be probable of achievement until the triggering event occurs. At the end of each reporting period, the Company re-evaluates the probability of achievement of each milestone and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenue and net loss in the period of adjustment. For arrangements that include sales-based royalties, including milestone payments based upon the achievement of a certain level of product sales, wherein the license is deemed to be the sole or predominant item to which the payments relate, the Company recognizes revenue upon the later of: (i) when the related sales occur or (ii) when the performance obligation to which some or all of the payment has been allocated has been satisfied (or partially satisfied). Consideration that would be received for optional goods and/or services is excluded from the transaction price at contract inception.

The Company generally allocates the transaction price to each performance obligation based on a relative standalone selling price basis. The Company develops assumptions that require judgment to determine the standalone selling price for each performance obligation in consideration of applicable market conditions and relevant entity-specific factors, including factors that were contemplated in negotiating the agreement with the customer and estimated research and development costs. However, in certain instances, the Company allocates variable consideration entirely to one or more performance obligation if the terms of the variable consideration relate to the satisfaction of the respective performance obligation and the amount allocated is consistent with the amount the Company would expect to receive for the satisfaction of the respective performance obligation.

The Company recognizes revenue based on the amount of the transaction price that is allocated to each respective performance obligation when or as the performance obligation is satisfied by transferring a promised good or service to the customer. For performance obligations that are satisfied at a point in time, the Company recognizes revenue when control of the goods and/or services is transferred to the customer. For performance obligations that are satisfied over time, the Company recognizes revenue by measuring the progress toward complete satisfaction of the performance obligation using a single method of measuring progress which depicts the performance in transferring control of the associated goods and/or services to the customer. The Company generally uses input methods to measure the progress toward the complete satisfaction of performance obligations satisfied over time. With respect to arrangements containing a license to its intellectual property that is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenue from amounts allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes

judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. Significant management judgment is required in determining the level of effort required under an arrangement and the period over which the Company is expected to complete its performance obligations under an arrangement. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenue and net loss in the period of adjustment.

#### *Contract costs*

The Company recognizes as an asset the incremental costs of obtaining a contract with a customer if the costs are expected to be recovered. The Company has elected the practical expedient in ASC 340, *Other Assets and Deferred Costs*, wherein it recognizes the incremental costs of obtaining a contract as an expense when incurred if, at inception, the expected amortization period of the asset that the Company otherwise would have recognized is one year or less. In connection with the Roche License Agreement, the Company incurred an incremental cost of \$7,000, which was included in general and administrative costs in the accompanying statement of operations and comprehensive loss for the year ended December 31, 2020.

#### **Cash and Cash Equivalents**

The Company considers all highly-liquid investments purchased with maturities of 90 days or less at acquisition to be cash equivalents. Cash and cash equivalents include bank demand deposits and money market funds that invest in U.S. government and U.S. government agency obligations. Cash equivalents are reported at fair value.

#### **Concentrations of Credit Risk and Significant Suppliers**

Financial instruments that potentially subject the Company to concentrations of credit risk are primarily cash and cash equivalents. The Company maintains its cash and cash equivalents with a financial institution that management believes is creditworthy. The Company's investment policy includes guidelines on the quality of the financial institutions and financial instruments and defines allowable investments that the Company believes minimizes the exposure to concentration of credit risk.

The Company is dependent on third-party manufacturers to supply products for research and development activities in its programs. In particular, the Company relies and expects to continue to rely on a small number of manufacturers to supply it with its requirements for the active pharmaceutical ingredients and formulated drugs related to these programs. These programs could be adversely affected by a significant interruption in the supply of active pharmaceutical ingredients and formulated drugs.

#### **Fair Value Measurements**

Assets and liabilities recorded at fair value on a recurring basis in the consolidated balance sheets are categorized based upon the level of judgment associated with the inputs used to measure their fair values. Fair value is defined as the exchange price that would be received for an asset or an exit price that would be paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The authoritative guidance on fair value measurements establishes a three-tier fair value hierarchy for disclosure of fair value measurements as follows:

Level 1—Observable inputs such as unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date.

Level 2—Observable inputs (other than quoted prices included in Level 1) that are either directly or indirectly observable for the asset or liability. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active.

Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to determination of fair value of the assets or liabilities.



Cash, cash equivalents and restricted cash are Level 1 assets which are comprised of funds held in checking and money market accounts. Cash, cash equivalents and restricted cash were recorded at fair value as disclosed in Note 4. The carrying amounts of accounts payable, accrued expenses and unbilled other receivables approximate their fair values due to their short-term maturities.

**Property and Equipment**

Property and equipment are stated at cost, less accumulated depreciation and amortization. Property and equipment are depreciated using the straight-line method over the estimated useful lives of the asset. The Company estimates the useful life of its assets as follows:

<b>Asset</b>	<b>Estimated useful life</b>
Laboratory equipment	Five years
Office furniture and fixtures	Five years
Computer hardware	Two years
Leasehold improvements	Shorter of useful life or remaining lease term

Maintenance and repairs that do not improve or extend the life of the respective asset are expensed to operations as incurred. Upon disposal of an asset, the related cost and accumulated depreciation are removed from the accounts and any resulting gain or loss is included in the consolidated statements of operations.

**Other Assets**

Other assets consist of a right-of-use asset of \$161 and bank deposits of \$305, classified as restricted cash, to collateralize two letters of credit.

**Impairment of Long-lived Assets**

The Company reviews long-lived assets when events or changes in circumstances indicate the carrying value of the assets may not be recoverable. Recoverability is measured by comparing the book value of the assets to the estimated undiscounted future net cash flows that the asset is expected to generate. If the estimated undiscounted future net cash flows are less than the book value, the asset is impaired, and the impairment loss to be recognized in income is measured as the amount by which the book value of the asset exceeds its fair value, which is measured based on the estimated discounted future net cash flows that the asset is expected to generate. No impairment losses were recorded during the years ended December 31, 2021, 2020 and 2019.

**Research and Development Costs**

Research and development costs are expensed as incurred. Research and development expenses consist principally of costs associated with outsourced research and development activities, including preclinical and clinical development, manufacturing and research conducted by contract research organizations and academic institutions, employee compensation, including stock-based compensation and consulting expenses together with related expenses, professional fees and facility and overhead costs. Facility and overhead costs primarily include the allocation of rent, utility and office-related expenses attributable to research and development personnel. In circumstances where amounts have been paid in advance or in excess of costs incurred, the Company records a prepaid expense, which is expensed as services are performed or goods are delivered.

The Company has entered into various research and development contracts with third parties. These agreements are generally cancelable, and related payments are recorded as research and development expenses as incurred. The Company records accruals for estimated ongoing research costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies, including the phase of completion of events, invoices received and contracted costs. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates. The Company's historical accrual estimates have not been materially different from the actual costs.

### **Patent Costs**

Costs to secure and maintain the Company's patents are expensed as incurred and are classified as general and administrative expenses in the Company's consolidated statements of operations.

### **Stock-based Compensation**

Stock-based compensation expense is classified in the consolidated statement of operations in the same manner in which the award recipient's payroll costs or service payments are classified. Stock-based awards granted to employees and non-employees are measured based on the estimated fair value of the awards using the Black-Scholes option pricing model ("Black-Scholes"). Stock-based compensation expense with respect to awards with service conditions is recognized using the straight-line method over the service period. Stock-based compensation with respect to awards with performance conditions is recognized when satisfaction of the performance conditions is probable. Stock-based compensation is based on awards ultimately expected to vest and, as such, it is reduced by forfeitures. The Company accounts for forfeitures as they occur.

Black-Scholes requires the use of subjective assumptions which determine the fair value of stock-based awards. These assumptions include:

#### *Fair value of common stock*

Prior to the IPO, because there was no public market for the Company's common stock, the fair value of the Company's common stock underlying stock-based awards was estimated on each grant date by the board of directors. The Company developed an estimate on each grant date of the fair value of its common stock based on valuations from an independent third-party valuation firm using information known to the Company on the date of grant and a review of any recent events and their potential impact on the estimated fair value per share of the common stock. The third-party valuations of the Company's common stock were determined in accordance with the guidelines outlined in the American Institute of Certified Public Accountants Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation, or the Practice Aid. The assumptions used to determine the estimated fair value of the Company's common stock were based on numerous objective and subjective factors, combined with management judgment, including:

- external market conditions affecting the pharmaceutical and biotechnology industry and trends within the industry;
- the Company's stage of development and business strategy;
- the rights, preferences and privileges of the Company's then-outstanding redeemable convertible preferred stock relative to those of its common stock;
- the prices at which the Company sold shares of its then-outstanding redeemable convertible preferred stock;
- the Company's financial condition and operating results, including its levels of available capital resources;
- the progress of the Company's research and development efforts;
- equity market conditions affecting comparable public companies; and
- general U.S. market conditions and the lack of marketability at the time of the Company's common stock.

The Practice Aid identifies various available methods for allocating enterprise value across classes and series of capital stock to determine the estimated fair value of common stock at each valuation date. In accordance with the Practice Aid, the Company considered the following methods:

- *Option Pricing Method.* Under the option pricing method ("OPM"), shares are valued by creating a series of call options with exercise prices based on the liquidation preferences and conversion terms of each equity class. The estimated fair values of the then-outstanding preferred stock and common stock were inferred by analyzing these options.

- **Probability-Weighted Expected Return Method.** The probability-weighted expected return method ("PWERM"), is a scenario-based analysis that estimates value per share based on the probability-weighted present value of expected future investment returns, considering each of the possible outcomes available to the Company, as well as the economic and control rights of each share class.

Based on the Company's early stage of development and other relevant factors, the Company determined that OPM method as well as a hybrid approach of the OPM and the PWERM methods were the most appropriate methods for allocating its enterprise value to determine the estimated fair value of its common stock. In determining the estimated fair value of the Company's common stock, its board of directors also considered the fact that its stockholders could not freely trade its common stock in the public markets. Accordingly, the Company applied discounts to reflect the lack of marketability of its common stock based on the weighted-average expected time to liquidity. The estimated fair value of the Company's common stock at each grant date reflected a non-marketability discount partially based on the anticipated likelihood and timing of a future liquidity event.

Upon the completion of the Company's initial public offering, the fair value of its common stock is based on the daily closing quoted market price of its common stock.

**Risk-free interest rate**—The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of a stock-based award.

**Expected term**—The expected term represents the period that stock-based awards are expected to be outstanding. Given the Company's lack of specific history, the expected term for option grants is determined using the simplified method. The simplified method deems the term to be the average of the time-to-vesting and the contractual life of the stock-based awards.

**Expected volatility**—Since the Company was privately held through October 29, 2020 and did not have any trading history for its common stock, the expected volatility was estimated based on the average volatility for comparable publicly traded biotechnology companies over a period equal to the expected term of the stock-based awards. The comparable companies were chosen based on their similar size, stage in the life cycle or area of specialty. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

**Expected dividend yield**—The Company has never paid dividends on its common stock and has no plans to pay dividends on its common stock. Therefore, the Company used an expected dividend yield of zero.

The Company also accounts for any modifications to share based payments in accordance with ASC Topic 718, *Compensation – Stock Compensation* (ASC 718).

#### **Income Taxes**

The Company uses the asset and liability method of accounting for income taxes. Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax base. Deferred tax assets are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. Deferred tax expense or benefit is the result of changes in the deferred tax assets and liabilities. Valuation allowances are established to reduce deferred tax assets where, based upon the available evidence, the Company concludes that it is more-likely-than-not that the deferred tax assets will not be realized. In evaluating its ability to recover deferred tax assets, the Company considers all available positive and negative evidence, including its operating results, ongoing tax planning and forecasts of future taxable income.

Reserves are provided for tax benefits for which realization is uncertain. Such benefits are only recognized when the underlying tax position is considered more-likely-than-not to be sustained on examination by a taxing authority. Interest and penalties related to uncertain tax positions are recognized in the provision of income taxes.

#### **Comprehensive Income (Loss)**

Comprehensive income (loss) includes net income (loss) as well as other changes in stockholders' equity (deficit) that result from transactions and economic events other than those with equity holders. The Company did not have any items of comprehensive income or loss other than net income (loss) for the years ended December 31, 2021, 2020 and 2019.

**Net Income (Loss) Per Share Attributable to Common Stockholders**

Basic net income (loss) per share attributable to common stockholders is computed by dividing the net income (loss) attributable to common stockholders by the weighted average number of shares of common stock outstanding for the period. Diluted net income per share attributable to common stockholders is computed by dividing the diluted net income attributable to common stockholders by the weighted average number of common shares outstanding for the period, including potential dilutive common shares assuming the dilutive effect of outstanding stock options.

Prior to the Company's IPO, basic and diluted net loss per share attributable to common stockholders was determined using the two-class method, which is required for participating securities. The Company considered its convertible preferred stock to be participating securities as, in the event a dividend is paid on common stock, the holders of convertible preferred stock would be entitled to receive dividends on a basis consistent with the common stockholders. Under the two-class method, the net loss attributable to common stockholders is not allocated to the convertible preferred stock as the holders of the convertible preferred stock do not have a contractual obligation to share in losses.

Under the two-class method, basic net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted average number of shares of common stock. Due to net losses for the years ended December 31, 2020 and 2019, basic and diluted net loss per share attributable to common stockholders were the same, as the effect of all potentially dilutive securities would have been anti-dilutive.

**In-process Research and Development Assets**

In-process research and development assets that are acquired in a transaction that does not qualify as a business combination under GAAP and that do not have an alternative future use are expensed in the period in which the assets are acquired.

**Segments**

Operating segments are defined as components of an entity for which separate financial information is available and that is regularly reviewed by the chief operating decision maker (the "CODM"), in deciding how to allocate resources to an individual segment and in assessing performance. The Company's CODM is its chief executive officer, who manages and allocates resources to the operations on a total company basis. Accordingly, there is a single operating segment and one reportable segment.

**SEC Filing Status**

Based on its public float as of June 30, 2021, the Company became a large accelerated filer, and lost emerging growth company status, as of December 31, 2021. As of December 31, 2021, the Company is required to adopt new or revised accounting standards when they are applicable to public companies that are not emerging growth companies and is required to comply with the auditor attestation requirements Section 404(b) of the Sarbanes-Oxley Act.

**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. Unless otherwise disclosed below, 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.

**Recently Adopted Accounting Pronouncements**

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* ("ASU 2016-02" or "ASC 842"), which requires a lessee to record a right-of-use asset and a corresponding lease liability on the balance sheet for all leases with terms longer than 12 months. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the

beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available.

In July 2018, an amendment was made that allows companies the option of using the effective date of the new standard as the initial application date (at the beginning of the period in which the new standard is adopted, rather than at the beginning of the earliest comparative period). This update includes a short-term lease exception for leases with a term of 12 months or less, in which a lessee can make an accounting policy election not to recognize the associated lease assets and lease liabilities on its balance sheet.

Additionally, in March 2019, the FASB issued ASU 2019-01 ("ASU No. 2019-01"). ASU No. 2019-01 clarifies the transition guidance related to interim disclosures provided in the year of adoption. Lessees will continue to differentiate between finance leases (previously referred to as capital leases) and operating leases, using classification criteria that are substantially similar to the previous guidance. For lessees, the recognition, measurement, and presentation of expenses and cash flows arising from a lease did not significantly change from previous U.S. GAAP. The modified retrospective method includes several optional practical expedients that entities may elect to apply, as well as transition guidance specific to nonstandard leasing transactions.

The Company adopted the new standard effective January 1, 2021 using the modified retrospective method as of the beginning of the period of the adoption. The Company has elected the package of practical expedients permitted in ASC Topic 842. Accordingly, the Company accounted for its existing operating lease as an operating lease under the new guidance, without reassessing (a) whether the contracts contain a lease under ASC Topic 842, (b) whether classification of the operating leases would be different in accordance with ASC Topic 842, or (c) whether the unamortized initial direct costs would have met the definition of initial direct costs in ASC Topic 842 at lease commencement.

The adoption of this standard resulted in the recording of operating lease liabilities and right-of-use assets on the Company's consolidated balance sheet (see Note 7). The adoption of the standard did not have a material effect on the Company's consolidated statements of operations and comprehensive income (loss), consolidated statements of cash flows or consolidated statements of convertible preferred stock and stockholders' equity (deficit).

In July 2017, the FASB issued ASU No. 2017-11, *Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), Derivatives and Hedging (Topic 815) I. Accounting for Certain Financial Instruments with Down Round Features II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception ("ASU 2017-11")*. Part I applies to entities that issue financial instruments such as warrants, convertible debt or convertible preferred stock that contain down-round features. Part II replaces the indefinite deferral for certain mandatorily redeemable noncontrolling interests and mandatorily redeemable financial instruments of nonpublic entities contained within ASC Topic 480 with a scope exception and does not impact the accounting for these mandatorily redeemable instruments. The standard was effective for the Company beginning January 1, 2021, with early adoption permitted. The adoption of this standard did not have a material impact on the Company's consolidated financial position and results of operations.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Statements*. The new standard requires that expected credit losses relating to financial assets measured on an amortized cost basis and available-for-sale debt securities be recorded through an allowance for credit losses. It also limits the amount of credit losses to be recognized for available-for-sale debt securities to the amount by which carrying value exceeds fair value and also requires the reversal of previously recognized credit losses if fair value increases. The Company adopted the standard effective December 31, 2021. The adoption of this standard did not have a material impact on the Company's consolidated financial position and results of operations.

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*, which is intended to simplify the accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application. The Company adopted the standard effective

January 1, 2021. The adoption of the standard did not have a material effect on the Company's consolidated balance sheets, consolidated statements of operations and comprehensive income (loss), consolidated statements of cash flows or consolidated statement of stockholders' equity (deficit).

### 3. Collaboration Revenue

#### *Background*

In October 2020, the Company licensed to Roche ex-US rights to develop and commercialize certain of the Company's compounds, including bemnifosbuvir.

On November 12, 2021, Roche provided the Company with a notice of termination of the Roche License Agreement. Under the terms of the Roche License Agreement, the termination was 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, and the Company has full 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 was responsible for completing certain ongoing clinical and non-clinical and manufacturing activities at its own expense. These obligations are referred to as the Atea Ongoing Studies and the Atea Manufacturing Obligations, respectively. Through the agreement termination in February 2022, the parties were collaboratively executing a global development plan intended to support regulatory approvals and were sharing joint development costs equally.

The Roche License Agreement provided for a nonrefundable upfront payment of \$350,000 which the Company received in November 2020. In addition, the Roche License Agreement further provided that Roche was obligated to pay the Company up to \$330,000 in the aggregate upon the achievement of certain development and regulatory milestone events; up to \$320,000 in the aggregate upon the achievement of certain sales-based milestone events; and tiered royalties based on annual net sales of the products covered by the agreement, ranging between low double-digits and mid-twenties, subject to certain adjustments and limitations. The Company achieved a development milestone in the amount of \$50,000 in the quarter ended June 30, 2021. Further, under the Roche License Agreement, the Company had a one-time option to request that Roche co-promote with the Company in the United States products covered by the Roche License Agreement that were successfully developed and commercialized. Roche had the right to terminate the Roche License Agreement for convenience pursuant to the terms of the agreement.

#### *Accounting Analysis*

The Company concluded that the Roche License Agreement was under the scope of ASC 808 as both parties were actively participating in a joint operating activity and were exposed to significant risks and rewards that depended on the activity's commercial success. ASC 808 provides that certain transactions between collaborative arrangement participants should be accounted for as revenue under ASC 606 when the collaborative arrangement participant is a customer in the context of a unit of account. In those situations, all of the guidance in ASC 606 should be applied, including recognition, measurement, presentation, and disclosure requirements related to such unit of account. The unit-of-account guidance in ASC 808, which aligns with the guidance in ASC 606 (that is, a distinct good or service) is used when an entity is assessing whether the collaborative arrangement or a part of the arrangement is within the scope of ASC 606. Based on the Company's analysis, it concluded that the delivery of the license to Roche, the performance of the Atea Ongoing Studies and the Atea Manufacturing Obligations should be accounted for under ASC 606. The Company's efforts under the global development plan and certain Atea Manufacturing Obligations in the initial year of the contract, were accounted for under ASC 808.

The Company concluded that the provision of the license to Roche, the performance of the Atea Ongoing Studies and the Atea Manufacturing Obligations should be combined as one performance obligation ("Combined Performance Obligation") as Roche could receive the benefit of each promise without the other promises. Specifically, Roche was dependent on the Company's expertise and ability to complete

the Atea Ongoing Studies and the Atea Manufacturing Obligations, which could not be performed by other third parties, in order to exploit the value from the license.

The initial transaction price was \$350,000 which consisted of the upfront payment. During the quarter ended June 30, 2021, the transaction price was increased to \$400,000 which included the \$350,000 upfront payment and \$50,000 related to the development milestone payment achieved during the quarter ended June 30, 2021. The Company concluded that all other forms of variable consideration, including future development and regulatory milestones should be constrained. As part of this conclusion, the Company assessed the stage of development and risk associated with remaining development required to achieve each milestone, including whether the achievement of certain milestones was outside the control of the Company. Sales based milestone payments and royalty payments qualified for the sales-based royalty exception and would have been recognized when the underlying sale transactions have occurred.

The transaction price was being recognized as collaboration revenue over the period in which the Company performs the Atea Ongoing Studies and the Atea Manufacturing Obligations. The Company concluded that an inputs method based on costs incurred compared to total estimated costs-to-complete approach most faithfully depicts the Company's progress towards completion.

The Company concluded that the notice of termination represents a contract modification for accounting purposes. The Company further concluded that upon receipt of the notice of termination, the Combined Performance Obligation 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 for the year ended December 31, 2021.

The activities to complete the global development plan were accounted for under ASC 808. Expenses incurred and reimbursements made or received from Roche are 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.

The Company classifies all revenues recognized under the Roche License Agreement as collaboration revenues within the accompanying consolidated statements of operations and comprehensive income (loss). For the years ended December 31, 2021 and 2020, the Company recognized collaboration revenue of \$351,367 and \$48,633, respectively, related to the Combined Performance Obligation. As of December 31, 2021 and 2020, the Company recorded Deferred Revenue of \$0 and \$301,367, respectively, related to the Roche License Agreement. Deferred Revenue is classified in current liabilities in the accompanying balance sheet as of December 31, 2020 as the Combined Performance Obligation associated with the deferred revenue as of December 31, 2020 was expected to be completed within twelve months.

For the years ended December 31, 2021 and 2020, costs reimbursable by Roche which are reflected as a reduction to operating expenses were \$7,264 and \$7,901, respectively. The Company recorded research and development expense of \$76,567 and \$2,086 during the years ended December 31, 2021 and 2020, respectively, related to its share of costs incurred by Roche. As of December 31, 2021, the Company recorded accrued expenses of \$10,417 related to amounts payable to Roche. As of December 31, 2020 the Company had recorded unbilled other receivable of \$5,815 related to amounts due from Roche. This amount was offset against amounts payable to Roche for costs incurred during 2021.

#### 4. Fair Value Measurements

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

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

	Fair Value Measurements as of December 31, 2020			
	Level 1	Level 2	Level 3	Total
Cash equivalents				
Money market funds	\$ 846,701	\$ —	\$ —	\$ 846,701
Total cash equivalents	\$ 846,701	\$ —	\$ —	\$ 846,701

The Company's assets with fair value categorized as Level 1 within the fair value hierarchy include money market accounts which invest in money market funds that are publicly traded mutual funds and are presented as cash equivalents on the consolidated balance sheets as of December 31, 2021 and 2020.

There were no transfers among Level 1, Level 2 or Level 3 categories in the years ended December 31, 2021 and 2020.

#### 5. Property and Equipment, net

Property and equipment, net, consist of the following:

	December 31,	
	2021	2020
Laboratory equipment	\$ 5	\$ 5
Office furniture and fixtures	13	13
Computer hardware	37	37
Leasehold improvements	129	125
Total property and equipment, at cost	184	180
Less: accumulated depreciation and amortization	(161)	(132)
Property and equipment, net	\$ 23	\$ 48

Depreciation and amortization expense was \$29, \$19 and \$17 for the years ended December 31, 2021, 2020 and 2019, respectively.

#### 6. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following:

	December 31,	
	2021	2020
Research and development, including manufacturing and clinical expenditures	\$ 18,080	\$ 10,546
License fee	25,000	—
Income taxes	2,572	—
Payroll and payroll related	4,209	2,743
Professional fees and other	2,488	1,079
Total accrued expenses and other current liabilities	\$ 52,349	\$ 14,368



## 7. Commitments and Contingencies

### Operating Lease Agreements

The Company leases an office facility under a non-cancelable operating lease that expires July 2022. The office lease includes commitments obligating the Company to pay a pro rata share of certain building operating costs and annual rent escalations which will result in higher lease payments in future years.

As of January 1, 2021, the date of adoption of ASC 842, the Company utilized operating classification for its facility lease and recorded a right-of-use asset and lease liability.

The following assets and liabilities are recorded on the Company's consolidated balance sheet as of December 31, 2021.

		As of December 31, 2021
Right-of-use asset	\$	161
Current lease liability		197
Non-current lease liability		—

The right-of-use asset is included in other assets, the current lease liability is included in accrued expenses and other current liabilities and the non-current lease liability is included in other liabilities, respectively.

The components of the lease allocated between the general and administrative and the research and development expenses on the consolidated statement of operations for the year ended December 31, 2021 were as follows:

		Year Ended December 31, 2021
Operating lease costs	\$	281
Variable lease costs		37
Total lease costs	\$	318

The variable lease costs for the year ended December 31, 2021 include common area maintenance and other operating charges associated with the Company's lease of its principal office facilities in Boston, MA. As the Company's lease does not provide an implicit rate, the Company utilized its incremental borrowing rate to discount lease payments, which reflects the fixed rate at which the Company could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment.

	As of December 31, 2021
Remaining lease term (in years)	0.5
Discount rate	7%

On July 19, 2021, the Company entered into a sublease (the "Sublease") pursuant to which the Company leases additional office space in Boston, Massachusetts (the "Premises"). The term of the Sublease commenced on January 1, 2022 (the "Commencement Date") and will end on December 31, 2026.

The Sublease provides that the initial base rent for the Premises is \$66 per month, subject to upward adjustment of 2% each year starting on the first anniversary of the Commencement Date. In addition to base rent, the Company is required to pay certain operating expenses and taxes associated with the Premises as well as certain utilities supplied to the Premises.

As of December 31, 2021, future minimum payments for operating leases are as follows:

2022	989
2023	805
2024	821
2025	838
2026	855
Total future minimum lease payments	\$ 4,308

Rent expense recognized under all operating leases was \$318, \$303 and \$305 for the years ended December 31, 2021, 2020 and 2019, respectively.

The Company is required to maintain letters of credit for the duration of the office leases. The Company maintains bank deposits of \$305, to collateralize the letters of credit which are classified as restricted cash and a long-term asset in the consolidated balance sheets as of December 31, 2021 and 2020.

#### **License Agreement**

##### **Background**

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

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

In consideration for the rights the Company acquired under the Merck License Agreement, the Company paid Merck a non-refundable upfront payment in the amount of \$25,000 in February 2022 and will be required to pay Merck milestone payments up to \$135,000 in the aggregate upon its achievement of certain development and regulatory milestones and up to \$300,000 in the aggregate upon its achievement of certain sales-based milestones. Additionally, the Company will pay Merck tiered royalties based on annual net sales of Products ranging from high single digits to mid-teens percentages. The Company's royalty payment obligations will continue until the later of (i) the expiration of the last to expire valid claim of a licensed Merck patent claiming such Product (or a Compound contained in such Product) and (ii) a period of years after the first commercial sale of such Product in such country. The Company may terminate the Merck License Agreement for convenience upon prior written notice. The first potential milestone would be payable upon the commencement of a Phase 3 clinical trial.

The Company recognized, as research and development expense, the \$25,000 non-refundable upfront payment amount as a cost of the asset acquired in the year ended December 31, 2021 because the in-process research and development asset does not have an alternative future use. The upfront payment, payable in February 2022, is included in accrued expenses as of December 31, 2021.

##### **Contingent Consulting Fee**

The Company has an agreement with a consultant that requires payment of a success fee calculated as a percentage of certain product sales, subject to a cumulative maximum payout of \$5.0 million. This success payment is contingent upon the occurrence of future events and the timing and likelihood of such payment is neither probable nor estimable.

##### **Indemnification**

The Company enters into certain types of contracts that contingently requires the Company to indemnify various parties against claims from third parties. These contracts primarily relate to (i) the Company's

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

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

#### 8. Convertible Preferred Stock

As of December 31, 2021 the Company has 10,000,000 shares of preferred stock authorized. No shares of preferred stock have been issued.

As of December 31, 2019, the Company had 33,645,447 shares of convertible preferred stock ("Convertible Preferred Stock"), authorized, issued and outstanding, of which 20,000,000 shares were designated as Series A convertible preferred stock ("Series A Preferred"); 7,592,830 shares were designated as Series B convertible preferred stock ("Series B Preferred"); and 6,052,617 shares were designated as Series C convertible preferred stock ("Series C Preferred"). The Company's Series A Preferred, Series B Preferred and Series C Preferred were issued at \$1.00, \$3.03 and \$4.56 per share, respectively.

In May 2020, the Company authorized 15,313,382 shares of Series D convertible preferred stock ("Series D Preferred") and 8,973,261 shares of Series D-1 convertible preferred stock ("Series D-1 Preferred"). In May 2020 the Company entered into a stock purchase agreement with certain investors and issued 15,313,382 shares of Series D Preferred for net proceeds of \$106,631. In October 2020, the Company issued 8,973,261 shares of Series D-1 Preferred at a purchase price of \$11.98 per share for aggregate net proceeds of \$107,485.

In connection with the Company's IPO, all shares of its convertible preferred stock converted into 57,932,090 shares of common stock.

#### 9. Common Stock

As of December 31, 2021, the authorized capital of the Company included 300,000,000 shares of common stock, of which 83,102,730 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 are entitled to receive dividends, when declared by the board, and to share ratably in the Company's assets legally available for distribution to the holders of the Company's stock in the event of liquidation. The holders of common stock have no preemptive, redemption or conversion rights.

The Company had the following reserved shares of common stock:

	December 31, 2021	December 31, 2020
Outstanding options	10,516,972	7,917,783
Options available for future grant	7,963,829	7,059,000
Shares reserved under ESPP	1,187,000	1,187,000
	<u>19,667,801</u>	<u>16,163,783</u>

## 10. Stock-based Compensation

In October 2020, the Company's shareholders approved the Company's 2020 Incentive Award Plan (the "2020 Plan"), which became effective in connection with the Company's IPO. The 2020 Plan provides for the issuance of up to 7,924,000 shares of common stock and for the grant of incentive stock options or other incentive awards to employees, members of the board of directors and consultants of the Company. The number of shares of common stock that may be issued under the 2020 Plan is also subject to increase on the first day of each calendar year equal to the lesser of i) 5% of the aggregate number of shares of common stock outstanding on the final day of the immediately preceding calendar year or ii) such smaller number of shares as is determined by the board of directors. In January 2021, the shares available under the plan were increased by 4,130,847 shares. As of December 31, 2021 there were 7,963,829 shares of common stock remaining available for future issuance under the 2020 Plan. In January 2022, the shares available under the plan were increased by 4,155,136 shares

The 2020 Plan replaced and is the successor of the Company's 2013 Equity Incentive Plan, as amended (the "2013 Plan"), which provided for the grant of incentive stock options, non-qualified stock options, restricted common stock awards and other awards for up to 7,807,200 shares of common stock to employees, officers, directors and consultants of the Company. Upon the closing of the Company's IPO the 2013 Plan was terminated and no further awards will be made under the 2013 Plan. Any cancellation of outstanding awards at the time of the Company's IPO under the 2013 Plan will be made available for grant under the 2020 Plan.

### Restricted Common Stock

Restricted stock awards generally include vesting and risk of forfeiture provisions that lapse upon satisfaction of performance conditions or over time periods commencing on the grant date and concluding on the third or fourth anniversary of the grant date. As of December 31, 2021, there were no unvested shares of restricted stock.

### Employee Stock Purchase Plan

In October 2020, the Company's shareholders approved the 2020 Employee Stock Purchase Plan (the "ESPP"), which became effective in connection with the Company's IPO. A total of 1,187,000 shares of common stock are reserved for issuance under this plan. As of December 31, 2021 the Company had not commenced any offering under the ESPP and no shares have been issued.

### Stock Options

The following summarizes stock option activity:

	Number of Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (\$000s)
Outstanding at January 1, 2021	7,917,783	\$ 6.68	8.6	\$ 277,894
Granted	3,561,295	\$ 55.14		
Exercised	(665,793)	\$ 2.20		
Cancelled	(296,313)	\$ 24.64		
Outstanding at December 31, 2021	10,516,972	\$ 22.87	8.1	\$ 31,239
Options exercisable at December 31, 2021	4,561,016	\$ 11.33	7.2	\$ 23,500
Vested or expected to vest at December 31, 2021	10,516,972	\$ 22.87	8.1	\$ 31,239

The aggregate intrinsic value of options granted is calculated as the difference between the exercise price of the options and the estimated fair value of the Company's common stock for those options that had exercise prices lower than the fair value of the Company's common stock.

Option grants generally vest over a service period of three or four years and have a contractual term of ten years. As of December 31, 2021, total unrecognized compensation expense related to stock option

awards was \$128,036, which amount is being recognized over a remaining weighted average period of 2.7 years.

The weighted average grant date fair value per option granted during the years ended December 31, 2021, 2020 and 2019 was \$39.10, \$14.93 and \$1.19, respectively. The fair value of each award was estimated using Black-Scholes based on the following assumptions:

	2021	2020	For the Year Ended December 31, 2019
Risk-free interest rate	0.80%	0.31 - 0.56%	1.61 - 2.02%
Expected term	5.99 years	6.25 years	5.52 - 10.0 years
Expected volatility	85.0%	80.0% - 91.7%	49.2% - 78.0%
Expected dividend yield	0%	0%	0%

#### Stock-based Compensation Expense

Stock-based compensation expense is classified as follows:

	2021	2020	For the Year Ended December 31, 2019
Research and development expense	\$ 18,127	\$ 3,565	\$ 255
General and administrative	21,494	3,892	369
Total stock-based compensation expense	\$ 39,621	\$ 7,457	\$ 624

The components of stock-based compensation expense were:

	2021	2020	For the Year Ended December 31, 2019
Restricted common stock	\$ —	\$ 657	\$ —
Stock options	39,621	6,800	624
Total stock-based compensation expense	\$ 39,621	\$ 7,457	\$ 624

#### 11. Income Taxes

For the year ended December 31, 2021, the Company recorded a provision for income taxes for \$17,400. During the years ended December 31, 2020 and 2019, the Company did not record a current or deferred income tax expense or benefit.

The reconciliation of federal statutory income tax rate to the Company's effective income tax rate is as follows:

	2021	2020	For the Year Ended December 31, 2019
Expected income tax benefit at the federal statutory rate	21.0 %	21.0 %	21.0 %
State and local taxes	3.2	(2.6)	6.2
Research and development credits	(4.1)	12.5	0.9
Stock-based compensation	—	(13.6)	—
Foreign derived intangible income	(6.1)	—	—
Uncertain tax positions	4.3	—	—
Other	(1.4)	—	(0.5)
Change in valuation allowance	(4.4)	(17.3)	(27.6)
Total	12.5 %	0.0 %	0.0 %

Deferred income taxes reflect the net effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The principal components of the Company's deferred tax assets consisted of the following:

	December 31,	
	2021	2020
Deferred tax assets (liabilities)		
Net operating loss carryforwards	\$ —	\$ 14,069
License agreement	6,261	—
Stock-based compensation	5,643	1,072
Research and development credits	—	1,791
Other	256	53
Prepaid expenses	(1,256)	—
Gross deferred tax assets (liabilities)	10,904	16,985
Less: valuation allowance	(10,904)	(16,985)
Net deferred tax assets (liabilities)	\$ —	\$ —

As of December 31, 2021, the Company had federal net operating losses of \$377 and state net operating loss carryforwards of \$9, which may be used to offset future tax liabilities. The federal net operating losses and research and development tax credits begin to expire in 2034. The Company utilized net operating losses and research and development tax credit carryforwards of \$52,820 and \$665, respectively.

Management has evaluated the positive and negative evidence bearing upon the realizability of the Company's deferred tax assets. Based on the Company's projected net operating losses for 2022 and beyond, the Company determined that it is more likely than not that it will not recognize the benefits of the deferred tax assets. As a result, the Company has recorded a full valuation allowance of approximately \$10,904 at December 31, 2021. The Company recorded a net decrease of \$6,081 to its valuation allowance for the year ended December 31, 2021 as a result of utilization of certain net operating loss and research and development credit carryforwards during 2021 and in order to maintain a full valuation allowance against its remaining deferred tax assets.

Under the provisions of Sections 382 and 383 of the Internal Revenue Code (the "IRC"), net operating loss and credit carryforwards and other tax attributes may be subject to limitation if there has been a significant change in ownership of the Company, as defined by the IRC.

The Company performed an analysis through December 31, 2020 pursuant to Section 382 of the IRC to determine whether any limitations might exist on the utilization of net operating losses and other tax attributes. Based on this analysis, the Company has determined that ownership changes occurred in 2014, resulting in an annual limitation of \$169 on the use of its net operating losses and other tax attributes generated prior to the ownership change. In addition, based on publicly available statements of acquisition of beneficial ownership, the Company identified an ownership change on December 31, 2021 which did not have an impact on the Company's consolidated financial statements. The Company is in the process of completing a Section 382 study for the fiscal year 2021, the results of which could indicate that the ownership shift occurred prior to December 31, 2021. Should a shift have occurred prior to December 31, 2021, any resulting limitation is not expected to have a material impact on the Company's consolidated financial statements. To the extent that the Company raises additional equity financing or other changes in the ownership interest of significant stockholders occurs, additional tax attributes may become subject to an annual limitation. This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities.

The Company files federal and various state income tax returns. The statute of limitations for assessment by the Internal Revenue Service (the "IRS"), and state tax authorities remains open for all tax years ended since the inception of the Company. To the extent the Company has tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by the IRS or state tax authorities to the extent utilized in a future period. No federal or state tax audits are currently in process.

The Company evaluates tax positions for recognition using a more-likely-than-not recognition threshold, and those tax positions eligible for recognition are measured as the largest amount of tax benefit that is greater than 50% likely of being realized upon the effective settlement with a taxing authority that has full knowledge of all relevant information. During the year ended December 31, 2021, the Company recorded an unrecognized tax benefit of \$5,932 related to certain tax positions which is included in other liabilities in the consolidated balance sheet. The Company did not have any unrecognized tax benefits prior to the year ended December 31, 2021.

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

Basic and diluted earnings per share are calculated as follows:

	Year Ended December 31,		
	2021	2020	2019
Net income (loss)	\$ 121,190	\$ (10,947)	\$ (14,034)
Weighted average common shares outstanding, basic	82,820,037	21,592,441	10,091,100
Dilutive effect of outstanding stock options	5,429,206	—	—
Weighted average common shares outstanding, diluted	88,249,243	21,592,441	10,091,100
Net income (loss) per share, basic	\$ 1.46	\$ (0.51)	\$ (1.39)
Net income (loss) per share, diluted	\$ 1.37	\$ (0.51)	\$ (1.39)

Stock options for the purchase of 3,661,548 weighted average shares were excluded from the computation of diluted net income per share attributable to common stockholders for the year ended December 31, 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.

For the year ended December 31, 2020, options to purchase 7,917,783 shares of common stock have been excluded from the calculation of diluted net loss per share, as their effect is anti-dilutive.

For the year ended December 31, 2019, 33,645,447 shares of convertible preferred stock, 3,911,633 options to purchase common stock and 200,000 shares of restricted stock have been excluded from the calculation of diluted net loss per share, as their effect is anti-dilutive.

## 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 the participant's eligible compensation. During the year ended December 31, 2021, the Company recognized expense of \$272 relating to matching contributions to the 401(k) Plan.

## 14. Related Party Transactions

During the year ended December 31, 2021, the Company entered into a consulting agreement with an entity controlled by one of its directors. The agreement provides for an annual retainer of \$110. The Company recognized expense in the amount of \$67 for the year ended December 31, 2021.

There were no other material transactions with related parties.

ATEA PHARMACEUTICALS, INC.  
2020 INCENTIVE AWARD PLAN

## PERFORMANCE-BASED RESTRICTED STOCK UNIT GRANT NOTICE

Capitalized terms not specifically defined in this Performance-Based Restricted Stock Unit Grant Notice (the "**Grant Notice**") have the meanings given to them in the 2020 Incentive Award Plan (as amended from time to time, the "**Plan**") of Atea Pharmaceuticals, Inc. (the "**Company**").

The Company has granted to the participant listed below ("**Participant**") the performance-based Restricted Stock Units described in this Grant Notice (the "**PSUs**"), subject to the terms and conditions of the Plan and the Performance-Based Restricted Stock Unit Agreement attached as **Exhibit A** (the "**Agreement**"), both of which are incorporated into this Grant Notice by reference.

**Participant:****Grant Date:** January 31, 2022**Target Number of PSUs:****Performance Period:** February 1, 2022 through January 31, 2025**Vesting Schedule:** The PSUs will vest based on the achievement of vesting conditions set forth in **Exhibit A** and **Exhibit B** to this Grant Notice.

By Participant's signature below, Participant agrees to be bound by the terms of this Grant Notice, the Plan and the Agreement. Participant has reviewed the Plan, this Grant Notice and the Agreement in their entirety, has had an opportunity to obtain the advice of counsel prior to executing this Grant Notice and fully understands all provisions of the Plan, this Grant Notice and the Agreement. Participant hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Administrator upon any questions arising under the Plan, this Grant Notice or the Agreement.

ATEA PHARMACEUTICALS, INC.

PARTICIPANT

By:  
Name:  
Title:



## PERFORMANCE-BASED RESTRICTED STOCK UNIT AGREEMENT

Capitalized terms not specifically defined in this Agreement have the meanings specified in the Grant Notice or, if not defined in the Grant Notice, in the Plan.

ARTICLE I.  
GENERAL1.1 Award of PSUs and Dividend Equivalents

(a) The Company has granted the PSUs to Participant effective as of the grant date set forth in the Grant Notice (the "**Grant Date**"). Each PSU represents the right to receive one Share or, at the option of the Company, an amount of cash, in either case, as set forth in this Agreement. Participant will have no right to the distribution of any Shares or payment of any cash until the time (if ever) the PSUs have vested.

(b) The Company hereby grants to Participant, with respect to each PSU, a Dividend Equivalent for ordinary cash dividends paid to substantially all holders of outstanding Shares with a record date after the Grant Date and prior to the date the applicable PSU is settled, forfeited or otherwise expires. Each Dividend Equivalent entitles Participant to receive the equivalent value of any such ordinary cash dividends paid on a single Share. The Company will establish a separate Dividend Equivalent bookkeeping account (a "**Dividend Equivalent Account**") for each Dividend Equivalent and credit the Dividend Equivalent Account (without interest) on the applicable dividend payment date with the amount of any such cash paid.

1.2 Incorporation of Terms of Plan

The PSUs are subject to the terms and conditions set forth in this Agreement and the Plan, which is incorporated herein by reference. In the event of any inconsistency between the Plan and this Agreement, the terms of the Plan will control.

1.3 Unsecured Promise

The PSUs and Dividend Equivalents will at all times prior to settlement represent an unsecured Company obligation payable only from the Company's general assets.

ARTICLE II.  
VESTING; FORFEITURE AND SETTLEMENT2.1 Vesting; Forfeiture

(a) Subject to Sections 2.1(b), (c) and (d) below, the PSUs will become eligible to vest based on the Company's achievement of the performance metrics set forth on **Exhibit B** to the Grant Notice (the "**Metrics**" and such PSUs that become eligible to vest, the "**Eligible PSUs**"), upon and subject to the determination by the Administrator of the extent to which the Metrics were achieved during the Performance Period (the "**Determination**"). The number of PSUs that become Eligible PSUs on the Determination will equal (i) the Target Number of PSUs set forth in the Grant Notice multiplied by (ii) the Percentage of PSUs Eligible to Vest as set forth in **Exhibit B** to the Grant Notice based on the Company's achievement of the Metrics. The Administrator will make the Determination reasonably promptly following expiration of the Performance Period or, if earlier, a reasonable period of time before the occurrence of a Change in Control during the Performance Period.

(b) Subject to Section 2.1(d) below, in the event of a Change in Control during the Performance Period, a number of PSUs will become Eligible PSUs and vest upon such Change in Control equal to the greater of (i) the Target Number of PSUs set forth in the Grant Notice and (ii) the actual number

of PSUs that would become Eligible PSUs based upon the Administrator's Determination, in each case, subject to the Participant remaining a Service Provider until such Change in Control and provided, for the avoidance of doubt, that in the case of the foregoing clause (ii), the Administrator's Determination may in the Administrator's discretion include any PSUs that the Administrator determines were, as of the date of such Determination, reasonably likely to become Eligible PSUs absent such Change in Control.

(c) Except as otherwise provided in Section 2.1(b), to the extent any PSUs become Eligible PSUs, 50% of such Eligible PSUs will vest upon the date of the Determination and the remaining 50% of such Eligible PSUs will vest on the first anniversary of such date, in each case, subject to the Participant remaining a Service Provider through the applicable vesting date.

(d) Any PSUs that do not become Eligible PSUs as of the Determination will immediately and automatically be cancelled and forfeited, except as otherwise determined by the Administrator. In the event of Participant's Termination of Service for any reason, all unvested PSUs (including Eligible PSUs) will immediately and automatically be cancelled and forfeited, except as otherwise determined by the Administrator or provided in a binding written agreement between Participant and the Company and provided that if Participant's employment is terminated by the Company without Cause or by Participant for Good Reason (as such terms are defined in Participant's employment agreement with the Company) during the three months prior to a Change in Control and Participant executes a separation and release agreement in substantially the form attached to such employment agreement during the time periods set forth therein, the PSUs will remain outstanding and eligible to vest under Section 2(b) as if Participant had remained employed until the applicable Change in Control (and, for the avoidance of doubt, will be forfeited upon such Change in Control to the extent they do not become vested or upon expiration of such three month period if no Change in Control occurs). Dividend Equivalents (including any Dividend Equivalent Account balance) will vest or be forfeited, as applicable, upon the vesting or forfeiture of the PSU with respect to which the Dividend Equivalent (including the Dividend Equivalent Account) relates.

## 2.2 Settlement

(a) PSUs and Dividend Equivalents (including any Dividend Equivalent Account balance) will be paid in Shares or cash at the Company's option as soon as administratively practicable after the vesting of the applicable PSU, but in no event more than sixty (60) days after the PSU's vesting date. Notwithstanding the foregoing, the Company may delay any payment under this Agreement that the Company reasonably determines would violate Applicable Law until the earliest date the Company reasonably determines the making of the payment will not cause such a violation (in accordance with Treasury Regulation Section 1.409A-2(b)(7)(ii)), provided the Company reasonably believes the delay will not result in the imposition of excise taxes under Section 409A.

(b) If a PSU is paid in cash, the amount of cash paid with respect to the PSU will equal the Fair Market Value of a Share on the day immediately preceding the payment date. If a Dividend Equivalent is paid in Shares, the number of Shares paid with respect to the Dividend Equivalent will equal the quotient, rounded down to the nearest whole Share, of the Dividend Equivalent Account balance divided by the Fair Market Value of a Share on the day immediately preceding the payment date.

## ARTICLE III TAXATION AND TAX WITHHOLDING

### 3.1 Representation

Participant represents to the Company that Participant has reviewed with Participant's own tax advisors the tax consequences of this Award and the transactions contemplated by

the Grant Notice and this Agreement. Participant is relying solely on such advisors and not on any statements or representations of the Company or any of its agents.

3.2 Tax Withholding

(a) The Company has the right and option, but not the obligation, to treat Participant's failure to provide timely payment in accordance with the Plan of any withholding tax arising in connection with the PSUs or Dividend Equivalents as Participant's election to satisfy all or any portion of the withholding tax by requesting the Company retain Shares otherwise issuable under the Award.

(b) Participant acknowledges that Participant is ultimately liable and responsible for all taxes owed in connection with the PSUs and the Dividend Equivalents, regardless of any action the Company or any Subsidiary takes with respect to any tax withholding obligations that arise in connection with the PSUs or Dividend Equivalents. Neither the Company nor any Subsidiary makes any representation or undertaking regarding the treatment of any tax withholding in connection with the awarding, vesting or payment of the PSUs or the Dividend Equivalents or the subsequent sale of Shares. The Company and the Subsidiaries do not commit and are under no obligation to structure the PSUs or Dividend Equivalents to reduce or eliminate Participant's tax liability.

(c) By accepting this Award, Participant understands and agrees, to (1) sell that number of Shares determined in accordance with this Section 3.2(c) as may be necessary to satisfy all the minimum statutory withholding obligations with respect to any taxable event arising in connection with the PSUs (the "**Sell to Cover Election**") and (2) allow the transfer agent (together with any other party the Company determines necessary to execute the Sell to Cover Election, the "**Agent**") to remit the cash proceeds of any such sale(s) to the Company. Furthermore, Participant directs the Company to make a cash payment equal to the minimum statutory tax withholding from the cash proceeds of such sale(s) directly to the appropriate taxing authorities.

(d) Participant hereby appoints the Agent as Participant's agent and authorizes the Agent to (1) sell on the open market at the then prevailing market price(s), on the Participant's behalf, as soon as practicable on or after the date the Shares are issued upon the vesting of the PSUs, that number (rounded up to the next whole number) of the Shares so issued necessary to generate proceeds to cover (A) the minimum statutory tax withholding obligations incurred with respect to such vesting or issuance and (B) all applicable fees and commissions due to, or required to be collected by, the Agent with respect thereto and (2) apply any remaining funds to Participant's tax withholding obligations hereunder. Participant hereby authorizes the Company and the Agent to cooperate and communicate with one another to determine the number of Shares that must be sold pursuant to this Section 3.2(d). Participant understands that the Agent may effect sales as provided in this Section 3.2(d) in one or more sales and that the average price for executions resulting from bunched orders will be assigned to Participant's account. In addition, Participant acknowledges that it may not be possible to sell Shares as provided by this Section 3.2(d) due to a legal or contractual restriction applicable to Participant or the Agent, a market disruption, or rules governing order execution priority on the national exchange where the Shares may be traded. Participant further agrees and acknowledges that in the event the sale of Shares would result in material adverse harm to the Company, as determined by the Company in its sole discretion, the Company may instruct the Agent not to sell Shares as provided by this Section 3.2(d). In the event of the Agent's inability to sell Shares, Participant will continue to be responsible for the timely payment to the Company and/or its affiliates of all federal, state, local and foreign taxes that are required by applicable laws and regulations to be withheld. Participant acknowledges that regardless of any other term or condition of this Section 3.2(d), the Agent will not be liable to Participant for special, indirect, punitive, exemplary, or consequential damages, or incidental losses or damages of any kind, or any failure to perform or for any delay in performance that results from a cause or circumstance that is beyond its reasonable control. Participant hereby agrees to execute and deliver to

the Agent any other agreements or documents as the Agent reasonably deems necessary or appropriate to carry out the purposes and intent of Sections 3.2(c) and (d). The Agent is a third-party beneficiary of this Section 3.2(d). Sections 3.2(c) and (d) shall terminate on the date on which all tax withholding obligations arising in connection with the Award have been satisfied.

#### ARTICLE IV. OTHER PROVISIONS

##### 4.1 Adjustments

. Participant acknowledges that the PSUs, the Shares subject to the PSUs and the Dividend Equivalents are subject to adjustment, modification and termination in certain events as provided in this Agreement and the Plan. In addition, if the Board determines that due to an unusual, extraordinary or nonrecurring transaction or event materially affecting the PSUs, an adjustment in the Metrics is necessary or appropriate to avoid the dilution or enlargement of the benefits or potential benefits intended to be made available under the PSUs, the Board may adjust the Metrics in such a manner as the Board determines in good faith to be equitable to reflect such transactions or events.

##### 4.2 Notices

. Any notice to be given under the terms of this Agreement to the Company must be in writing and addressed to the Company in care of the Company's Secretary at the Company's principal office or the Secretary's then-current email address or facsimile number. Any notice to be given under the terms of this Agreement to Participant must be in writing and addressed to Participant at Participant's last known mailing address, email address or facsimile number in the Company's personnel files. By a notice given pursuant to this Section, either party may designate a different address for notices to be given to that party. Any notice will be deemed duly given when actually received, when sent by email, when sent by certified mail (return receipt requested) and deposited with postage prepaid in a post office or branch post office regularly maintained by the United States Postal Service, when delivered by a nationally recognized express shipping company or upon receipt of a facsimile transmission confirmation.

##### 4.3 Titles

. Titles are provided herein for convenience only and are not to serve as a basis for interpretation or construction of this Agreement.

##### 4.4 Conformity to Securities Laws

. Participant acknowledges that the Plan, the Grant Notice and this Agreement are intended to conform to the extent necessary with all Applicable Laws and, to the extent Applicable Laws permit, will be deemed amended as necessary to conform to Applicable Laws.

##### 4.5 Successors and Assigns

. The Company may assign any of its rights under this Agreement to single or multiple assignees, and this Agreement will inure to the benefit of the successors and assigns of the Company. Subject to the restrictions on transfer set forth in the Plan, this Agreement will be binding upon and inure to the benefit of the heirs, legatees, legal representatives, successors and assigns of the parties hereto.

##### 4.6 Limitations Applicable to Section 16 Persons

. Notwithstanding any other provision of the Plan or this Agreement, if Participant is subject to Section 16 of the Exchange Act, the Plan, the Grant Notice, this Agreement, the PSUs and the Dividend Equivalents will be subject to any additional limitations set forth in any applicable exemptive rule under Section 16 of the Exchange Act (including any amendment to Rule 16b-3) that are requirements for the application of such exemptive rule. To the extent Applicable Laws permit, this Agreement will be deemed amended as necessary to conform to such applicable exemptive rule.

##### 4.7 Entire Agreement

. The Plan, the Grant Notice and this Agreement (including any exhibit hereto) constitute the entire agreement of the parties and supersede in their entirety all prior undertakings and agreements of the Company and Participant with respect to the subject matter hereof.

4.8 Agreement Severable

. In the event that any provision of the Grant Notice or this Agreement is held illegal or invalid, the provision will be severable from, and the illegality or invalidity of the provision will not be construed to have any effect on, the remaining provisions of the Grant Notice or this Agreement.

4.9 Limitation on Participant's Rights

. Participation in the Plan confers no rights or interests other than as herein provided. This Agreement creates only a contractual obligation on the part of the Company as to amounts payable and may not be construed as creating a trust. Neither the Plan nor any underlying program, in and of itself, has any assets. Participant will have only the rights of a general unsecured creditor of the Company with respect to amounts credited and benefits payable, if any, with respect to the PSUs and Dividend Equivalents, and rights no greater than the right to receive cash or the Shares as a general unsecured creditor with respect to the PSUs and Dividend Equivalents, as and when settled pursuant to the terms of this Agreement.

4.10 Not a Contract of Employment

. Nothing in the Plan, the Grant Notice or this Agreement confers upon Participant any right to continue in the employ or service of the Company or any Subsidiary or interferes with or restricts in any way the rights of the Company and its Subsidiaries, which rights are hereby expressly reserved, to discharge or terminate the services of Participant at any time for any reason whatsoever, with or without Cause, except to the extent expressly provided otherwise in a written agreement between the Company or a Subsidiary and Participant.

4.11 Counterparts

. The Grant Notice may be executed in one or more counterparts, including by way of any electronic signature, subject to Applicable Law, each of which will be deemed an original and all of which together will constitute one instrument.

\* \* \* \* \*

## PERFORMANCE CONDITIONS

## Metrics

The performance Metrics for the PSU award are as follows:

•Expand COVID-19 pipeline through the addition of a protease inhibitor (“PI”) differentiated from current standard of care
•Successful generation of positive data for Phase 2 combination of bemnifosbuvir + PI leading to a Phase 3 for COVID-19
•Positive Phase 2 data in HCV
•Enrollment of 1 <sup>st</sup> patient in Phase 3 for HCV
•Clinical data establishing proof of concept of AT-752 in dengue
•Expand pipeline to include an additional candidate beyond the current clinical indications

## Percentage of PSUs Eligible to Vest

The PSUs will become Eligible PSUs based on the Company’s achievement of the Metrics during the Performance Period as follows:

Level of Achievement	Percentage of PSUs Eligible to Vest
If the Administrator determines that two Metrics were achieved during the Performance Period	50%
If the Administrator determines that three Metrics were achieved during the Performance Period	100%
If the Administrator determines that four Metrics were during the Performance Period	150%
If the Administrator determines that five Metrics were achieved during the Performance Period	200%

ATEA PHARMACEUTICALS, INC.  
2020 INCENTIVE AWARD PLAN

## PERFORMANCE-BASED RESTRICTED STOCK UNIT GRANT NOTICE

Capitalized terms not specifically defined in this Performance-Based Restricted Stock Unit Grant Notice (the "**Grant Notice**") have the meanings given to them in the 2020 Incentive Award Plan (as amended from time to time, the "**Plan**") of Atea Pharmaceuticals, Inc. (the "**Company**").

The Company has granted to the participant listed below ("**Participant**") the performance-based Restricted Stock Units described in this Grant Notice (the "**PSUs**"), subject to the terms and conditions of the Plan and the Performance-Based Restricted Stock Unit Agreement attached as **Exhibit A** (the "**Agreement**"), both of which are incorporated into this Grant Notice by reference.

**Participant:****Grant Date:** January 31, 2022**Target Number of PSUs:****Performance Period:** February 1, 2022 through January 31, 2025**Vesting Schedule:** The PSUs will vest based on the achievement of vesting conditions set forth in **Exhibit A** and **Exhibit B** to this Grant Notice.

By Participant's signature below, Participant agrees to be bound by the terms of this Grant Notice, the Plan and the Agreement. Participant has reviewed the Plan, this Grant Notice and the Agreement in their entirety, has had an opportunity to obtain the advice of counsel prior to executing this Grant Notice and fully understands all provisions of the Plan, this Grant Notice and the Agreement. Participant hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Administrator upon any questions arising under the Plan, this Grant Notice or the Agreement.

ATEA PHARMACEUTICALS, INC.

PARTICIPANT

By:

Name:

Title:

## PERFORMANCE-BASED RESTRICTED STOCK UNIT AGREEMENT

Capitalized terms not specifically defined in this Agreement have the meanings specified in the Grant Notice or, if not defined in the Grant Notice, in the Plan.

ARTICLE I.  
GENERAL1.1 Award of PSUs and Dividend Equivalents

(a) The Company has granted the PSUs to Participant effective as of the grant date set forth in the Grant Notice (the "**Grant Date**"). Each PSU represents the right to receive one Share or, at the option of the Company, an amount of cash, in either case, as set forth in this Agreement. Participant will have no right to the distribution of any Shares or payment of any cash until the time (if ever) the PSUs have vested.

(b) The Company hereby grants to Participant, with respect to each PSU, a Dividend Equivalent for ordinary cash dividends paid to substantially all holders of outstanding Shares with a record date after the Grant Date and prior to the date the applicable PSU is settled, forfeited or otherwise expires. Each Dividend Equivalent entitles Participant to receive the equivalent value of any such ordinary cash dividends paid on a single Share. The Company will establish a separate Dividend Equivalent bookkeeping account (a "**Dividend Equivalent Account**") for each Dividend Equivalent and credit the Dividend Equivalent Account (without interest) on the applicable dividend payment date with the amount of any such cash paid.

1.2 Incorporation of Terms of Plan

The PSUs are subject to the terms and conditions set forth in this Agreement and the Plan, which is incorporated herein by reference. In the event of any inconsistency between the Plan and this Agreement, the terms of the Plan will control.

1.3 Unsecured Promise

The PSUs and Dividend Equivalents will at all times prior to settlement represent an unsecured Company obligation payable only from the Company's general assets.

ARTICLE II.  
VESTING; FORFEITURE AND SETTLEMENT2.1 Vesting; Forfeiture

(a) Subject to Sections 2.1(b), (c) and (d) below, the PSUs will become eligible to vest based on the Company's achievement of the performance metrics set forth on **Exhibit B** to the Grant Notice (the "**Metrics**" and such PSUs that become eligible to vest, the "**Eligible PSUs**"), upon and subject to the determination by the Administrator of the extent to which the Metrics were achieved during the Performance Period (the "**Determination**"). The number of PSUs that become Eligible PSUs on the Determination will equal (i) the Target Number of PSUs set forth in the Grant Notice multiplied by (ii) the Percentage of PSUs Eligible to Vest as set forth in **Exhibit B** to the Grant Notice based on the Company's achievement of the Metrics. The Administrator will make the Determination reasonably promptly following expiration of the Performance Period or, if earlier, a reasonable period of time before the occurrence of a Change in Control during the Performance Period.

(b) Subject to Section 2.1(d) below, in the event of a Change in Control during the Performance Period, a number of PSUs will become Eligible PSUs and vest upon such Change in Control equal to the greater of (i) the Target Number of PSUs set forth in the Grant Notice and (ii) the actual number



of PSUs that would become Eligible PSUs based upon the Administrator's Determination, in each case, subject to the Participant remaining a Service Provider until such Change in Control and provided, for the avoidance of doubt, that in the case of the foregoing clause (ii), the Administrator's Determination may in the Administrator's discretion include any PSUs that the Administrator determines were, as of the date of such Determination, reasonably likely to become Eligible PSUs absent such Change in Control.

(c) Except as otherwise provided in Section 2.1(b), to the extent any PSUs become Eligible PSUs, 50% of such Eligible PSUs will vest upon the date of the Determination and the remaining 50% of such Eligible PSUs will vest on the first anniversary of such date, in each case, subject to the Participant remaining a Service Provider through the applicable vesting date.

(d) Any PSUs that do not become Eligible PSUs as of the Determination will immediately and automatically be cancelled and forfeited, except as otherwise determined by the Administrator. In the event of Participant's Termination of Service for any reason, all unvested PSUs (including Eligible PSUs) will immediately and automatically be cancelled and forfeited, except as otherwise determined by the Administrator or provided in a binding written agreement between Participant and the Company. Dividend Equivalents (including any Dividend Equivalent Account balance) will vest or be forfeited, as applicable, upon the vesting or forfeiture of the PSU with respect to which the Dividend Equivalent (including the Dividend Equivalent Account) relates.

## 2.2 Settlement

(a) PSUs and Dividend Equivalents (including any Dividend Equivalent Account balance) will be paid in Shares or cash at the Company's option as soon as administratively practicable after the vesting of the applicable PSU, but in no event more than sixty (60) days after the PSU's vesting date. Notwithstanding the foregoing, the Company may delay any payment under this Agreement that the Company reasonably determines would violate Applicable Law until the earliest date the Company reasonably determines the making of the payment will not cause such a violation (in accordance with Treasury Regulation Section 1.409A-2(b)(7)(ii)), provided the Company reasonably believes the delay will not result in the imposition of excise taxes under Section 409A.

(b) If an PSU is paid in cash, the amount of cash paid with respect to the PSU will equal the Fair Market Value of a Share on the day immediately preceding the payment date. If a Dividend Equivalent is paid in Shares, the number of Shares paid with respect to the Dividend Equivalent will equal the quotient, rounded down to the nearest whole Share, of the Dividend Equivalent Account balance divided by the Fair Market Value of a Share on the day immediately preceding the payment date.

## ARTICLE III. TAXATION AND TAX WITHHOLDING

### 3.1 Representation

Participant represents to the Company that Participant has reviewed with Participant's own tax advisors the tax consequences of this Award and the transactions contemplated by the Grant Notice and this Agreement. Participant is relying solely on such advisors and not on any statements or representations of the Company or any of its agents.

### 3.2 Tax Withholding

(a) The Company has the right and option, but not the obligation, to treat Participant's failure to provide timely payment in accordance with the Plan of any withholding tax arising in connection with the PSUs or Dividend Equivalents as Participant's election to satisfy all or any portion of the withholding tax by requesting the Company retain Shares otherwise issuable under the Award.

(b) Participant acknowledges that Participant is ultimately liable and responsible for all taxes owed in connection with the PSUs and the Dividend Equivalents, regardless of any action the Company or any Subsidiary takes with respect to any tax withholding obligations that arise in connection with the PSUs or Dividend Equivalents. Neither the Company nor any Subsidiary makes any representation or undertaking regarding the treatment of any tax withholding in connection with the awarding, vesting or payment of the PSUs or the Dividend Equivalents or the subsequent sale of Shares. The Company and the Subsidiaries do not commit and are under no obligation to structure the PSUs or Dividend Equivalents to reduce or eliminate Participant's tax liability.

(c) By accepting this Award, Participant understands and agrees, to (1) sell that number of Shares determined in accordance with this Section 3.2(c) as may be necessary to satisfy all the minimum statutory withholding obligations with respect to any taxable event arising in connection with the PSUs (the "**Sell to Cover Election**") and (2) allow the transfer agent (together with any other party the Company determines necessary to execute the Sell to Cover Election, the "**Agent**") to remit the cash proceeds of any such sale(s) to the Company. Furthermore, Participant directs the Company to make a cash payment equal to the minimum statutory tax withholding from the cash proceeds of such sale(s) directly to the appropriate taxing authorities.

(d) Participant hereby appoints the Agent as Participant's agent and authorizes the Agent to (1) sell on the open market at the then prevailing market price(s), on the Participant's behalf, as soon as practicable on or after the date the Shares are issued upon the vesting of the PSUs, that number (rounded up to the next whole number) of the Shares so issued necessary to generate proceeds to cover (A) the minimum statutory tax withholding obligations incurred with respect to such vesting or issuance and (B) all applicable fees and commissions due to, or required to be collected by, the Agent with respect thereto and (2) apply any remaining funds to Participant's tax withholding obligations hereunder. Participant hereby authorizes the Company and the Agent to cooperate and communicate with one another to determine the number of Shares that must be sold pursuant to this Section 3.2(d). Participant understands that the Agent may effect sales as provided in this Section 3.2(d) in one or more sales and that the average price for executions resulting from bunched orders will be assigned to Participant's account. In addition, Participant acknowledges that it may not be possible to sell Shares as provided by this Section 3.2(d) due to a legal or contractual restriction applicable to Participant or the Agent, a market disruption, or rules governing order execution priority on the national exchange where the Shares may be traded. Participant further agrees and acknowledges that in the event the sale of Shares would result in material adverse harm to the Company, as determined by the Company in its sole discretion, the Company may instruct the Agent not to sell Shares as provided by this Section 3.2(d). In the event of the Agent's inability to sell Shares, Participant will continue to be responsible for the timely payment to the Company and/or its affiliates of all federal, state, local and foreign taxes that are required by applicable laws and regulations to be withheld. Participant acknowledges that regardless of any other term or condition of this Section 3.2(d), the Agent will not be liable to Participant for special, indirect, punitive, exemplary, or consequential damages, or incidental losses or damages of any kind, or any failure to perform or for any delay in performance that results from a cause or circumstance that is beyond its reasonable control. Participant hereby agrees to execute and deliver to the Agent any other agreements or documents as the Agent reasonably deems necessary or appropriate to carry out the purposes and intent of Sections 3.2(c) and (d). The Agent is a third-party beneficiary of this Section 3.2(d). Sections 3.2(c) and (d) shall terminate on the date on which all tax withholding obligations arising in connection with the Award have been satisfied.

#### ARTICLE IV. OTHER PROVISIONS

##### 4.1 Adjustments

. Participant acknowledges that the PSUs, the Shares subject to the PSUs and the Dividend Equivalents are subject to adjustment, modification and termination in certain events as

provided in this Agreement and the Plan. In addition, if the Board determines that due to an unusual, extraordinary or nonrecurring transaction or event materially affecting the PSUs, an adjustment in the Metrics is necessary or appropriate to avoid the dilution or enlargement of the benefits or potential benefits intended to be made available under the PSUs, the Board may adjust the Metrics in such a manner as the Board determines in good faith to be equitable to reflect such transactions or events.

#### 4.2 Notices

. Any notice to be given under the terms of this Agreement to the Company must be in writing and addressed to the Company in care of the Company's Secretary at the Company's principal office or the Secretary's then-current email address or facsimile number. Any notice to be given under the terms of this Agreement to Participant must be in writing and addressed to Participant at Participant's last known mailing address, email address or facsimile number in the Company's personnel files. By a notice given pursuant to this Section, either party may designate a different address for notices to be given to that party. Any notice will be deemed duly given when actually received, when sent by email, when sent by certified mail (return receipt requested) and deposited with postage prepaid in a post office or branch post office regularly maintained by the United States Postal Service, when delivered by a nationally recognized express shipping company or upon receipt of a facsimile transmission confirmation.

#### 4.3 Titles

. Titles are provided herein for convenience only and are not to serve as a basis for interpretation or construction of this Agreement.

#### 4.4 Conformity to Securities Laws

. Participant acknowledges that the Plan, the Grant Notice and this Agreement are intended to conform to the extent necessary with all Applicable Laws and, to the extent Applicable Laws permit, will be deemed amended as necessary to conform to Applicable Laws.

#### 4.5 Successors and Assigns

. The Company may assign any of its rights under this Agreement to single or multiple assignees, and this Agreement will inure to the benefit of the successors and assigns of the Company. Subject to the restrictions on transfer set forth in the Plan, this Agreement will be binding upon and inure to the benefit of the heirs, legatees, legal representatives, successors and assigns of the parties hereto.

#### 4.6 Limitations Applicable to Section 16 Persons

. Notwithstanding any other provision of the Plan or this Agreement, if Participant is subject to Section 16 of the Exchange Act, the Plan, the Grant Notice, this Agreement, the PSUs and the Dividend Equivalents will be subject to any additional limitations set forth in any applicable exemptive rule under Section 16 of the Exchange Act (including any amendment to Rule 16b-3) that are requirements for the application of such exemptive rule. To the extent Applicable Laws permit, this Agreement will be deemed amended as necessary to conform to such applicable exemptive rule.

#### 4.7 Entire Agreement

. The Plan, the Grant Notice and this Agreement (including any exhibit hereto) constitute the entire agreement of the parties and supersede in their entirety all prior undertakings and agreements of the Company and Participant with respect to the subject matter hereof.

#### 4.8 Agreement Severable

. In the event that any provision of the Grant Notice or this Agreement is held illegal or invalid, the provision will be severable from, and the illegality or invalidity of the provision will not be construed to have any effect on, the remaining provisions of the Grant Notice or this Agreement.

#### 4.9 Limitation on Participant's Rights

. Participation in the Plan confers no rights or interests other than as herein provided. This Agreement creates only a contractual obligation on the part of the Company as to amounts payable and may not be construed as creating a trust. Neither the Plan nor any underlying program, in and of itself, has any assets. Participant will have only the rights of a general

unsecured creditor of the Company with respect to amounts credited and benefits payable, if any, with respect to the PSUs and Dividend Equivalents, and rights no greater than the right to receive cash or the Shares as a general unsecured creditor with respect to the PSUs and Dividend Equivalents, as and when settled pursuant to the terms of this Agreement.

4.10 Not a Contract of Employment

. Nothing in the Plan, the Grant Notice or this Agreement confers upon Participant any right to continue in the employ or service of the Company or any Subsidiary or interferes with or restricts in any way the rights of the Company and its Subsidiaries, which rights are hereby expressly reserved, to discharge or terminate the services of Participant at any time for any reason whatsoever, with or without Cause, except to the extent expressly provided otherwise in a written agreement between the Company or a Subsidiary and Participant.

4.11 Counterparts

. The Grant Notice may be executed in one or more counterparts, including by way of any electronic signature, subject to Applicable Law, each of which will be deemed an original and all of which together will constitute one instrument.

\* \* \* \* \*

## PERFORMANCE CONDITIONS

## Metrics

The performance Metrics for the PSU award are as follows:

•Expand COVID-19 pipeline through the addition of a protease inhibitor (“PI”) differentiated from current standard of care
•Successful generation of positive data for Phase 2 combination of bemnifosbuvir + PI leading to a Phase 3 for COVID-19
•Positive Phase 2 data in HCV
•Enrollment of 1 <sup>st</sup> patient in Phase 3 for HCV
•Clinical data establishing proof of concept of AT-752 in dengue
•Expand pipeline to include an additional candidate beyond the current clinical indications

## Percentage of PSUs Eligible to Vest

The PSUs will become Eligible PSUs based on the Company’s achievement of the Metrics during the Performance Period as follows:

Level of Achievement	Percentage of PSUs Eligible to Vest
If the Administrator determines that two Metrics were achieved during the Performance Period	50%
If the Administrator determines that three Metrics were achieved during the Performance Period	100%
If the Administrator determines that four Metrics were during the Performance Period	150%
If the Administrator determines that five Metrics were achieved during the Performance Period	200%

## ATEA PHARMACEUTICALS, INC.

## NON-EMPLOYEE DIRECTOR COMPENSATION PROGRAM

(Effective June 18, 2021)

Non-employee members of the board of directors (the “**Board**”) of Atea Pharmaceuticals, Inc. (the “**Company**”) shall receive cash and equity compensation as set forth in this Non-Employee Director Compensation Program (this “**Program**”). The cash and equity compensation described in this Program shall be paid or be made, as applicable, automatically and without further action of the Board, to each member of the Board who is not an employee of the Company or any subsidiary of the Company (each, a “**Non-Employee Director**”) who is entitled to receive such cash or equity compensation, unless such Non-Employee Director declines the receipt of such cash or equity compensation by written notice to the Company. This Program shall remain in effect until it is revised or rescinded by further action of the Board. This Program may be amended, modified or terminated by the Board at any time in its sole discretion. As of the effective date stated above (the “**Effective Date**”), the terms and conditions of this Program shall supersede any prior cash and/or equity compensation arrangements for service as a member of the Board between the Company and any of its Non-Employee Directors.

**I. CASH COMPENSATION**

A. **Annual Retainers.** Each Non-Employee Director shall receive an annual retainer of \$40,000 for service on the Board.

B. **Additional Annual Retainers.** In addition, each Non-Employee Director shall receive the following annual retainers:

1. **Chairman of the Board or Lead Independent Director.** A Non-Employee Director serving as Chairman of the Board or Lead Independent Director shall receive an additional annual retainer of \$25,000 for such service.

2. **Audit Committee.** A Non-Employee Director serving as Chairperson of the Audit Committee shall receive an additional annual retainer of \$20,000 for such service. A Non-Employee Director serving as a member other than the Chairperson of the Audit Committee shall receive an additional annual retainer of \$10,000 for such service.

3. **Compensation Committee.** A Non-Employee Director serving as Chairperson of the Compensation Committee shall receive an additional annual retainer of \$15,000 for such service. A Non-Employee Director serving as a member other than the Chairperson of the Compensation Committee shall receive an additional annual retainer of \$7,500 for such service.

4. **Nominating and Corporate Governance Committee.** A Non-Employee Director serving as Chairperson of the Nominating and Corporate Governance Committee shall receive an additional annual retainer of \$10,000 for such service. A Non-Employee Director serving as a member other than the Chairperson of the Nominating and

Corporate Governance Committee shall receive an additional annual retainer of \$5,000 for such service.

5. *Strategy and Public Policy Committee.* A Non-Employee Director serving as Chairperson of the Strategy and Public Policy Committee shall receive an additional annual retainer of \$20,000 for such service. A Non-Employee Director serving as a member other than the Chairperson of the Strategy and Public Policy Committee shall receive an additional annual retainer of \$10,000 for such service.

C. Payment of Retainers. The retainers described in Sections I(A) and (B) shall be earned on a quarterly basis based on a calendar quarter and shall be paid in cash by the Company in arrears not later than the fifteenth day following the end of each calendar quarter. In the event a Non-Employee Director does not serve as a Non-Employee Director, or in the applicable positions described in Section I(B), for an entire calendar quarter, the retainer paid to such Non-Employee Director shall be prorated for the portion of such calendar quarter actually served as a Non-Employee Director, or in such position, as applicable.

## II. EQUITY COMPENSATION

Non-Employee Directors shall be granted the equity awards described below. The awards described below shall be granted under and shall be subject to the terms and provisions of the Company's 2020 Incentive Award Plan or any other applicable Company equity incentive plan then-maintained by the Company (the "**Equity Plan**") and shall be granted subject to award agreements, including attached exhibits, in substantially the form previously approved by the Board. All applicable terms of the Equity Plan apply to this Program as if fully set forth herein, and all grants of stock options hereby are subject in all respects to the terms of the Equity Plan and the applicable award agreement.

A. Initial Awards. Each Non-Employee Director who is initially elected or appointed to the Board after the Effective Date shall receive an option to purchase a number of shares of the Company's common stock having a Black-Scholes Value (as defined below) equal to \$935,000 on the date of such initial election or appointment. The awards described in this Section II(A) shall be referred to as "**Initial Awards.**" No Non-Employee Director shall be granted more than one Initial Award.

B. Subsequent Awards. A Non-Employee Director who (i) has been serving as a Non-Employee Director on the Board for at least six months as of the date of any annual meeting of the Company's stockholders after the Effective Date and (ii) will continue to serve as a Non-Employee Director immediately following such meeting, shall receive an option to purchase a number of shares of the Company's common stock having a Black-Scholes Value equal to \$540,000 on the date of such annual meeting. The awards described in this Section II(B) shall be referred to as "**Subsequent Awards.**" For the avoidance of doubt, a Non-Employee Director elected for the first time to the Board at an annual meeting of the Company's stockholders shall only receive an Initial Award in connection with such election, and shall not receive any Subsequent Award on the date of such meeting as well.

For purposes of this Section II, "**Black-Scholes Value**" means the per share fair value of the Initial Award or Subsequent Award, as applicable, determined as of the applicable date of grant of such Initial Award or Subsequent Award using the Black-Scholes or other option pricing model that the Company most recently applied when valuing grants of options with service-based vesting conditions for purposes of preparing its (audited or unaudited) consolidated financial statements that have been filed with the Securities Exchange Commission ("**Financial Statements**") and using as inputs into such model (i) the Fair Market Value (as defined in the Equity Plan) of a share of the Company's common stock on the applicable date of grant and (ii) such other assumptions as determined by the Company's principal accounting officer on or before such date of grant.

C. Termination of Employment of Employee Directors. Members of the Board who are employees of the Company or any parent or subsidiary of the Company who subsequently terminate their employment with the Company and any parent or subsidiary of the Company and remain on the Board will not receive an Initial Award pursuant to Section II(A) above, but to the extent that they are otherwise entitled, will receive, after termination of employment with the Company and any parent or subsidiary of the Company, Subsequent Awards as described in Section II(B) above.

D. Terms of Awards Granted to Non-Employee Directors

1. *Exercise Price.* The per share exercise price of each option granted to a Non-Employee Director shall equal the Fair Market Value of a share of the Company's common stock on the date the option is granted.

2. *Vesting.* Each Initial Award shall vest and become exercisable in thirty-six (36) substantially equal monthly installments following the date of grant, such that the Initial Award shall be fully vested on the third anniversary of the date of grant, subject to the Non-Employee Director continuing in service as a Non-Employee Director through each such vesting date. Each Subsequent Award shall vest and become exercisable in twelve substantially equal monthly installments following the date of grant, such that the Subsequent Award shall be fully vested on the first anniversary of the date of grant, subject to the Non-Employee Director continuing in service on the Board as a Non-Employee Director through each such vesting date. Unless the Board otherwise determines, any portion of an Initial Award or Subsequent Award which is unvested or unexercisable at the time of a Non-Employee Director's termination of service on the Board as a Non-Employee Director shall be immediately forfeited upon such termination of service and shall not thereafter become vested and exercisable. All of a Non-Employee Director's outstanding Initial Awards and Subsequent Awards shall vest in full immediately prior to the occurrence of a Change in Control (as defined in the Equity Plan), to the extent outstanding at such time.

3. *Term.* The maximum term of each stock option granted to a Non-Employee Director hereunder shall be ten (10) years from the date the option is granted.

\* \* \* \* \*



Confidential

\*\*\* Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and is treated by the Registrant as private or confidential.

EXECUTION VERSION

**LICENSE AGREEMENT**

**by and between**

**MSD INTERNATIONAL GMBH**

**and**

**ATEA PHARMACEUTICALS, INC.**

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## LICENSE AGREEMENT

THIS LICENSE AGREEMENT (this “**Agreement**”), dated as of December 23, 2021 (the “**Effective Date**”), is made by and between MSD International GmbH, a company organized and existing under the laws of Switzerland (“**MSD**”), and Atea Pharmaceuticals, Inc., a corporation organized and existing under the laws of Delaware (“**Licensee**”). MSD and Licensee are sometimes referred to herein individually as a “**Party**” and collectively as the “**Parties**”.

**WHEREAS**, MSD together with its Affiliates, has certain rights to the Compound, and the Parties desire Licensee to further Develop and Commercialize the Compound and the Products in the Territory for use in the Field; and

**WHEREAS**, Licensee and MSD desire to enter into this Agreement pursuant to which, among other things, Licensee will Develop and Commercialize the Compound and the Products in the Territory for use in the Field.

**NOW, THEREFORE**, in consideration of the foregoing premises and the mutual covenants herein contained, the receipt and sufficiency of which are hereby acknowledged, MSD and Licensee hereby agree as follows:

### ARTICLE I DEFINITIONS

As used in this Agreement, the following capitalized terms, whether used in the singular or plural, will have the respective meanings set forth below or as otherwise defined in this Agreement:

**1.01** “**Accounting Principles**” means, with respect to Licensee, MSD or any other Person, United States generally accepted accounting principles, or International Financial Reporting Standards, in each case as used by the relevant Party in its books and records, and consistently applied.

**1.02** “**Affiliate**” means, with respect to a Party, any other Person that directly or indirectly controls, is controlled by or is under common control with such Party. A Person will be deemed to control another Person if such Person possesses the power to direct or cause the direction of the management, business and policies of such Person, whether through the ownership of fifty percent (50%) or more (or such lesser percentage which is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction) of the voting securities of such Person, by contract or otherwise.

**1.03** “**Agents**” has the meaning set forth in Section 7.01(b).

**1.04** “**Agreement Payments**” has the meaning set forth in Section 5.06(b).

**1.05** “**Annual Net Sales-Based Milestone Payment**” has the meaning set forth in Section 5.03.

**1.06** “**Annual Net Sales-Based Milestone Table**” has the meaning set forth in Section 5.03.

**1.07** “**Annual Net Sales Milestone Threshold**” has the meaning set forth in Section 5.03.

- 1.08** “**Applicable Law**” means any and all laws of any jurisdiction that are applicable to any of the Parties or their respective Affiliates in carrying out activities hereunder or to which any of the Parties or their respective Affiliates carrying out the activities hereunder is subject, and will include all statutes, enactments, acts of legislature, laws, ordinances, rules, regulations, notifications, guidelines, policies, directions, directives and orders of any statutory authority, tribunal, arbitral body, board, or court or any central, state, or provincial government or local authority or other governmental entity in such jurisdictions, including Good Laboratory Practices, Good Clinical Practices and Good Manufacturing Practices.
- 1.09** “**AT-511**” means Licensee’s proprietary compound currently under development by Licensee, as set forth on Schedule 1.09.
- 1.10** “**AT-527**” means the hemisulfate salt form of AT-511 currently under development by Licensee, as set forth on Schedule 1.10.
- 1.11** “**AT-527/511 Combination Grantback Field**” means any Field in which an AT-527/511 Combination Product is [\*\*\*] as of the effective date of termination, [\*\*\*].
- 1.12** “**AT-527/511 Combination Grantback Know-How**” means Licensee Know-How and Know-How Improvements Controlled by Licensee or any of its Affiliates as of the effective date of termination that are reasonably necessary to Develop, Manufacture, or Commercialize any AT-527/511 Combination Product.
- 1.13** “**AT-527/511 Combination Grantback Patents**” means Licensee Patents and Improvement Patents Controlled by Licensee or any of its Affiliates as of the effective date of termination that are reasonably necessary to Develop, Manufacture, or Commercialize any AT-527/511 Combination Product.
- 1.14** “**AT-527/511 Combination Product**” means any Product that contains the Compound in combination with AT-527 or AT-511, as such Product exists as of the effective date of termination.
- 1.15** “**Auditor**” has the meaning set forth in Section 5.07(a).
- 1.16** “**Business Day**” means any day (other than a Saturday or Sunday) when banks are open for business in New York, New York.
- 1.17** “**Calendar Quarter**” means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31, for so long as this Agreement is in effect; provided, however, that (a) the first Calendar Quarter of the Term will extend from the Effective Date to the end of the first full Calendar Quarter thereafter, and (b) the last Calendar Quarter of the Term will end upon the expiration of this Agreement.
- 1.18** “**Calendar Year**” means each successive period of twelve (12) months commencing on January 1 and ending on December 31, for so long as this Agreement is in effect; provided, however, that (a) the first Calendar Year of the Term will commence on the Effective Date and end on December 31, 2021 and (b) the last Calendar Year of the Term will commence on January

1 of the Calendar Year in which this Agreement terminates or expires and end on the date of termination or expiration of this Agreement.

**1.19** “**Change of Control**” means, with respect to a Party: (a) the sale of all or substantially all of such Party’s assets or business relating to this Agreement; (b) a merger, reorganization or consolidation involving such Party in which the voting securities of such Party outstanding immediately prior thereto cease to represent at least fifty percent (50%) of the combined voting power of the surviving entity immediately after such merger, reorganization or consolidation; or (c) a Person, or group of Persons acting in concert, acquires fifty percent (50%) or more of the voting equity securities or management control of such Party, in each case, directly or indirectly.

**1.20** “**Clinical Trial**” means any human clinical study or clinical trial of a Product, including a Phase III Clinical Trial or post-Regulatory Approval study.

**1.21** “**Combination Product**” means a Product which includes one or more active ingredients other than a Compound, in combination with a Compound, including any coformulation, co-pack or co-administration of such one or more active ingredients with a Compound and/or sold or promoted as a bundle or package. For clarity, this definition of “Combination Product”, and the use thereof in this Agreement, will not be interpreted as a grant of a license or any other rights by MSD to Licensee to any other proprietary compounds of MSD or any of its Affiliates other than the Compound (or any Patents, Know-How or other intellectual property rights related to such other proprietary compounds of MSD or any of its Affiliates) for use in a Combination Product.

**1.22** “**Commercialization**” or “**Commercialize**” means, with respect to a product, any and all activities directed to the marketing, promotion, distribution, offering for sale and selling such product, importing and exporting such product for sale, including all post-launch regulatory activities and interactions with Regulatory Authorities regarding the foregoing.

**1.23** “**Commercially Reasonable Efforts**” means, with respect to the efforts to be expended by Licensee with respect to any objective (including Development or Commercialization of a Compound or Product, as applicable), [the performance of obligations or tasks in a manner consistent with the reasonable practices of companies having comparable resources in the biopharmaceutical industry to accomplish such objective, including, with respect to the Development or Commercialization (as applicable) of a Compound or Product, as applicable, such efforts consistent with the reasonable practices of companies having comparable resources in the biopharmaceutical industry for a product having similar technical and regulatory factors and similar market potential, profit potential and strategic value, and that is at a similar stage in its development or product life cycle as the Compound or Product, in each case based on conditions then prevailing and without regard to any competitive internal program of Licensee or the payment obligations of Licensee under this Agreement.]

**1.24** “**Compound**” means (a) that certain MSD compound currently known as MK-8408, as more particularly described on Schedule 1.24 [\*\*\*].

**1.25** “**Confidential Information**” means, as applicable, all Know-How and all proprietary or non-public scientific, clinical, regulatory, marketing, financial, commercial or other information



or data, whether communicated in writing, verbally, electronically or by other means, that is provided by or on behalf of one Party to the other Party in connection with this Agreement. The Parties hereby agree and acknowledge that any information disclosed under the Existing Confidentiality Agreement will be deemed disclosed under this Agreement.

**1.26** “Control”, “Controls” or “Controlled by” means, with respect to any Patents, Know- How or other intellectual property assets or rights, as applicable, the legal authority or right (whether by ownership or license or other right, other than pursuant to a license under this Agreement) of a Party to grant access to, or a license or sublicense of, such items or right, or otherwise disclose such proprietary or trade secret information to another Person without violating the terms of any agreement or other arrangement with any Third Party existing at the time such Party would be required hereunder to grant the other Party such access or license or sublicense or misappropriating the proprietary or trade secret information of a Third Party.

**1.27** “Development Report” has the meaning set forth in [Section 3.03](#).

**1.28** “Development” or “Develop” means all preclinical drug development activities and all clinical drug development activities, including test method development, stability testing, assay development, audit development, toxicology, formulation, quality assurance/quality control development, statistical analysis and report writing, conducting Clinical Trials (including any post-marketing studies), packaging development, regulatory affairs, and the preparation, filing, and prosecution of all regulatory filings and documentation as necessary to obtain Regulatory Approval to market or sell a product.

**1.29** “Dollar” and “\$” means a U.S. dollar.

**1.30** “Existing Confidentiality Agreement” means that certain Mutual Confidential Disclosure Agreement, [\*\*\*].

**1.31** “FDA” means the United States Food and Drug Administration, or any successor entity thereto.

**1.32** “Field” means all therapeutic or prophylactic uses in humans.

**1.33** “First Commercial Sale” means, with respect to a given Product in a given country in the Territory, the first shipment of commercial quantities of such Product sold in such country to a Third Party on arm’s length terms by or on behalf of Licensee, its Affiliate or sublicensee for use in the Field after the receipt of Regulatory Approval in such country. Notwithstanding the foregoing, sales for sampling and promotional use, or compassionate use, will not be considered to constitute a First Commercial Sale. For clarity, First Commercial Sale will be determined on a Product-by-Product and country-by-country basis.

**1.34** “FTE” means the equivalent of a normal full-time employee’s work time over a twelve (12) month period, consisting of a total of [\*\*\*] hours of work, related to conducting activities hereunder in accordance with this Agreement. In the event that an individual devotes less than such full time of [\*\*\*] hours to conducting activities hereunder during such twelve (12) month period, then for purposes of this Agreement, such

individual shall only count as a portion of an FTE which shall be determined by dividing the actual number of hours worked by [\*\*\*].

**1.35** “**FTE Cost**” means, for a given period, the number of FTEs for such period multiplied by the FTE Rate.

**1.36** “**FTE Rate**” means [\*\*\*] per one (1) full FTE per Calendar Year; provided, however, that if an alternative rate is specifically set forth herein for a given activity, then such alternative rate shall apply for such activity.

**1.37** “**Good Clinical Practices**” means the then-current Good Clinical Practices as such term is defined from time to time by the FDA, or analogous set of regulations, guidelines or standards as defined by other relevant Regulatory Authority having jurisdiction over the Development, Manufacture or Commercialization of Product in a particular jurisdiction of the Territory, as applicable.

**1.38** “**Good Laboratory Practices**” means the then-current good laboratory practice regulations of the FDA as described in the United States Code of Federal Regulations and all applicable FDA rules, regulations, order, and guidances, or analogous set of regulations, guidelines or standards as defined by other relevant Regulatory Authority having jurisdiction over the Development, Manufacture or Commercialization of Product in a particular jurisdiction of the Territory, as applicable.

**1.39** “**Good Manufacturing Practices**” means the then-current Good Manufacturing Practices as such term is defined from time to time by the FDA or analogous set of regulations, guidelines or standards as defined by other relevant Regulatory Authority having jurisdiction over the Development, Manufacture or Commercialization of Product in a particular jurisdiction of the Territory, as applicable.

**1.40** “**Grantback MK-8408 Product**” means any Product that contains the Compound as the sole active ingredient, as such Product exists as of the effective date of termination.

**1.41** “**Improvement Patents**” means any and all Patents Controlled by a Party or any of its Affiliates claiming or covering any (a) composition of matter, use or manufacture of Compound alone or in combination with AT-511 or AT-527 with a first priority date that is on or after the Effective Date, regardless of the inventorship thereof, or (b) Know-How Improvement that is not already covered by (a) above, regardless of the inventorship thereof.

**1.42** “**IND**” means an Investigational New Drug application, Clinical Study Application, Clinical Trial Exemption, or similar application or submission for approval to conduct human clinical investigations filed with or submitted to a Regulatory Authority in conformance with the requirements of such Regulatory Authority.

**1.43** “**Indemnified Party**” has the meaning set forth in [Section 9.03](#).

**1.44** “**Indemnifying Party**” has the meaning set forth in [Section 9.03](#).

**1.45** “**Indirect Tax**” has the meaning set forth in [Section 5.06\(c\)](#).

- 1.46** “**Initiation**” means, with respect to a Clinical Trial, the enrollment of the first patient in such Clinical Trial.
- 1.47** “**Know-How**” means any and all proprietary information and materials (whether patentable or not) including (a) ideas, discoveries, inventions, improvements, technology or tradesecrets, (b) pharmaceutical, chemical and biological materials, products, components or compositions, (c) methods, procedures, formulas, processes, tests, assays, techniques, regulatory requirements and strategies, (d) biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, clinical or safety data and information, (e) technical and non-technical data and other information related to the foregoing, and (f) drawings, plans, designs, diagrams, sketches, specifications or other documents containing or relating to such information or materials.
- 1.48** “**Know-How Improvement**” means any and all Know-How (whether or not patentable) conceived, discovered, developed or reduced to practice by or on behalf of Licensee or any of its Affiliates in the performance of activities under this Agreement (including the Development, Manufacture or Commercialization of Compound or Product, or any data generated under any Clinical Trials) that (i) is an improvement, enhancement or other modification to Compound, Product or MSD Know-How or (ii) was otherwise discovered, developed or reduced to practice through the use of MSD Know-How or Confidential Information of MSD.
- 1.49** “**Liability**” has the meaning set forth in [Section 9.01](#).
- 1.50** “**Licensee Executive**” means Licensee’s chief executive officer.
- 1.51** “**Licensee Indemnified Party**” has the meaning set forth in [Section 9.01](#).
- 1.52** “**Licensee Know-How**” means any and all Know-How Controlled by Licensee or any of its Affiliates and incorporated into, or otherwise used in the Development, Manufacture or Commercialization of, any Compound or Product; provided that Licensee Know-How excludes all Know-How Improvements and any MSD Know-How.
- 1.53** “**Licensee Grantback Know-How**” means Licensee Know-How and Know-How Improvements Controlled by Licensee or any of its Affiliates as of the effective date of termination that are reasonably necessary to Develop, Manufacture, or Commercialize any Grantback MK- 8408 Product.
- 1.54** “**Licensee Grantback Patents**” means Licensee Patents and Improvement Patents Controlled by Licensee or any of its Affiliates as of the effective date of termination that are reasonably necessary to Develop, Manufacture, or Commercialize any Grantback MK-8408 Product.
- 1.55** “**Licensee Patents**” means any and all Patents that are Controlled by Licensee (or any of its Affiliates) that (a) claim or cover any Licensee Know-How or (b) are otherwise necessary for the Development, Manufacture or Commercialization of Compound or Product; provided that Licensee Patents excludes all Improvement Patents and any MSD Patents.



- 1.56** “**Major European Country**” means each of [\*\*\*]; collectively “Major European Countries”.
- 1.57** “**Manufacture**” or “**Manufacturing**” means all activities related to the manufacturing of a pharmaceutical product, or any ingredient thereof, including test method development and stability testing, formulation, process development, manufacturing for use in non-clinical or clinical studies, manufacturing scale-up, quality assurance and quality control development, quality control testing (including in-process release and stability testing), packaging, release of product or any component or ingredient thereof, quality assurance activities related to manufacturing and release of product, and regulatory activities related to all of the foregoing.
- 1.58** “**Marketing Authorization**” means all approvals from the relevant Regulatory Authority necessary to market and sell a pharmaceutical product in any country or region, as applicable.
- 1.59** “**Marketing Authorization Application**” means an application or submission for Marketing Authorization of a pharmaceutical product filed with a Regulatory Authority that is the equivalent of an NDA filed pursuant to the United States Food & Drug Act to obtain marketing approval for a pharmaceutical product in a given country or region, as applicable.
- 1.60** “**MSD Executive**” means someone at the Vice-President level or higher at MSD with responsibility for the area of discussion.
- 1.61** “**MSD Indemnified Party**” has the meaning set forth in [Section 9.02](#).
- 1.62** “**MSD Know-How**” means all Know-How that is (a) Controlled by MSD (or its Affiliate) as of the Effective Date, and (b) necessary or reasonably useful to Develop, Manufacture, or Commercialize a Compound or Product in the Field in the Territory. In all cases, MSD Know- How excludes [\*\*\*].
- 1.63** “**MSD Patents**” means all Patents that (a) are Controlled by MSD (and/or any of its Affiliates) as of the Effective Date or thereafter during the Term, and (b)(i) have claims specifically covering the Compound or the Manufacture and/or use thereof or (ii) are necessary to Develop, Manufacture, or Commercialize a Compound or Product in the Field in the Territory [\*\*\*].
- 1.64** “**NDA**” means a New Drug Application filed pursuant to the United States Food & Drug Act or any application or submission for Regulatory Approval of a pharmaceutical product filed with a Regulatory Authority that is the equivalent thereof.
- 1.65** “**Net Sales**” means, in respect of each Product, the total gross amounts invoiced for all commercial sales of such Product by or on behalf of Licensee, its Affiliates or sublicensees to Persons who or which are neither Licensee nor an Affiliate of Licensee, less the following deductions actually allowed or reserved in accordance with Licensee’s Accounting Principles, consistently applied:
- (a) normal and customary trade, quantity discounts, allowances and credits for such Product;
  - (b) credits or allowances actually granted for [\*\*\*];

- (c) fees to [\*\*\*] and chargebacks, rebates or similar payments to customers with respect to such Product, including [\*\*\*];
- (d) [\*\*\*] incurred or allowed, or other [\*\*\*] imposed upon [\*\*\*];
- (e) [\*\*\*], freight, postage, shipping and insurance charges related to delivery of such Product, to the extent incurred;
- (f) [\*\*\*]; and
- (g) [\*\*\*].

There will be no double counting in determining the foregoing deductions from gross amounts invoiced to calculate Net Sales. The calculations set forth in this section will be determined in accordance with [\*\*\*].

If any Product is, or is sold as part of, a Combination Product for a given indication, Net Sales will be calculated assuming that [\*\*\*] is equal to the product of (i) [\*\*\*], and (ii) the fraction  $(A/(A+B))$ , where:

“A” is [\*\*\*]; and

“B” is [\*\*\*].

- (1) If “B” cannot be determined because [\*\*\*], then the Net Sales shall be calculated by multiplying

[\*\*\*] by the fraction  $(A/C)$ , where “A” is as defined above, and “C” is [\*\*\*].

(2) If “A” cannot be determined because [\*\*\*], then the Net Sales shall be calculated by multiplying [\*\*\*] by the fraction  $((D-E)/D)$ , where “D” is [\*\*\*], and “E” is [\*\*\*].

(3) If both “A” and “B” cannot be determined by reference to [\*\*\*], then Net Sales will be calculated as above, but the gross amount received in the above equation  $(A/(A+B))$  [\*\*\*] prior to the end of the accounting period in question based on an equitable method of determining the same that takes into account,

[\*\*\*].

**1.66** “**Patent**” means (a) all patents and patent applications in any country or supranational jurisdiction worldwide, (b) any substitutions, divisionals, continuations, continuations-in-part, reissues, renewals, registrations, confirmations, re-examinations, extensions, supplementary protection certificates and the like of any such patents or patent applications, and (c) foreign counterparts of any of the foregoing.

**1.67** “**Person**” means any individual, partnership, joint venture, limited liability company, corporation, firm, trust, association, unincorporated organization, governmental authority or agency, or any other entity not specifically listed herein.

**1.68** “**Phase III Clinical Trial**” means a human clinical trial that would satisfy the requirements of 21 CFR 312.21(c), or a comparable clinical study prescribed by the relevant Regulatory Authority in a country other than the United States.

**1.69** “**Product**” means any pharmaceutical or biological composition or preparation that contains Compound, including a Combination Product.

**1.70** “**Regulatory Approval**” means all approvals from the relevant Regulatory Authority necessary to market and sell a pharmaceutical product in the applicable country or region.

- 1.71 “**Regulatory Authority**” means any multinational, federal, state, or local government, or political subdivision thereof, or any authority, agency or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, any court or tribunal (or any department, bureau or division thereof), or any governmental arbitrator or arbitral body, in each case, where such entity has responsibility for granting licenses or approvals, including Regulatory Approvals, for the marketing, sale or manufacture of Product in any country.
- 1.72 “**Royalties**” has the meaning set forth in [Section 5.04\(a\)](#).
- 1.73 “**Royalty Term**” has the meaning set forth in [Section 5.04\(b\)](#).
- 1.74 “**Safety Issue**” means, with respect to a Product, (a) a Regulatory Authority or safety data review board for the Clinical Trials of such Product has required (i) termination of a Clinical Trial of such Product [\*\*\*], or (ii) the withdrawal or withholding of a Regulatory Approval of such Product [\*\*\*], in each case where such requirement is attributable to such Product in whole or in part, or (b) [\*\*\*].
- 1.75 “**Subcontract Agreement**” has the meaning set forth in [Section 2.06](#).
- 1.76 “**Sublicense Agreement**” has the meaning set forth in [Section 2.06](#).
- 1.77 “**Tax Action**” has the meaning set forth in [Section 5.06\(b\)](#).
- 1.78 “**Term**” has the meaning set forth in [Section 10.01](#).
- 1.79 “**Territory**” means the world.
- 1.80 “**Third Party Claim**” has the meaning set forth in [Section 9.01](#).
- 1.81 “**Third Party License Agreement**” has the meaning set forth in [Section 5.04\(c\)\(ii\)](#).
- 1.82 “**Third Party**” means any Person other than (a) MSD and its Affiliates and (b) Licensee and its Affiliates.
- 1.83 “**Transferred Compound**” has the meaning set forth in [Section 3.08\(a\)](#).
- 1.84 “**United States**” or “**U.S.**” means the United States of America, including its territories and possessions.
- 1.85 “**Valid Claim**” means a claim of

[\*\*\*].

1.86 “VAT” means any value added tax, sales tax or any other similar type of turnover tax.

1.87 “Withholding Taxes” has the meaning set forth in [Section 5.06\(b\)](#).

**ARTICLE II  
LICENSE AND COVENANTS; AMENDMENT AND RESTATEMENT**

**2.01 License Grant to Licensee.** Subject to the terms and conditions of this Agreement (including [Section 2.03](#)), MSD hereby grants to Licensee, during the Term, a royalty-bearing license, with the right to grant sublicenses as provided herein (including [Section 2.06](#)), under the MSD Patents and MSD Know-How, in each case, solely to research, Develop, Manufacture, have Manufactured, use, import, export, sell, offer for sale, and otherwise Commercialize the Compound and the Products in the Field in the Territory during the Term. Subject to the retained rights of MSD set forth in [Section 2.03](#), the license set forth in this [Section 2.01](#) shall be exclusive, even as to MSD and its Affiliates.

**2.02 No Non-Permitted Use.** Licensee hereby covenants that it will not, and will require its Affiliates and sublicensees not to, use or practice, directly or indirectly, any MSD Know-How or MSD Patents for any purposes other than those expressly permitted by [Section 2.01](#). Without limiting the foregoing, no rights or licenses are granted to Licensee hereunder with respect to any compound that is not the Compound or any product that is not a Product.

**2.03 Retained Rights.** Notwithstanding anything to the contrary contained herein, MSD hereby retains the right, for itself and its Affiliates, sublicensees and other designees, including under the MSD Patents and MSD Know-How, to use the Compound solely for MSD's and its Affiliates' internal research purposes (but excluding any clinical Development activities, including the conduct of Clinical Trials). [\*\*\*]

**2.04 Know-How Unrelated to Compound or Products.** Licensee acknowledges that some of the MSD Know-How disclosed by MSD to Licensee under this Agreement may include documents or materials that include information, data, or Know-How which is unrelated to the Compound or the Products, and MSD will use commercially reasonable efforts to delete such information, data, or Know-How prior to disclosure or to otherwise exclude portions of such documents or materials

from disclosure to the extent such portions are unrelated to the Compound or Products. Notwithstanding such efforts, to the extent such information, data, or Know-How is disclosed to Licensee or its Affiliates, no license is granted to Licensee to use such information, data, or Know-How for any purpose or to disclose such information, data, or Know-How to any Person. Any such information, data, or Know-How shall be deemed to be MSD's Confidential Information and subject to ARTICLE VII. [\*\*\*]

**2.05 No Other Licenses.** Neither Party grants to the other Party any rights or licenses in or to any Know-How or other intellectual property, whether by implication, estoppel, or otherwise, other than the license rights that are expressly granted under this Agreement.

**2.06 Sublicenses; Subcontracts.**

- (a) **Sublicenses.** Subject to the provisions of this Section 2.06(a), Licensee may grant sublicenses (through multiple tiers) in the Territory under the licenses granted to Licensee in Section 2.01. For each such sublicense, Licensee will enter into a written and enforceable sublicense agreement with the sublicensee that is consistent with the terms of this Agreement, including this Section 2.06(a) (each, a "**Sublicense Agreement**"). In each Sublicense Agreement, Licensee will use reasonable efforts to require that in the event of termination of this Agreement, the Sublicense Agreement will be assignable by Licensee to MSD (at MSD's request, subject to Section 10.05(c)(iv)). Licensee will (i) ensure that all Sublicense Agreements will include provisions for the benefit of MSD corresponding to the applicable provisions of this Agreement, including Section 6.01(b), (ii) require in each such Sublicense Agreement the performance by its sublicensees of the applicable obligations of Licensee hereunder, and (iii) require that its sublicensees comply with the applicable terms and conditions of this Agreement. The grant of any such sublicense will not relieve Licensee of its obligations under this Agreement and Licensee will be liable for the performance or non-performance of its sublicensees hereunder. Licensee will promptly (but in all cases within [\*\*\*] Business Days after entering into any Sublicense Agreement) provide MSD with a fully executed copy of each Sublicense Agreement, [\*\*\*].
- (b) **Subcontracts.** Subject to the provisions of this Section 2.06(b), Licensee will be entitled to engage the services of its Affiliates and Third Parties to perform the Development and Commercialization and other activities on behalf of Licensee with respect to the Compound and the Products in the Field in the Territory hereunder. For each such engagement, Licensee will enter into a written and enforceable subcontract agreement with the Affiliates or Third Party that is consistent with the terms of this Agreement, including this Section 2.06(b) (each, a "**Subcontract Agreement**"). In each Subcontract Agreement that primarily relates to the Compound or Products, Licensee will use reasonable efforts to require that in the event of termination of this Agreement, the Subcontract Agreement (or portion thereof relating to the Compound or Products) will be assignable by Licensee to MSD (at MSD's request). Licensee will (i) require in each such Subcontract Agreement

the performance by its subcontractors of the applicable obligations of Licensee hereunder, and (ii) require that its subcontractors comply with the applicable terms and conditions of this Agreement, including ownership and allocation of intellectual property rights consistent with [Section 6.01](#). [The subcontracting of any such activities will not relieve Licensee of its obligations under this Agreement and Licensee will be liable for the performance or non-performance of its subcontractors hereunder. If Licensee is granting a sublicense to a Third Party other than a distributor to Commercialize Compound or Product\(s\) under the licenses granted to Licensee in Section 2.01 in the Territory, then the provisions of Section 2.06\(a\), and not the provisions of this Section 2.06\(b\), will apply to such Third Party agreement.](#)

**ARTICLE III  
DEVELOPMENT, MANUFACTURE, AND COMMERCIALIZATION**

**3.01 Development, Manufacture, and Commercialization.**

- (a) **Overview.** During the Term, Licensee will be solely responsible for the Development, Manufacture, and Commercialization, including all costs thereof, of Compound and the Products in the Field in the Territory.
- (b) **Diligence.** Licensee will use Commercially Reasonable Efforts to Develop (including filing NDAs and seeking Regulatory Approval) at least one Product in the Field in [\*\*\*]. Following receipt of Regulatory Approval in any such countries, Licensee will use Commercially Reasonable Efforts to Commercialize at least one Product in the Field in such countries.

**3.02 Development and Development Plan.** The initial development plan for the Compound and the Products is attached hereto as [Exhibit A](#). If [\*\*\*], Licensee will promptly submit to MSD an updated development plan (such initial development plan, as updated, the “**Development Plan**”). Licensee will Develop the Compound and the Products in the Field in the Territory (i) [\*\*\*], and (ii) in a [\*\*\*] and in compliance with Good Laboratory Practices, Good Clinical Practices, and Good Manufacturing Practices and all other Applicable Laws.

**3.03 Development Reports.** Licensee will provide MSD with reasonably detailed written reports describing its progress with respect to its Development efforts (each, a “**Development Report**”). Such Development Reports will be furnished on [\*\*\*].

**3.04 Know-How Transfer.**

- (a) **MSD Know-How.** MSD shall promptly provide to Licensee, but no later than [\*\*\*] days after the Effective Date, a copy (in electronic format, if it is available in electronic format, or, if it is not available in electronic format, a hard copy) of the documentation listed in **Schedule 1.62**. The Parties acknowledge that the disclosure of such Know-How by MSD will consist of the disclosure of data residing in MSD's databases, and will not include any database architecture or require any experimental work to be performed by MSD for the purpose of the technology transfer. During the [\*\*\*] period following the Effective Date, if either Party [\*\*\*]. After expiration of such [\*\*\*] period specified in the immediately foregoing sentence, [\*\*\*].
- (b) **Know-How Transfer Assistance.** [\*\*\*]. Except as otherwise agreed by the Parties, all assistance pursuant to this **Section 3.04(b)** will be provided [\*\*\*]. MSD's [\*\*\*] will be limited to [\*\*\*] unless the Parties otherwise agree in writing.

**3.05 Regulatory Filings and Regulatory Approvals.** If any regulatory filings or Regulatory Approvals for the Compound or any Product are required for any of Licensee's (or its Affiliate's, sublicensee's or subcontractor's, as applicable) activities hereunder (including INDs, NDAs and other Regulatory Approvals, as applicable) with respect to the Compound or any Product in the Field in the Territory, then as between the Parties, Licensee will be solely responsible for obtaining, maintaining and complying with such regulatory filings or Regulatory Approvals and for communicating with Regulatory Authorities. All such regulatory filings and regulatory approvals will be filed in the name of and owned by Licensee or its designee, and Licensee or its designee will hold all Regulatory Approvals for Products throughout the Territory for use in the Field.

**3.06 Recalls and Withdrawals.** In the event that any Regulatory Authority (a) threatens or initiates any action to recall or withdraw a Product from the market in any country in the Field in the Territory or (b) requires Licensee, its Affiliates, or its sublicensees to distribute a "Dear Doctor" letter or a similar letter or notification regarding use of Product in the Field in the Territory, Licensee will notify MSD of such event within [\*\*\*] Business Days after Licensee becomes aware of the action, threat, or requirement (as applicable). In all cases, Licensee will be responsible, at its sole expense, for conducting any recalls or withdrawals or taking such other necessary remedial action with respect to Product in the Field in the Territory.

**3.07 Pharmacovigilance.**

- (a) **Adverse Events.** Licensee will be solely responsible for the collection, review, assessment, tracking and filing of information related to adverse events associated with Product in the Field in the Territory, in accordance with all Applicable Law and will, upon request of MSD, provide MSD with copies of adverse event reports and information related thereto.
- (b) **Global Safety Database.** From and after the Effective Date, Licensee will assume responsibility for maintaining a global safety database for the Compound and the Products consistent with industry practices. [\*\*\*].

**3.08 Materials Transfer.**



- (a) **Transfer of Compound.** Promptly after the Effective Date and not later than [\*\*\*] days after the Effective Date, MSD will make available for pickup ([\*\*\*], Incoterms 2020) the quantity of available physical inventory of Compound solely as listed in Schedule 3.08(a) (the “**Transferred Compound**”), in the form as such Transferred Compound currently exists, from MSD’s or its Affiliates’ facilities where such TransferredCompound is currently stored. [\*\*\*]. It is understood that MSD shall retain any remaining quantity of Compound for research purposes pursuant to Section 2.03. **Transfer of the Transferred Compound shall be** [\*\*\*], which schedule shall be [\*\*\*] (and upon such delivery, shall be attached to and become part of this Agreement). The pickup of the Transferred Compound must be [\*\*\*] days [\*\*\*]. Any Transferred Compound [\*\*\*].
- (b) **Disclaimer.** Any Transferred Compound transferred to Licensee is provided “as is” and “where is”, and without representation or warranty of any kind, and MSD hereby expressly disclaims any and all other warranties with respect to such Transferred Compound, including any implied warranties of merchantability and fitness for a particular purpose.
- (c) **Documentation and Transfer Process.** [\*\*\*]
  - (i) [\*\*\*].



(ii)[\*\*\*].

(iii)[\*\*\*].

(iv)[\*\*\*].

(v)[\*\*\*].

#### ARTICLE IV COMPLIANCE

**4.01 Compliance with Legal and Ethical Requirements.** Licensee will conduct, and will ensure that its Affiliates, sublicensees, and Third-Party contractors conduct, all activities hereunder, including all Development, Manufacturing and Commercialization of Compound and Product, in compliance with all Applicable Law and ethical business practices. Licensee hereby certifies that it has not employed or otherwise used in any capacity, and will not employ or otherwise use in any capacity, the services of any person debarred under United States law (including 21 U.S.C. § 335a) or any foreign equivalent thereof, in performing any portion of the activities hereunder, including any Development, Manufacturing and Commercialization of Compound or Product. Licensee will notify MSD in writing of any material deviations from Applicable Law or if any such debarment occurs or comes to its attention, and will, with respect to any person or entity so debarred promptly remove such person or entity from performing any such activities, function or capacity related to any such activities.

**4.02 Anti-Corruption and Anti-Bribery.** Licensee will have in place formal anti-corruption and anti-bribery compliance policies, with terms that comply with Applicable Law and that are consistent with reasonable practices of prudent companies having comparable resources in the biopharmaceutical industry, and will ensure that it, its Affiliates and their respective employees, agents, officers and other members of its management, and any employees, agents, officers and other members of management of any of their respective sublicensees or contractors acting on their behalf in connection with this Agreement, comply with such compliance policies.

#### ARTICLE V FINANCIAL PROVISIONS; REPORTS

**5.01 Upfront Payment.** In accordance with the terms and conditions of this Agreement, Licensee will pay to MSD a non-refundable, non-creditable, up-front payment of twenty-five million Dollars (\$25,000,000), which will be wire transferred within [\*\*\*] days after the Effective Date.

**5.02 Development and Regulatory Milestones.**

- (a) In accordance with the terms and conditions of this Agreement, upon the achievement of each of the following milestones set forth below for [\*\*\*]Products developed by or on behalf of Licensee, its Affiliates, or its or their sublicensees (as applicable), the corresponding one-time milestone payment will be due to MSD, [\*\*\*]:

Milestone	[***]	[***]
Initiation of Phase III Clinical Trial	\$[***]	\$[***]
[***]	\$[***]	\$[***]
[***]	\$[***]	\$[***]
[***]	\$[***]	\$[***]
[***]	\$[***]	\$[***]
[***]	\$[***]	\$[***]
[***]	\$[***]	\$[***]

- (b) [\*\*\*].  
(c) [\*\*\*].  
(d) [\*\*\*].

**5.03 Sales-Based Milestone Payments.** In accordance with the terms and conditions of this Agreement, in the event that the aggregate of all Net Sales of all Products made by Licensee or any of its Affiliates or sublicensees (as applicable) in a given Calendar Year exceeds a threshold

(each, an “**Annual Net Sales Milestone Threshold**”) set forth in the left-hand column of the table immediately below (the “**Annual Net Sales-Based Milestone Table**”), Licensee shall pay to MSD a one-time milestone payment (each, an “**Annual Net Sales-Based Milestone Payment**”) in the corresponding amount set forth in the right-hand column of the Annual Net Sales-Based Milestone Table with respect to the first time such milestone event is achieved. In the event that in a given Calendar Year more than one (1) Annual Net Sales Milestone Threshold is exceeded, Licensee shall pay to MSD a separate Annual Net Sales-Based Milestone Payment with respect to each Annual Net Sales Milestone Threshold that is exceeded in such Calendar Year. Each such milestone payment shall be due within [\*\*\*] days of the end of the Calendar Year in which such milestone was achieved.

<b>Annual Net Sales Milestone Thresholds</b>	<b>Annual Net Sales-Based Milestone Payments</b>
Annual Net Sales by Licensee or its Affiliates or sublicensees of all Products exceeds \$[***] in any single Calendar Year	\$[***]
Annual Net Sales by Licensee or its Affiliates or sublicensees of all Products exceeds \$[***] in any single Calendar Year	\$[***]
Annual Net Sales by Licensee or its Affiliates or sublicensees of all Products exceeds \$[***] in any single Calendar Year	\$[***]

#### 5.04 Royalties.

- (a) **Royalties; Royalty Rates.** In accordance with the terms and conditions of this Agreement, Licensee will pay to MSD, on a Product-by-Product and country-by-country basis, royalties on total annual aggregate Net Sales of each Product by Licensee, its Affiliates, and its and their sublicensees (as applicable), at the rates set forth below (the “**Royalties**”):

<b>Annual Net Sales of Product</b>	<b>Royalty Rate</b>
Portion of Net Sales up to \$[***]	[***]%
Portion of Net Sales equal to or exceeding \$[***] up to \$[***]	[***]%
Portion of Net Sales equal to or exceeding \$[***] up to \$[***]	[***]%
Portion of Net Sales equal to or exceeding \$[***]	[***]%

- (b) **Term of Royalty Obligation.** Royalties on a given Product will be payable commencing upon the First Commercial Sale of such Product in a particular country in the Territory and will continue, on a Product-by-Product and country-by-country basis, until the later of
- (i) the expiration of the last to expire Valid Claim of a MSD Patent claiming such Product (or a Compound contained in such Product) (which Valid Claim may include a MSD Patent claiming [\*\*\*], as applicable) and (ii) the [\*\*\*] year anniversary of the date of the First Commercial Sale of such Product in such country (collectively, the “**Royalty Term**”).
- (c) **Royalty Adjustments.**
- (i) **Know-How Royalty.** Notwithstanding Section 5.04(a), in the event that, in a given country in the Territory, a given Product (or a Compound contained in such Product, as applicable) is not claimed by a Valid Claim of a MSD Patent (which Valid Claim may include a MSD Patent claiming [\*\*\*], as applicable) during a given portion of the Royalty Term for such Product in such country pursuant to Section 5.04(b), then the royalty rate set forth in Section 5.04(a) will be reduced by [\*\*\*] solely with respect to Net Sales of such Product in such country solely during such portions of the Royalty Term, which reduced royalty will be in consideration for, among other things, the continuing license to MSD Know-How during such period.
- (ii) **Anti-Stacking.** If, after the Effective Date of this Agreement, (x) Licensee reasonably determines that, in order to avoid infringement of a Patent not licensed hereunder that covers or claims a given Product (or Compound contained in such Product), or the manufacture, use, sale or other exploitation thereof in a country, Licensee or its Affiliate or sublicensee is required to acquire or license rights under such Patent from a Third Party, (y) Licensee or its Affiliate or sublicensee actually enters into an agreement to acquire or license such Patent rights (such agreement, a “**Third Party License Agreement**”), and (z) Licensee reasonably determines that Licensee or its Affiliate or sublicensee is required to pay a royalty or sales-based milestone payment to such Third Party under the Third Party License Agreement, then Licensee will have the right to deduct such payments actually paid by Licensee or its Affiliate or sublicensee to such Third Party under the Third Party License Agreement from the Royalties payable under this Agreement. For the avoidance of doubt, any Patent rights that are licensed or acquired by Licensee to exploit any ingredient in a Product other than a Compound shall not be subject to this provision.
- (iii) **Limitations.** The reductions set forth in this Section 5.04(c) are cumulative and shall apply, in each case, to the maximum extent applicable; provided that in no event shall any Royalty payment due to MSD from Licensee in respect of any given Calendar Quarter be reduced by more than [\*\*\*] through operation of Section 5.04(c)(i) and Section 5.04(c)(ii).

- (d) **Net Sales Reporting and Payment.** From and after the First Commercial Sale of a Product, within [\*\*\*] days following the end of each Calendar Quarter thereafter, Licensee will furnish to MSD a written report for the Calendar Quarter showing the Net Sales of Product, on a Product-by-Product and country-by-country basis, sold by Licensee or its Affiliates or sublicensees during such Calendar Quarter and Calendar Year-to-date, together with the Royalties and, if applicable, the Annual Net Sales-Based Milestone Payment payable under this Agreement with respect to such Calendar Quarter (each, a “**Net Sales Report**”). Each such Net Sales Report will also include the [\*\*\*]. Each Net Sales Report will also include [\*\*\*]. Simultaneously with the submission of each Net Sales Report, Licensee will pay to MSD a sum equal to [\*\*\*].

**5.05 Third Party Obligations.** In the event that the grant of any license by MSD to Licensee with respect to any MSD Know-How or MSD Patents or the exercise of such license by Licensee (or its sublicensees) could trigger any royalties or other payments to a Third Party(ies) pursuant to, or could require compliance with any provision of, any license or other agreement between MSD (or its Affiliate) and a Third Party(ies), MSD may notify Licensee in writing thereof, and in such case, such MSD Know-How or MSD Patents, as applicable, will only be included in the licenses to Licensee hereunder if, within [\*\*\*] days following receipt of such notice, Licensee agrees in writing to reimburse MSD for all such payments to such Third Party(ies) and comply with any such provisions. [\*\*\*]

**5.06 Payments; Payment Exchange Rate and Currency Conversions.**

- (a) **Method of Payment.** All payments to be made by Licensee to MSD under this Agreement will be paid by bank wire transfer in immediately available funds to such bank account as is designated by MSD, in writing on letterhead with MSD signature, from time to time upon at least [\*\*\*] Business Days’ prior written notice.

All payments will be made in Dollars. With respect to Net Sales invoiced in a currency other than Dollars, currency conversions will be performed in accordance with the monthly rate of exchange utilized by Licensee in its worldwide accounting system as applied to its external reporting. If, due to restrictions or prohibitions imposed by national or international authority, payments cannot be made as set forth herein, the Parties will consult with a view to finding a prompt and acceptable solution, and Licensee will make such payments in any manner as MSD may lawfully direct. Notwithstanding the foregoing, if Royalties or other payments in any country or any other payments due to MSD under this Agreement cannot be remitted to MSD for any reason within [\*\*\*] months after the end of the Calendar Quarter to which they relate, then, at the request of MSD, Licensee will be obligated to deposit the Royalties or other payments, as applicable, in a bank account in such country in the name of MSD.

- (b) **Withholdings.** If Applicable Laws require Licensee to withhold income or other similar taxes (“**Withholding Taxes**”), from the payments made by Licensee to MSD under this Agreement (“**Agreement Payments**”), then Licensee will make such withholding payments and will subtract the amount thereof from the Agreement Payments. It is understood by the Parties that German law requires withholding of taxes related to German registered or exploited intellectual property in the absence of a current German withholding tax exemption certificate. [\*\*\*]. Licensee will submit to MSD appropriate proof of

payment of the withheld Taxes as well as the official receipts and other information received by Licensee and reasonably requested by MSD in order for MSD to obtain a refund for any such Withholding Taxes within a reasonable period of time. In addition, upon written request from MSD, Licensee will provide MSD reasonable information in its possession and will otherwise provide reasonable assistance to MSD in order to allow MSD to obtain the benefit of any present or future treaty against double taxation which may apply to the Agreement Payments. MSD shall provide to Licensee, at the time or times reasonably requested by Licensee or as required by Applicable Law, such properly completed and duly executed documentation (for example, IRS Form W-9 or applicable Form W-8) as will permit payments made under this Agreement to be made without, or at a reduced rate of, Withholding Taxes. Notwithstanding anything in this Agreement to the contrary,  
[\*\*\*].

(c) **Indirect Tax.** All prices and amounts are exclusive of sales, use, GST, VAT, excise, and other taxes, duties or charges of a similar nature (such taxes “**Indirect Taxes**”) imposed by any federal, state, provincial, or local government, or other taxing authority. If any such Indirect Tax is chargeable, Licensee shall pay, or upon receipt of invoice from MSD, shall reimburse, these in addition to the sums otherwise payable, at the rate in force at the due time for payment or such other time as is stipulated under the relevant legislation. The Parties shall cooperate in accordance with Applicable Law to minimize any Indirect Taxes

incurred in connection with this Agreement.

**5.07 Maintenance of Records; Audits.**

- (a) **Record-Keeping by Licensee; Audits.** Licensee will keep, and will cause its Affiliates and sublicensees to keep, complete and accurate records in accordance with its Accounting Principles and in sufficient detail to enable the Royalties and other amounts payable hereunder to be calculated and determined for at least [\*\*\*] months after the end of the period to which such records pertain, or such longer period as may be required under Applicable Law. Upon reasonable prior written notice from MSD, Licensee will permit an independent certified public accounting firm selected by MSD and reasonably acceptable to Licensee (the “**Auditor**”) to have access during normal business hours to examine the pertinent books and records of Licensee and its Affiliates as may be reasonably necessary to verify the accuracy of the Net Sales Reports or other reports hereunder. An audit under this [Section 5.07\(a\)](#), will not occur more than [\*\*\*] in any Calendar Year and [\*\*\*]. Upon completion of the audit, the Auditor shall provide a report to both Parties, [\*\*\*].
- (b) **Expense of Audit.** Any audit conducted pursuant to this [Section 5.07](#) shall be at MSD’s expense; provided, that if the audit reveals an underpayment that exceeds the lesser of [\*\*\*] and [\*\*\*] of the sums correctly due to MSD, then the costs of the audit will be paid by Licensee (including any fees charged by any Third Party Auditor for the work associated with the audit).
- (c) **Underpayments/Overpayments.** If the audit indicates that additional Royalties or other amounts were owed during a given period, Licensee will pay such additional amounts within [\*\*\*] days after the date the Auditor provides the audit results to MSD and Licensee. Any overpayments by Licensee will be credited against future payment obligations or refunded within [\*\*\*] days after the date the Auditor provides the audit results to MSD and Licensee if no amounts payable remain outstanding.
- (d) **Record-Keeping by Sublicensee.** Licensee will include in each Sublicense Agreement a provision requiring the sublicensee to make reports available to Licensee and to keep and maintain records to the same extent required of Licensee under this Agreement. Licensee will include audit rights in each Sublicense Agreement and exercise their audit rights no less than [\*\*\*] every [\*\*\*] years to ensure the accuracy of sublicensee reporting. Licensee will communicate and compensate MSD for any findings with respect to such sublicensee audits.
- (e) **Confidentiality.** MSD will treat all financial information subject to review under this [Section 5.07](#) in accordance with the confidentiality provisions of ARTICLE VII [of this Agreement](#), and will cause its accounting firm to enter into a reasonably acceptable confidentiality agreement with Licensee obligating it to retain all such financial information in confidence pursuant to such confidentiality agreement.



**5.08 Late Payments.** Any amount owed by Licensee to MSD under this Agreement that is not paid within the applicable time period set forth herein will accrue interest at a rate equal to [\*\*\*].

**5.09 Licensee Third Party Agreements.** For the avoidance of doubt, notwithstanding anything to the contrary herein but subject to Licensee's right to deduct payments under Section 5.04(c)(ii), Licensee will be solely responsible for (and will reimburse MSD for, to the extent paid or payable by MSD or any of its Affiliates) all costs and payments of any kind (including all upfront fees, annual payments, milestone payments and royalty payments) arising under any agreements between Licensee (or any of its Affiliates) and any Third Party arising in connection with the activities hereunder, including the Development, Manufacture or Commercialization of Compound or Product in the Field in the Territory.

#### ARTICLE VI INTELLECTUAL PROPERTY

##### 6.01 Ownership and Disclosure.

- (a) **Licensee.** As between the Parties, Licensee (or its Affiliate) will own all right, title and interest in and to the Licensee Know-How, the Licensee Patents, the Know-How Improvements, and the Improvement Patents, and all other intellectual property rights in and to the foregoing. MSD is not acquiring any ownership interest in any Licensee Know-How, Licensee Patents, Know-How Improvements, or Improvement Patents hereunder. MSD shall and hereby does assign to Licensee all of MSD's right, title and interest in and to any Know-How Improvements and Improvement Patents. MSD shall take (and cause its Affiliates and its and their employees, contractors and agents to take) such further actions reasonably requested by Licensee to evidence such assignment, including the execution of any assignments or other legal documentation, and to assist Licensee in obtaining Patent and other intellectual property rights protection for such Know-How Improvements.
- (b) **MSD.** As between the Parties, MSD (or its Affiliate) will own all right, title and interest in and to the MSD Know-How and MSD Patents, and Licensee is not acquiring any ownership interest in any MSD Know-How or MSD Patents hereunder.

##### 6.02 Prosecution and Maintenance of Patents.

- (a) **MSD Patents.** Subject to the provisions of this Section 6.02, as between the Parties, MSD will prosecute and maintain in the Territory, on its own or through outside counsel, the MSD Patents, provided that Licensee will reimburse MSD for its FTE Costs and reasonable out-of-pocket expenses, including legal fees, relating to such patent prosecution and maintenance in all countries. MSD shall keep Licensee advised of such patent prosecution and maintenance and consider in good faith any comments by Licensee. Upon the written request of the Licensee, MSD will provide advance copies of any substantive papers related

to the prosecution and maintenance of such patent filings. MSD shall give prior written notice to Licensee of any desire to abandon or cease prosecution and/or maintenance of the MSD Patents reasonably in advance of any relevant deadlines to continue such prosecution and maintenance and, in such case, shall permit Licensee, at Licensee's sole discretion, to continue the prosecution or maintenance at its own expense.

- (b) **Improvement Patents.** As between the Parties, Licensee will have the sole right to file, prosecute and maintain any and all Improvement Patents at its own expense. Licensee will consult with MSD with respect to the preparation, filing, prosecution and maintenance of the Improvement Patents in the Territory, to the extent such Improvement Patents claim Compound, Product or uses thereof, reasonably prior to any deadline for an action with respect thereto, and will consider in good faith any comments of MSD. Notwithstanding the foregoing, Licensee will have the right to discontinue the prosecution and maintenance of one or more Improvement Patents in the Territory, and in such case, Licensee will give notice to MSD thereof and will permit MSD to continue the prosecution or maintenance of such Improvement Patent(s) in the Territory at its own expense; provided that [\*\*\*]; and provided, further that MSD consults with Licensee with respect thereto prior to any deadline for an action, including providing to Licensee a copy of any filings or submissions in connection therewith.
- (c) **Licensee Patents.** As between the Parties, Licensee will have the sole right, but not the obligation, to file, prosecute and maintain Licensee Patents, at its sole discretion and expense.

**6.03 Enforcement and Defense of MSD Patents and Improvement Patents.** In the event that either Licensee or MSD becomes aware of any alleged or threatened infringement of any issued patent within the MSD Patents or Improvement Patents, or misappropriation of Know-How within the Merck Know-How or the Know-How Improvements, it will promptly notify the other Party in writing to that effect. Licensee shall have [\*\*\*] months from the date of said notice to obtain a discontinuance of such infringement or misappropriation or bring a legal action against the Third Party infringer to obtain a discontinuance of, and/or to seek damages for, such infringement or misappropriation. Each Party shall have the right to be represented by counsel of its own choice at its own expense.

- (a) **First Right of Licensee; Backup Right of MSD to Assume.** Licensee shall have the first right to initiate, prosecute or control any such legal action, at its own expense. Licensee shall keep MSD advised of such legal action and consider in good faith any comments by MSD. MSD shall have the right to join as a party to such legal action and participate with its own counsel at its own expense, provided that Licensee shall retain control of the prosecution and settlement of such legal action. If Licensee fails, within the foregoing [\*\*\*]-month period, to obtain a discontinuance of such infringement or misappropriation, or to bring a legal action, or if Licensee notifies MSD in writing that it elects not to exercise such first right, then MSD shall thereafter have the right, but not the obligation, to either initiate, prosecute or control, entirely under its own direction, any such legal action at its own expense, in the name of MSD and, if necessary, Licensee.

- (b) **Cooperation.** The Party entitled to bring legal action in accordance with this Section 6.03 shall have the right to settle such action; provided that no settlement, consent judgment or other voluntary final disposition of the suit that would adversely affect the other Party may be entered into without the consent of such other Party, which consent shall not be unreasonably withheld. Each Party will reasonably cooperate with the other Party in any suit or action such other Party brings pursuant to this Section 6.03.
- (c) **Recovery.** Any recovery or damages derived from any legal action brought under Section 6.03(a), shall be used first to reimburse each of Licensee and MSD for its documented out-of-pocket legal expenses relating to the legal action (which amounts will be allocated pro rata if insufficient to cover the totality of such expenses), with any remaining amounts to be allocated as follows: (i) if Licensee is the Party bringing legal action, then [\*\*\*]; and (ii) if MSD is the Party bringing legal action, then [\*\*\*]

#### 6.04 Infringement and Third-Party Licenses.

- (a) **Course of Action.** In the event that either Party becomes aware that Licensee's, its Affiliates' or its sublicensees' Developing, Manufacturing or Commercializing Compound or Product in the Field in the Territory infringes, will infringe, or is alleged by a Third Party to infringe, a claim of a patent that specifically covers the Compound or Product, the Party becoming aware of same will promptly notify the other. The Parties will thereafter consult and cooperate to determine a course of action that may include (i) obtaining a license or assignment from said Third Party or (ii) taking action to invalidate said patent.
- (b) **Licensee Right to Negotiate.** In the event the Parties cannot agree on taking action to invalidate the patent pursuant to Section 6.04(a), Licensee shall have the right to negotiate with said Third Party for a suitable license or assignment with respect to the Compound or Product in the Field in the Territory. Licensee shall bear all expenses associated with such Third Party License Agreement, except as set forth in Section 5.04(c)(i).
- (c) **Third Party Infringement Suit.** In the event that a Third Party brings an action against Licensee alleging that Licensee's, its Affiliates' or its sublicensees' developing, making, having made, importing, exporting, using, manufacturing, or having manufactured Compound or Product, or distributing, marketing, promoting, commercializing, offering for sale or selling Product infringes or will infringe a claim of a patent that covers the Compound, Product or the manufacture or use thereof, then Licensee shall have the first right to elect to defend such action at its expense. Licensee shall keep MSD advised of such action and consider in good faith any comments by MSD. Licensee shall promptly notify MSD in writing if it elects not to defend such action, in which case, the Parties shall confer.
- (d) **No Limitation.** For clarity, the provisions of this Section 6.04 will not limit the rights and obligations of the Parties under ARTICLE IX.

6.05 Interference, Derivation, Opposition, Reexamination, Reissue,  
Supplemental Examination, *Inter Partes* Review and Post-Grant Review Proceedings.

- (a) **Third Party Initiated Proceedings.** Each Party shall, within [\*\*\*] days of learning of such event, inform the other Party of any request for, or filing or declaration of, any interference, derivation proceeding, opposition, reexamination requested by a Third Party, *inter partes* review, post-grant review or similar contested administrative proceeding involving a Third Party relating to the MSD Patents and the Improvement Patents. The Parties shall thereafter consult and cooperate fully to determine a course of action with respect to any such proceeding. Licensee shall have the first right, but not the obligation, to control such proceedings relating to the MSD Patents, and shall have the sole right at its discretion, but not the obligation, to control such proceedings relating to the Improvement Patents, and MSD shall have the right to review and comment on any submission to be made in connection with such proceedings, which Licensee will consider in good faith. In the event Licensee determines not to control any such proceedings relating to the MSD Patents, then it shall so notify MSD and MSD shall have the right, but not the obligation, to assume control of such action.
- (b) **Party Initiated Proceedings.** Licensee shall have the first right, but not the obligation, to initiate and control a reexamination, supplemental examination, reissue or similar administrative proceeding relating to the MSD Patents, and shall have the sole right at its discretion, but not the obligation, to initiate and control a reexamination, supplemental examination, reissue or similar administrative proceeding relating to the Improvement Patents. MSD shall have the right to review and comment on any submission to be made in connection with such proceedings, which Licensee will consider in good faith. In the event Licensee determines not to initiate or control any such proceedings relating to the MSD Patents, then it shall so notify MSD and MSD shall have the right, but not the obligation, to assume control of such actions.
- (c) Notwithstanding the foregoing, neither Party shall initiate any such proceedings relating to the MSD Patents without the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed. The non-initiating Party shall have the right to review and approve any submission to be made in connection with such proceedings, which approval will not be unreasonably withheld or delayed. If there is disagreement regarding whether a reexamination, supplemental examination, reissue or similar administrative proceeding related to MSD Patents should be initiated, such disagreement shall be referred to the senior intellectual property officers of the Parties. In the event that these two executives do not, after good faith efforts, reach agreement, [\*\*\*].
- (d) **Cooperation.** In connection with any administrative proceeding under Sections 6.05(a) or 6.05(b), MSD and Licensee shall cooperate fully and provide each other with any information or assistance that either may reasonably request. The Parties shall keep each other informed of developments in any such action or proceeding, including the status of any settlement negotiations and the terms of any offer related thereto. For any proceeding not controlled by MSD, Licensee shall obtain MSD's prior written consent for any settlement offer or settlement agreement that could adversely affect MSD, which consent

shall not be unreasonably withheld.

- (e) **Expenses.** The Party controlling any administrative proceeding pursuant to Sections 6.05(a) or 6.05(b) shall bear all expenses related thereto.

**6.06 Patent Extensions; Supplementary Protection Certificates.** Notwithstanding anything to the contrary in this ARTICLE VI, with respect to each Compound or Product, Licensee shall have the right at its sole expense and as further set forth in this paragraph to make decisions regarding patent term extensions in the Territory, including in the United States with respect to extensions pursuant to 35 U.S.C. § 156 et. seq. and in Europe and other jurisdictions pursuant to supplementary protection certificates, and in all jurisdictions with respect to any other extensions (including pediatric exclusivity) that are now or become available in the future, wherever applicable, for any MSD Patents, Improvement Patents or Licensee Patents, in each case including whether or not to so apply. Licensee shall have the sole right to apply for such patent term extensions with respect to Improvement Patents and Licensee Patents, and the first right to apply for such patent term extensions with respect to MSD Patents. If Licensee decides not to apply for patent term extensions with respect to any MSD Patents, then MSD shall have the right, but not the obligation to apply for such patent term extensions following review and approval by Licensee of the documents for submission in connection therewith. MSD shall provide prompt and reasonable assistance, as requested by Licensee, including by taking such action as Patent holder as is required under any Applicable Law, to obtain extensions under this Section 6.06.

#### ARTICLE VII CONFIDENTIALITY AND PUBLICATION

##### 7.01 Confidentiality.

- (a) **Nondisclosure Obligation.** Each of MSD and Licensee will use Confidential Information received by it from, or on behalf of, the other Party only as permitted by and in accordance with this Agreement and, except as otherwise set forth in Sections 7.01(b) or 7.01(c), will not disclose to any Third Party any such Confidential Information without the prior written consent of the other Party. The foregoing obligations will survive the expiration or termination of this Agreement for a period of [\*\*\*] years. These obligations will not apply to Confidential Information that the receiving Party can reasonably demonstrate:
- (i) is known by the receiving Party at the time of its receipt, and not through a prior disclosure by the disclosing Party, as documented by the receiving Party's written records;
  - (ii) is at the time of disclosure, or thereafter becomes, published or otherwise part of the public domain without breach of this Agreement by the receiving Party;
  - (iii) is subsequently disclosed to the receiving Party by a Third Party who has the right to make such disclosure, as documented by the receiving Party's written records; or
  - (iv) is independently developed by the receiving Party or its Affiliates and without the aid, use or application of any of the disclosing Party's Confidential Information, and such independent development can be documented by the receiving Party's written records.

Any combination of features or disclosures will not be deemed to fall within the foregoing exclusions merely because individual features are published or available to the general public or in the rightful possession of the receiving Party unless the combination itself and principle of operation are published or available to the general public or in the rightful possession of the receiving Party, as applicable.

- (b) **Disclosure to Agents.** Notwithstanding the provisions of Section 7.01(a) and subject to the other terms of this Agreement, each of Licensee and MSD will have the right to disclose Confidential Information of the other Party to their respective sublicensees, agents, employees, contractors, consultants, collaboration partners, Affiliates or other Third Parties (collectively “Agents”) who are directly involved in the Development, Manufacturing or Commercialization of the Compound or Products (or for any such potential Agents to determine their interest in performing such activities), and who have agreed to know such Confidential Information in order for the receiving Party to perform its obligations and exercise its rights under this Agreement. A Party disclosing Confidential Information of the other Party to its Agents will ensure that such Agents are bound in writing, prior to disclosure, by confidentiality and non-use obligations no less restrictive than those contained in this Agreement and will be fully liable to the other Party for breach of such confidentiality and non-use obligations of its Agents.
- (c) **Additional Permitted Disclosures.** Notwithstanding the provisions of Section 7.01(a), the following disclosures of the other Party’s Confidential Information is permitted as follows:
- (i) a Party may disclose Confidential Information of the other Party to any Regulatory Authority to gain approval to conduct Clinical Trials for Product or to market Product, or other governmental authority in order to obtain, enforce or defend MSD Patents, Improvement Patents or Licensee Patents, or in connection with prosecuting or defending litigation under ARTICLE VI or ARTICLE IX, in each case, in accordance with this Agreement; provided that such disclosure may be made only to the extent reasonably necessary to obtain such Patents or authorizations or to prosecute or defend such litigation; and provided, further, that notice of the intended disclosure is provided to the disclosing Party and the disclosing Party’s comments or concerns are considered in good faith by the receiving Party to the extent that the receiving Party’s good faith consideration does not result in any delay that materially prejudices the disclosing Party’s right to obtain such Patents or authorizations or to prosecute or defend such litigation;
- (ii) a Party may disclose Confidential Information of the other Party to such Party’s attorneys, independent accountants or financial advisors for the sole purpose of enabling such attorneys, independent accountants or financial advisors to provide advice to the receiving Party, on the condition that such attorneys, independent accountants and financial advisors are bound by confidentiality and non-use obligations that substantially are no less stringent than those confidentiality and non-use provisions contained in this Agreement or are otherwise bound by substantially similar confidentiality and non-use obligations under professional codes of conduct or the like;
- (iii) a Party may disclose such Confidential Information as is required to be disclosed

by Applicable Law (including rules of any securities exchange); provided that notice is promptly delivered to the other Party in order to provide an opportunity to seek a protective order or other similar order with respect to such Confidential Information and thereafter the receiving Party discloses to the requesting entity only the minimum information required to be disclosed in order to comply with the request, whether or not a protective order or other similar order is obtained by the other Party; and

(iv) Licensee may disclose Confidential Information of MSD to bona fide potential or actual acquirers of all or substantially all of the business to which this Agreement relates, as may be necessary in connection with their evaluation of such potential or actual acquisition; provided that any such Third Party is bound in writing, prior to disclosure, by confidentiality and non-use obligations no less restrictive than those contained in this Agreement.

**7.02 Breach of Confidentiality.** The Parties agree that the disclosure of the other Party's Confidential Information in violation of this Agreement may cause such other Party irreparable harm and that any breach or threatened breach of this Agreement by the receiving Party entitles such other Party to seek injunctive relief, in addition to any other legal or equitable remedies available to it, in any court of competent jurisdiction.

**7.03 No Publicity.**

- (a) A Party may not use the name of the other Party in any publicity or advertising in connection with this Agreement or the activities hereunder, and may not issue a press release or otherwise publicize or disclose any information related to the existence of this Agreement or the terms or conditions herein or the activities hereunder, except (i) on the advice of its counsel as required by Applicable Law or rules of a securities exchange (*e.g.*, any Securities and Exchange Commission filings and disclosures), and provided the Party who will be disclosing such information has consulted with the other Party to the extent practicable prior to such disclosure with respect to the substance of the disclosure (and subject further to the provisions of Section 7.04 with respect to disclosure of the terms and conditions of this Agreement); or (ii) as consented to in advance by the other Party in writing.
- (b) The Parties acknowledge the interest in publishing the results of research to obtain recognition within the scientific community and to advance the state of scientific knowledge. The Parties also recognize the interest in obtaining valid patent protection and in protecting business interests and trade secret information. Consequently, except for disclosures permitted pursuant to Section 7.01(b), 7.01(c) or 7.03(a), if a Party (or its Affiliates or sublicensees) wishes to make a publication that includes any substantive description of or comment about the results of the Development activities hereunder, it will deliver to the other Party a copy of the proposed written publication or an outline of an oral disclosure at least [\*\*\*] days prior to submission for publication or presentation. [\*\*\*] the Party proposing to publish or present will

[\*\*\*] days to [\*\*\*] days, the Party proposing to publish or present will be [\*\*\*]. Upon request of [\*\*\*] prior to submission of the publication or presentation, and will [\*\*\*] the non-publishing Party in good faith.

**7.04 Terms of Agreement.** The terms and conditions of this Agreement will be deemed Confidential Information of both Parties, and neither Party nor its Affiliates will disclose any terms or conditions of this Agreement to any Third Party without the prior consent of the other Party, except as follows: A Party and its Affiliates may disclose the terms or conditions of this Agreement (but not any other Confidential Information, which may be disclosed only as described elsewhere in this ARTICLE VII), (a) on a need-to-know basis to its legal and financial advisors to the extent such disclosure is reasonably necessary, provided that such advisors are subject to confidentiality with regard to such information under an agreement or ethical obligation; (b) to a Third Party in connection with (i) a potential or actual merger, consolidation, collaboration, sublicense, investment, financing or similar transaction by such Party or its Affiliates, (ii) the potential or actual sale of all or substantially all of the assets of such Party or its Affiliates to which this Agreement relates, or (iii) with respect to disclosure by MSD, in connection with a potential or actual sale of the royalties or other rights to payments contained herein, provided that, in each case, the disclosing Party will ensure that such Third Party is bound in writing, prior to disclosure, by confidentiality and non-use obligations with respect to Confidential Information of the other Party substantially no less restrictive than those contained in this Agreement and such disclosing Party will be fully liable to the other Party for breach of such confidentiality and non-use obligations by such Third Parties; (c) to the United States Securities and Exchange Commission or any other securities exchange or governmental authority, including as required to make an initial or subsequent public offering; or (d) as otherwise required by Applicable Law; [\*\*\*].

**7.05 Existing Confidentiality Agreement.** As of the Effective Date, the terms of this ARTICLE VII will supersede the Existing Confidentiality Agreement, and will apply to any "Confidential Information" (as defined in the Existing Confidentiality Agreement) disclosed by a Party or any of its Affiliates or representatives thereunder.

#### ARTICLE VIII REPRESENTATIONS AND WARRANTIES; COVENANTS

**8.01 Representations and Warranties of Each Party.** Each of MSD and Licensee hereby represents and warrants to the other Party as of the Effective Date as follows:



- (a) it is a corporation duly organized and validly existing under the laws of the state or other jurisdiction of its incorporation;
- (b) the execution, delivery and performance of this Agreement by such Party has been duly authorized by all requisite corporate action;
- (c) it has the corporate power and authority to execute and deliver this Agreement and to perform its obligations hereunder;
- (d) the execution, delivery and performance by such Party of this Agreement and its compliance with the terms and provisions herein does not and will not conflict with or result in a breach of any of the terms and provisions of or constitute a default under (i) any loan agreement, guaranty, financing agreement, or other agreement or instrument binding or affecting it or its property; (ii) the provisions of its corporate charter or other operative documents or bylaws; or (iii) any order, writ, injunction or decree of any court or governmental authority entered against it or by which any of its property is bound;
- (e) except for the Regulatory Approvals required to market the Product, the execution, delivery and performance of this Agreement by such Party do not require the consent, approval or authorization of, or notice, declaration, filing or registration with, any governmental authority or Regulatory Authority and the execution, delivery or performance of this Agreement will not violate any Applicable Law applicable to such Party; and
- (f) this Agreement has been duly authorized, executed and delivered and constitutes such Party's legal, valid and binding obligation enforceable against it in accordance with its terms subject, as to enforcement, to bankruptcy, insolvency, reorganization and other laws of general applicability relating to or affecting creditors' rights and to the availability of particular remedies under general equity principles.

**8.02 Additional MSD Representations and Warranties.** MSD hereby represents and warrants to Licensee, as of the Effective Date, as follows:

- (a) MSD has the right, power and authority to grant the licenses under the MSD Patents and MSD Know-How granted to Licensee under this Agreement, and it has not granted (and, to MSD's knowledge, is not under any obligation to grant) any license, right or interest in, to or under the MSD Patents and MSD Know-How to any Third Party in a manner that would conflict with or limit the licenses and rights granted to Licensee under this Agreement.
- (b) [\*\*\*].
- (c) Except as otherwise set forth on Schedule 1.63, to the knowledge of MSD, the MSD Patents have not been abandoned, withdrawn, canceled or held invalid or unenforceable by any court of competent jurisdiction in the Territory in a final non-appealable judgment, and to the knowledge of MSD, the issued patents within the MSD Patents are not invalid or unenforceable, in whole or in part. Schedule 1.63 sets forth a true, correct and complete

list of MSD Patents existing as of the Effective Date.

- (e) It owns or Controls [\*\*\*] that would [\*\*\*] to Licensee under this Agreement.
- (f) There is no pending litigation, or to the knowledge of MSD, threatened litigation, that alleges that MSD has infringed or misappropriated any intellectual property rights of any Third Party in connection with the Development, Manufacture or use of the Compound.
- (g) To MSD's knowledge, neither it nor its Affiliates has employed or used in any capacity in the Development, Manufacture or Commercialization of the Compound or Products any Person that is debarred under 21 U.S.C. § 335a or any foreign equivalent thereof.
- (h) To MSD's knowledge, all [\*\*\*] (or its Affiliates) to Licensee on or before the Effective Date in contemplation of this Agreement was and is [\*\*\*], and, to MSD's knowledge, [\*\*\*] would reasonably be expected to [\*\*\*].
- (i) To MSD's knowledge, there are no agreements in effect as of the Effective Date between MSD and a Third Party under which [\*\*\*].

**8.03 Licensee Covenants.** Licensee covenants to MSD during the Term that:

- (a) It will comply in all material respects with all Applicable Law in the Development, Manufacture and Commercialization of the Compound and Products in the Field in the Territory and in the performance of its obligations under this Agreement.
- (b) Neither it nor its Affiliates will employ or use in any capacity in connection with any activities performed under this Agreement any Person that is debarred under 21 U.S.C. § 335a or any foreign equivalent thereof.
- (c) Licensee has the capacity and resources to Develop Compound and Products in accordance with the Development Plan.

**8.04 Disclaimer.** EXCEPT AS EXPRESSLY SET FORTH IN THIS ARTICLE VIII, THE COMPOUND, PRODUCTS, MSD PATENTS AND MSD KNOW-HOW ARE PROVIDED "AS IS" AND WITHOUT ANY REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE OR ANY WARRANTY THAT THE USE THEREOF WILL NOT INFRINGE OR VIOLATE ANY PATENT OR OTHER PROPRIETARY RIGHTS OF ANY THIRD PARTY.

**8.05 No Warranty.** EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY HERETO MAKES ANY REPRESENTATION AND EXTENDS NO WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED. IN PARTICULAR, BUT WITHOUT LIMITATION, MSD MAKES NO REPRESENTATION AND EXTENDS NO WARRANTY CONCERNING WHETHER THE COMPOUND OR PRODUCTS ARE FIT FOR ANY PARTICULAR PURPOSE OR SAFE FOR HUMAN CONSUMPTION.

#### **ARTICLE IX INDEMNIFICATION AND LIMITATION ON LIABILITY**

**9.01 Indemnification by Licensee.** Licensee will indemnify, defend and hold harmless MSD and its Affiliates, and each of its and their respective employees, officers, directors, agents, successors and assigns (each, a “**MSD Indemnified Party**”) from and against any and all liability, loss, damage, cost and expense (including reasonable attorneys’ fees) (collectively, a “**Liability**”) arising out of or related to claims, allegations, suits, actions or proceedings asserted by any Third Party (each, a “**Third Party Claim**”) to the extent arising out of or relating to (a) the Development, Manufacture, Commercialization or other use or disposition of Compound or Product by or on behalf of Licensee, its Affiliates or sublicensees (including any Third Party Claims arising out of or relating to any Product withdrawals or recalls) during the Term, (b) any breach by Licensee of any of its representations, warranties or covenants under this Agreement, or (c) the negligence or willful misconduct of Licensee, its Affiliates or sublicensees, or their respective employees, officers, directors or agents in performing any activities or obligations hereunder. Notwithstanding the foregoing, Licensee will have no obligation under this Agreement to indemnify, defend or hold harmless any MSD Indemnified Party against any such Third Party Claim to the extent resulting from the gross negligence or willful misconduct of MSD or any other MSD Indemnified Party or to the extent resulting from MSD’s breach of its obligations, representations, warranties or covenants under this Agreement.

**9.02 Indemnification by MSD.** MSD will indemnify, defend and hold harmless Licensee and its Affiliates, and each of its and their respective employees, officers, directors, agents, successors and assigns (each, an “**Licensee Indemnified Party**”) from and against any Liability to the extent arising out of or related to a Third Party Claim arising out of or relating to (a) the Development, Manufacture, Commercialization or other use or disposition of Compound or Product by or on behalf of MSD or its Affiliates prior to the Effective Date or after the Term; (b) any breach by MSD of any of its representations, warranties or covenants under this Agreement or (c) the negligence or willful misconduct of MSD or its Affiliates, or their respective employees, officers, directors or agents in performing any activities or obligations hereunder. Notwithstanding the foregoing, MSD will have no obligation under this Agreement to indemnify, defend or hold harmless any Licensee Indemnified Party with respect to any such Third Party Claim to the extent resulting from the gross negligence or willful misconduct of Licensee or any other Licensee Indemnified Party or to the extent resulting from Licensee’s breach of its obligations, representations, warranties or covenants under this Agreement.

**9.03 Process for Indemnification.** If either Party is seeking indemnification under [Sections 9.01](#) and [9.02](#) (the “**Indemnified Party**”), it will inform the other Party (the “**Indemnifying Party**”) of the Third Party Claim giving rise to the obligation to indemnify pursuant to such Section as soon as reasonably practicable after receiving notice of the Third Party Claim (

[\*\*\*]). The Indemnifying Party will have the right to assume the defense of any Third-Party Claim if it has assumed responsibility for the Third Party Claim in writing. The Indemnified Party will cooperate with the Indemnifying Party and the Indemnifying Party's insurer as the Indemnifying Party may reasonably request, and at the Indemnifying Party's cost and expense. The Indemnified Party will have the right to participate, at its own expense and with counsel of its choice, in the defense of any Third-Party Claim that has been assumed by the Indemnifying Party. The Indemnifying Party will not settle any Third-Party Claim without the prior written consent of the Indemnified Party, not to be unreasonably withheld. The Indemnified Party will not settle or compromise any indemnifiable Third-Party Claim without the prior written consent of the Indemnifying Party, not to be unreasonably withheld. If the Parties cannot agree as to the application of [Sections 9.01](#) and [9.01](#) to any Third Party Claim, pending resolution of the dispute, [\*\*\*].

**9.04 Limitation of Liability.** NEITHER PARTY WILL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES (INCLUDING LOST PROFITS OR LOST REVENUES) ARISING FROM OR RELATING TO THIS AGREEMENT (INCLUDING BREACH OF THIS AGREEMENT) OR THE EXERCISE OF ITS RIGHTS HEREUNDER, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS [SECTION 9.04](#) IS INTENDED TO OR WILL LIMIT OR RESTRICT (1) THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY WITH RESPECT TO LIABILITIES TO THIRD PARTIES UNDER THIRD PARTY CLAIMS UNDER [SECTION 9.01](#) OR [9.02](#), OR (2) DAMAGES AVAILABLE FOR A PARTY'S BREACH OF ITS CONFIDENTIALITY OBLIGATIONS UNDER [ARTICLE VII](#).

**9.05 Insurance.** During the Term, Licensee will, at its own expense, procure and maintain (and cause its Affiliates and sublicensees to procure and maintain) policies of insurance (including product liability insurance) in an amount and with terms which are consistent with normal business practices of prudent companies in the pharmaceutical industry, but in all cases, not less than [\*\*\*] per occurrence and [\*\*\*] in the aggregate, from an insurer with an A.M. Best rating of A- or better or Standard and Poor rating of A- or better, or otherwise acceptable to MSD. Such liability insurance will insure against any liability arising out of Licensee's (and its Affiliates', sublicensees' and contractors') actions under this Agreement, including bodily injury arising out of Product. All such policies will name MSD as an additional insured, and insurers will waive all rights of subrogation against MSD. Upon MSD's request, Licensee will promptly provide for itself and its sublicensees copies of certificates of insurance evidencing such coverages. Licensee will notify MSD not less than [\*\*\*] days in advance of any material change or cancellation of any policy. Licensee will continue to maintain such insurance in effect after the expiration or termination of this Agreement during any period in which Licensee or its Affiliates or sublicensees continue to Develop, Manufacture, or Commercialize Compound or Products. If any insurance is on a claims-made basis, Licensee will maintain such insurance for a period of not less than [\*\*\*] years after it has ceased all Development, Manufacture, and Commercialization of any Compound or Product. It is understood that such insurance will not be construed to create a limit of Licensee's liability with respect to its indemnification obligations or otherwise. Notwithstanding the foregoing, sublicensees of Licensee or its Affiliates shall be entitled to self-insure against the relevant claims, provided that such sublicensee is an entity that, together with its affiliates, has worldwide revenues from pharmaceutical sales in excess of [\*\*\*] per year and such self-insurance program is commercially reasonable.

## ARTICLE X

## TERM AND TERMINATION

**10.01 Term and Expiration.** This Agreement will be effective as of the Effective Date and, unless terminated earlier by mutual written agreement of the Parties or pursuant to Sections 10.02 or 10.03, will continue in effect on a Product-by-Product basis until the expiration of Licensee's obligations to pay Royalties under ARTICLE V (the "Term"). Upon expiration of the Royalty Term with respect to a given Product, and provided that Licensee has paid all Royalties due hereunder with respect to such Product, Licensee's license pursuant to Section 2.01 with respect to the Development, Manufacture, and Commercialization of such Product will become a fully paid-up, non-exclusive, irrevocable, perpetual license.

**10.02 Termination by Licensee.** Licensee may terminate this Agreement in its entirety without cause by giving [\*\*\*] days' advance written notice to MSD; provided, that any termination pursuant to this Section 10.02 shall require a specific reference to this Section, and provided, further, that if Licensee is terminating this Agreement pursuant to this Section 10.02 because of a Safety Issue with respect to a Product, then such notice shall so indicate. In the event of such termination, the rights and obligations hereunder shall terminate, provided, however, that any payment obligations due and owing as of the termination date shall continue.

**10.03 Termination for Cause.**

(a) **Termination for Cause.** This Agreement may be terminated upon written notice by either Party at any time during the Term:

(i) upon or after a material breach of this Agreement by the other Party if the breaching Party has not cured such breach within [\*\*\*] days following receipt of written notice from the non-breaching Party requesting cure of the breach; provided, however, any right to terminate under this Section 10.03(a)(i) will be stayed and the cure period tolled in the event that, during any cure period, the Party alleged to have been in material breach will have initiated dispute resolution in accordance with Section 11.05 with respect to the alleged breach, which stay and tolling will last so long as the allegedly breaching Party diligently and in good faith cooperates in the prompt resolution of such dispute resolution proceedings; or

(ii) upon the filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings by or against the other Party, or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other Party, or in the

event a receiver or custodian is appointed for such other Party's business, or if a substantial portion of such other Party's business is subject to attachment or similar process; provided, however, that in the case of any involuntary bankruptcy proceeding, such right to terminate will only become effective if the proceeding is not dismissed within [\*\*\*]days after the filing thereof.

- (b) **Termination by MSD for Patent Challenge by Licensee.** MSD may terminate this Agreement immediately upon written notice to Licensee if Licensee (or any of its Affiliates or sublicensees), directly or indirectly (including through assistance granted to a Third Party), (i) commences any interference or opposition proceeding or other challenge to the validity or enforceability of any MSD Patent, or (ii) otherwise opposes any extension of, or the grant of any supplementary protection certificate with respect to, any MSD Patent. ((i) and (ii) collectively, "**Patent Challenge**"). Notwithstanding the foregoing, if any of Licensee's sublicensees brings a Patent Challenge, [\*\*\*] pursuant to this [Section 10.03\(b\)](#) if, within [\*\*\*] days after first learning of such Patent Challenge, [\*\*\*].

#### 10.04 Effect of Termination Generally.

- (a) **Termination of Licenses.** Notwithstanding anything contained herein to the contrary, following any termination of this Agreement, all rights and licenses granted to Licensee hereunder (including under [Section 2.01](#)) will terminate and will revert back to MSD.
- (b) **Return of Confidential Information.** Upon termination of this Agreement, Licensee will return all documents, and copies thereof, including those in the possession of Licensee's Agents, containing MSD's Confidential Information, as well as all other physical embodiments of such Confidential Information. Notwithstanding the foregoing, Licensee may retain (i) one (1) copy of such documents in a secure location for archival purposes and for determining its rights and obligations hereunder, and (ii) such Confidential Information that is contained in any computer records or files that have been created solely by Licensee's automatic archiving and back-up procedures, to the extent created and retained in a manner consistent with Licensee's standard archiving and back-up procedures; provided that in each case of (i) and (ii), such Confidential Information shall continue to be subject to the non-disclosure and non-use obligations set forth in [ARTICLE VII](#).

#### 10.05 [10.02](#) **Product Reversion.** Upon termination of this Agreement by Licensee pursuant to [Section](#) other than for a Safety Issue, or upon termination of this Agreement by MSD pursuant to [Section 10.03](#), the following provisions will apply:

- (a) Effective upon such termination, without further action by either Party, MSD will have, and Licensee hereby grants to MSD, (1) an exclusive, fully paid-up, irrevocable, perpetual, royalty-free, worldwide license, with the right to grant sublicenses (through multiple tiers), under the Licensee Grantback Patents and Licensee Grantback Know-How, to Develop, Manufacture, use and Commercialize the Grantback MK-8408 Products in the Field in the

Territory, and (2) in accordance with the process set forth in Section 10.05(b), an exclusiveright to negotiate for a non-exclusive, royalty-bearing, worldwide license under the AT- 527/511 Combination Grantback Patents and AT-527/511 Combination Grantback Know-How to Develop, Manufacture, use and Commercialize the AT-527/511 Combination Products in the AT-527/511 Combination Grantback Field in the Territory (the “**AT- 527/511 Combination Grantback License**”).

- (b) MSD may exercise its rights under Section 10.05(a)(2) by providing written notice to Licensee at any time during the [\*\*\*] day period following the date that notice of termination is provided or received by MSD, as applicable. If MSD provides such notice exercising such rights, then the Parties will negotiate for up to [\*\*\*] days in good faithan agreement for the AT-527/511 Combination Grantback License, which will be on commercially reasonable, market standard terms, taking into consideration the reason for termination of this Agreement, subject to Section 10.05(b)(i) – Section 10.05(b)(iv). Uponthe expiration of such [\*\*\*] day negotiation period (or such other period the Parties mutually agree in writing) without the Parties executing an agreement for the AT-527/511Combination Grantback License, MSD’s rights and Licensee’s obligations under Section 10.05(a)(2) and this Section 10.05(b) will expire in their entirety.
- (i) [\*\*\*].
- (ii) During the negotiation specified in Section 10.05(b) for the AT-527/511 Combination Grantback License, if not adverse to patient safety or prohibited by Applicable Law or any Regulatory Authority, Licensee, its Affiliates and its sublicensees and subcontractors will continue, at Licensee’s sole expense, to conduct any Clinical Trials related to the AT-527/511 Combination Products in the AT- 527/511 Combination Grantback Field that are being conducted under Licensee’s (orits Affiliate’s or sublicensee’s or subcontractor’s) IND for such products and are ongoing as of the date this Agreement is terminated.
- (iii) If the Parties are unable to agree on commercially reasonable terms for the AT- 527/511 Combination Grantback License within [\*\*\*] days after MSD gives notice to Licensee of its election to exercise its rights under Section 10.05(a)(2), thenLicensee, its Affiliates and its sublicensees and subcontractors will wind-down, at Licensee’s sole expense and in accordance with accepted pharmaceutical industry norms, ethical and medical practices, and all Applicable Law and Regulatory Authority requirements, any Clinical Trials related to the AT-527/511 Combination Products in the AT-527/511 Combination Grantback Field that are being conducted under Licensee’s (or its Affiliate’s or sublicensee’s or subcontractor’s) IND for suchproducts and are ongoing as of the date this Agreement is terminated, including, if not adverse to patient safety, completing treatment for the patients then-enrolled andwho have commenced dosing in such Clinical Trials.
- (iv) If the Parties agree on commercially reasonable terms with respect to AT-527/511 Combination Grantback License then, if requested by MSD and not adverse to patient safety or prohibited by Applicable Law or any Regulatory Authority, Licensee, its Affiliates and its sublicensees (subject to Section 10.05(c)(iv)), and subcontractors will continue to conduct, at Licensee’s expense until the date that is [\*\*\*] days after the Parties execute an agreement for the AT-527/511 Combination Grantback License (or, if earlier, until the date MSD completes transfer of the applicable Clinical Trial) and at MSD’s expense thereafter, and until such timeas can be reasonably transferred to MSD, but in no case longer than [\*\*\*] days, any Clinical Trials related to the AT-527/511 Combination Products in the AT-527/511 Combination Grantback Field that (x) are being conducted under Licensee’s (or its Affiliate’s or sublicensee’s or subcontractor’s) IND for AT-527-511 Combination Products and are ongoing as of the date this Agreement is terminated, and (y) for which it is not practicable to transfer responsibility for conducting such studies to MSD promptly following termination (as reasonably determined by MSD), in each case, as and to the extent requested by MSD.

- (c) At MSD's option and upon MSD's request, Licensee will reasonably cooperate with MSD (or its designee(s)) in order to enable MSD (or its designee(s)) to assume responsibility for the Development, Manufacture and Commercialization of Grantback MK-8408 Products in the Field in the Territory. Such cooperation and assistance will be provided in a timely manner and without any additional consideration, except as expressly provided below, and will include, without limitation, as and to the extent requested by MSD, the following:
- (i) Licensee will, to the extent Licensee has the right to do so, transfer and assign to MSD (or its designee) all INDs, NDAs, Regulatory Approvals, and all supporting documentation for such filings and applications (including all data), made or obtained by or on behalf of Licensee or any of its Affiliates or any of its sublicensees (subject to Section 10.05(c)(iv) or subcontractors [\*\*\*]. If Licensee does not have the right to transfer and assign any such filings, applications or documentation for the [\*\*\*], then Licensee shall grant MSD (or its designee) a right to cross reference such filing, application or documentation, and to access such filing or application or any data therein.
  - (ii) Licensee will transfer and assign to MSD (or its designee) all rights in any trademarks



and trade dress, and will transfer and assign to MSD all rights in any domain names containing such trademarks, to the extent that such trademarks or trade dress, as applicable, have actually been utilized by Licensee or any of its Affiliates or any of its sublicensees (subject to Section 10.05(c)(iv)) or subcontractors in connection with, and are specific to, the [\*\*\*].

- (iii) Licensee will transfer to MSD (or its designee), to the extent not previously provided, a copy of all [\*\*\*].
- (iv) Licensee will [\*\*\*] to MSD (or its designee), upon written request of MSD, provided that [\*\*\*]. To the extent not covered under Section 10.05(c)(vii), at MSD's request, [\*\*\*], to the extent permitted under such Subcontract Agreement at the time of termination of this Agreement and provided that, upon any termination of this Agreement other than by MSD pursuant to Section 10.03, [\*\*\*].
- (v) If requested by MSD and not adverse to patient safety or prohibited by Applicable Law or any Regulatory Authority, Licensee, its Affiliates and its sublicensees (subject to Section 10.05(c)(iv)) and subcontractors will continue to conduct, [\*\*\*].
- (vi) If requested by MSD, Licensee will transfer to MSD (or its designee) any or all quantities of [\*\*\*] in the possession of Licensee or its Affiliates or sublicensees (subject to Section 10.05(c)(iv)) or subcontractors (

[\*\*\*]).

- (vii) At MSD's request, Licensee shall promptly provide to MSD copies of [\*\*\*], to the extent permitted under such agreements. At MSD's request, Licensee shall [\*\*\*]. In the event that such [\*\*\*].

Without limiting the foregoing, Licensee will use Commercially Reasonable Efforts to complete the transition of the Development, Manufacture and Commercialization of the Grantback MK- 8408 Products from Licensee to MSD (or its designee) pursuant to this [Section 10.05\(c\)](#) in a prompt manner, as and to the extent requested by MSD, and will provide MSD (or its designee) with such other transition assistance as reasonably requested by MSD, including, if requested by MSD, entering into a transition services agreement.

**10.06 Survival.** Expiration or termination of this Agreement will not relieve the Parties of any obligation accruing prior to such expiration or termination, and the provisions of Article I (Definitions) (as necessary for the interpretation of other surviving provisions), Section 5.07 (Maintenance of Records; Audits), Section 6.01 (Ownership and Disclosure), Article VII (Confidentiality and Publication), Article VIII (Representations and Warranties; Covenants), Article IX (Indemnification and Limitation on Liability), Section 10.01 (Term and Expiration) (last sentence), Section 10.2 (Termination by Licensee) (last sentence), Section 10.04 (Effect of Termination Generally), Section 10.05 (Product Reversion), this Section 10.06 (Survival), and Article XI (Miscellaneous) will survive the expiration or termination of this Agreement. Any expiration or early termination of this Agreement will be without prejudice to the rights of either Party against the other accrued or accruing under this Agreement prior to expiration or termination, including the obligation to pay Royalties and other amounts for Product sold prior to such expiration or termination. The provisions of this [ARTICLE X](#) are in addition to any other relief and remedies available to either Party under this Agreement and under Applicable Law.

#### ARTICLE XI MISCELLANEOUS

**11.01 Force Majeure.** Neither Party will be held liable to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in performing any obligation under this Agreement (except the obligation to make payments when due) to the extent such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party, including,

[\*\*\*]. The affected Party will notify the other Party of such force majeure circumstances as soon as reasonably practicable and will promptly undertake all reasonable efforts necessary to cure such force majeure circumstances.

**11.02 Assignment.** Except as provided in this [Section 11.02](#), this Agreement may not be assigned or otherwise transferred, nor may any right or obligation hereunder be assigned or transferred, in each case, in whole or in part (including as a result of a merger, transfer of going concern, sale of stock, sale of assets or other similar transaction (including by operation of law)) by either Party without the consent of the other Party. Notwithstanding the foregoing, (a) Licensee may, without MSD's consent, assign this Agreement (i) to an Affiliate of Licensee or (ii) in connection with a Change of Control of Licensee, (b) MSD may, without Licensee's consent, assign this Agreement or its rights and obligations hereunder in whole or in part (i) to an Affiliate of MSD or (ii) in connection with a Change of Control of MSD, and (c) MSD may, without Licensee's consent, assign to a Third Party its rights to receive royalties or other payments contained herein and any and all provisions related thereto (including audit rights and reporting rights). Any permitted assignee will assume all obligations of its assignor under this Agreement. This Agreement is binding upon the permitted successors and assigns of the Parties. Any attempted assignment not in accordance with this [Section 11.02](#) will be void *ab initio*.

**11.03 Severability.** If any one or more of the provisions contained in this Agreement is held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein will not in any way be affected or impaired thereby, unless the absence of the invalidated provision(s) adversely affects the substantive rights of the Parties. The Parties will in such an instance use their best efforts to replace the invalid, illegal or unenforceable provision(s) with valid, legal and enforceable provision(s) which, insofar as practical, implement the purposes of this Agreement.

**11.04 Notices.** All notices which are required or permitted hereunder will be in writing and sufficient if delivered personally, sent by e-mail (and promptly confirmed by personal delivery, registered or certified mail or overnight courier), sent by nationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:

if to Licensee, to:           Atea Pharmaceuticals, Inc. 125  
  Summer Street  
  Boston, MA 02110  
  Attn: General Counsel  
  Email: [\*\*\*]

with a copy to:               Latham & Watkins LLP 140  
  Scott Drive  
  Menlo Park, CA 94025 Attn:  
  Judith Hasko

if to MSD, to: MSD International GmbH  
Tribtschenstrasse 60  
6005 Lucerne Switzerland  
Attention: Director  
Facsimile: [\*\*\*]

with copies to (which shall not constitute notice): Merck Sharp & Dohme Corp. One  
Merck Drive  
PO Box 100  
Whitehouse Station, NJ 08889-0100  
Attention: [ \* \* \* ] Email: [\*\*\*]

Merck Sharp & Dohme Corp.  
2000 Galloping Hill Road PO  
Box 539  
Mail Stop K-1-4161  
Kenilworth, NJ 07033  
Attention: [ \* \* \* ]

or to such other address(es) as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice will be deemed to have been given:

(a) when delivered if personally delivered or sent by e-mail with receipt confirmed on a Business Day (or if delivered or sent on a non-Business Day, then on the next Business Day); (b) on the Business Day after dispatch if sent by nationally-recognized overnight courier; or (c) on the fifth (5th) Business Day following the date of mailing, if sent by registered or certified mail.

**11.05 Dispute Resolution; Choice of Law.**

- (a) **Informal Discussions.** Except as otherwise provided herein, in the event of any controversy or claim arising out of or relating to this Agreement, or the rights or obligations of the Parties hereunder, the Parties will first try to settle their differences amicably between themselves. Either Party may initiate such informal dispute resolution by sending written notice of the dispute to the other Party, and within [\*\*\*] days after such notice appropriate representatives of the Parties will meet for attempted resolution by good faith negotiations. If such representatives are unable to resolve promptly such disputed matter within the said [\*\*\*] days, either Party may refer the matter by written notice to the other to the MSD Executive and the Licensee Executive for discussion and resolution. If the MSD Executive and the Licensee Executive are unable to resolve such dispute within [\*\*\*] days of such written notice, either Party may commence an action in accordance with the provisions of Section 11.05(c).
- (b) **Governing Law.** This Agreement will be governed by and construed in accordance with the laws of the State of New York, without reference to any rules of conflict of laws, except

as to any issue which depends on the validity, scope or enforceability of any Patent, which issue shall be determined in accordance with the laws of the country in which such Patent was issued. The Parties hereby agree that the provisions of the United Nations Convention on Contracts for the International Sale of Goods shall not apply to this Agreement and are strictly excluded.

- (c) **Venue; Waiver of Jury Trial.** If the Parties do not fully settle following the procedure in Section 11.05(a), and a Party wishes to pursue the matter, each dispute, controversy or claim arising from or related to this Agreement or the breach thereof shall be brought in the federal court for the Southern District of New York, if federal jurisdiction is available, or, alternatively, in the state courts in New York, New York. Each of the Parties hereby submits to the exclusive jurisdiction of such courts for the purpose of any such litigation; provided, that a final judgment in any such litigation shall be conclusive and may be enforced in other jurisdictions by suit on the judgment or in any other manner provided by law. Each Party irrevocably and unconditionally agrees not to assert (i) any objection which it may ever have to the laying of venue of any such litigation in such courts, (ii) any claim that any such litigation brought in any such court has been brought in an inconvenient forum, or (iii) any claim that such court does not have jurisdiction with respect to such litigation. EACH PARTY IRREVOCABLY AND UNCONDITIONALLY WAIVES ANY RIGHT TO A TRIAL BY JURY AND AGREES THAT ANY OF THEM MAY FILE A COPY OF THIS PARAGRAPH WITH ANY COURT AS WRITTEN EVIDENCE OF THE KNOWING, VOLUNTARY AND BARGAINED-FOR AGREEMENT AMONG THE PARTIES IRREVOCABLY TO WAIVE ITS RIGHT TO TRIAL BY JURY IN ANY LITIGATION.

**11.06 Export Control.** This Agreement is made subject to any restrictions concerning the export of products or technical information from the United States of America that may be imposed upon or related to MSD or Licensee from time to time by the government of the United States of America. Furthermore, Licensee agrees that it will not export, directly or indirectly, any technical information acquired from MSD under this Agreement or any products using such technical information to any country for which the United States government or any agency thereof at the time of export requires an export license or other governmental approval, without first obtaining the written consent to do so from the Department of Commerce or other agency of the United States government when required by an applicable statute or regulation.

**11.07 Entire Agreement.** This Agreement, together with the Schedules and Exhibits hereto, contains the entire understanding of the Parties with respect to the subject matter hereof. Any other express or implied agreements and understandings, negotiations, writings and commitments, either oral or written, in respect to the subject matter hereof (including the Existing Confidentiality Agreement) are superseded by the terms of this Agreement. The Schedules and Exhibits to this Agreement are incorporated herein by reference and will be deemed a part of this Agreement.

**11.08 Amendments.** This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by authorized representative(s) of both Parties hereto.

**11.09 Headings.** The captions to the several Articles, Sections, subsections, Schedules and Exhibits hereof are not a part of this Agreement, but are merely for convenience to assist in locating and reading the several Articles, Sections, subsections, Schedules and Exhibits hereof.

**11.10 Independent Contractors.** It is expressly agreed that Licensee and MSD will be independent contractors and that the relationship between the two Parties will not constitute a partnership, joint venture or agency. Neither Licensee nor MSD will have the authority to make any statements, representations or commitments of any kind, or to take any action, which will be binding on the other Party, without the prior written consent of the other Party.

**11.11 Waiver.** The waiver by either Party hereto of any right hereunder, or of any failure of the other Party to perform, or of any breach by the other Party, will not be deemed a waiver of any other right hereunder or of any other breach by or failure of such other Party whether of a similar nature or otherwise.

**11.12 Cumulative Remedies.** No remedy referred to in this Agreement is intended to be exclusive, but each will be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.

**11.13 Waiver of Rule of Construction.** Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement will be construed against the drafting Party will not apply.

**11.14 Interpretation.** Any reference in this Agreement to an Article, Section, subsection, paragraph, clause, or Schedule or Exhibit will be deemed to be a reference to an Article, Section, subsection, paragraph, clause, or Schedule or Exhibit, of or to, as the case may be, this Agreement, unless otherwise indicated. Unless the context of this Agreement otherwise requires, (a) words of any gender include all genders, (b) words such as "herein", "hereof", and "hereunder" refer to this Agreement as a whole and not merely to the particular provision in which such words appear, (c) words using the singular will include the plural, and vice versa, (d) whenever any provision of this Agreement uses the term "including" (or "includes" or words of similar import), such term will not be limiting and such term will be deemed to mean "including without limitation" (or "includes without limitation"), (e) the word "or" will not be construed as exclusive and shall have the meaning ordinarily ascribed to the phrase "and/or", (f) references to any Articles or Sections include Sections and subsections that are part of the reference Article or section (e.g., a section numbered "Section 2.2(a)" would be part of "Section 2.2", and references to "Article 2" or "Section 2.2" would refer to material contained in the subsection described as "Section 2.2(a)"), (g) references to "days" will mean calendar days unless otherwise indicated.

**11.15 Counterparts.** This Agreement may be executed in two or more counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument. In addition, this Agreement may be executed by facsimile or by .pdf, .tif, .gif, .jpeg or similar attachment to electronic mail, and such signature by facsimile or .pdf, .tif, .gif, .jpeg or similar attachment to electronic mail will be deemed to be an original.

**11.16 Further Actions.** Each Party will execute, acknowledge and deliver such further instruments, and to do all such other ministerial, administrative or similar acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

**11.17 No Third-Party Rights.** The provisions of this Agreement are for the exclusive benefit of the Parties, and no other person or entity will have any right or claim against any Party by reason of these provisions or be entitled to enforce any of these provisions against any Party.

**11.18 Expenses.** Except as otherwise specifically provided in this Agreement, each Party (and its Affiliates) will bear its own costs and expenses in connection with entering into this Agreement and the consummation of the transactions and performance of its obligations contemplated hereby.

**11.19 Extension to Affiliates.** Each Party will have the right to extend the rights, licenses, immunities, and obligations granted in this Agreement to one or more of its Affiliates. All applicable terms and provisions of this Agreement will apply to any such Affiliate to which this Agreement has been extended to the same extent as such terms and provisions apply to such Party. Each Party will remain fully liable for any acts or omissions of such Affiliates.

*[Signature page follows]*

IN WITNESS WHEREOF, this Agreement has been made effective by the duly authorized representatives of the Parties as of the Effective Date.

**MSD INTERNATIONAL GMBH**

By: /s/ Carlos Fernandez  
Name: Carlos Fernandez  
Title: Director

**ATEA PHARMACEUTICALS, INC.**

By: /s/ Jean-Pierre Sommadossi  
Name: Jean-Pierre Sommadossi  
Chairman and CEO  
\_Title: \_





Legal Name

Atea Pharmaceuticals Securities Corporation

State of Organization

Massachusetts

**Consent of Independent Registered Public Accounting Firm**

We consent to the incorporation by reference in the registration statements (No. 333-249780) on Form S-8 and (No. 333-261344) on Form S-3, as amended, of our reports dated February 28, 2022, with respect to the consolidated financial statements of Atea Pharmaceuticals, Inc. and subsidiary and the effectiveness of internal control over financial reporting.

/s/ KPMG LLP

Boston, Massachusetts  
February 28, 2022

## CERTIFICATION

I, Jean-Pierre Sommadossi, certify that:

1. I have reviewed this Annual Report on Form 10-K 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: February 28, 2022

By:

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

## CERTIFICATION

I, Andrea Corcoran, certify that:

1. I have reviewed this Annual Report on Form 10-K 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: February 28, 2022

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

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

In connection with this Annual Report on Form 10-K of Atea Pharmaceuticals, Inc. (the "Company") for the year ended December 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 28, 2022

By: \_\_\_\_\_ /s/ Jean-Pierre Sommadossi

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



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

In connection with this Annual Report on Form 10-K of Atea Pharmaceuticals, Inc. (the "Company") for the year ended December 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of her knowledge:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 28, 2022

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